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

Paris, 3–7 October 2011

The OIE Aquatic Animal Health Standards Commission (hereinafter referred to as the Aquatic Animals Commission) met at the OIE Headquarters from 3 to 7 October 2011.

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

The Commission reviewed the documents identified in the agenda, addressing comments that Member Countries had submitted by 2 September 2011 and amended texts in the OIE *Aquatic Animal Health Code* (the *Aquatic Code*) where appropriate. The amendments are shown in the usual manner by double underline and strikethrough and may be found in the Annexes to the report. In Annex XIII (Killing of farmed fish for disease control purposes, new Chapter 7.4.), the amendments made at this meeting (October 2011) are shown with a coloured highlight to distinguish them from those made at previous meetings of the Commission.

Member Countries should note that, unless stated otherwise, texts submitted for comment may be proposed for adoption at the 80th OIE General Session in May 2012. Depending on the comments received on each text, the Commission will identify the texts proposed for adoption in May 2012 in the report of its March 2012 meeting.

The Aquatic Animals Commission strongly encourages Member Countries to participate in the development of the OIE's international standards by submitting comments on this report. It would be very helpful if comments were submitted as specific proposed text changes, supported by a scientific rationale. Proposed deletions should be indicated in 'strikethrough' and proposed additions with 'double underline'. Member Countries should not use the automatic 'track-change' function provided by word processing software as such changes are lost in the process of collating Member Countries' submissions into the Commission's working documents.

The table below summarises the texts presented in the Annexes. Annexes III to XV are presented for Members' comment; Annexes XVI to XIX are presented for Members' information.

Comments on this report must reach OIE Headquarters prior to **20 January 2012** to be considered at the March 2012 meeting of the Commission. All comments should be sent to the OIE International Trade Department at: trade.dept@oie.int.

Texts for Members' comment	Annex number
Glossary	Annex III
Criteria for listing aquatic animal diseases (Chapter 1.2.)	Annex IV
Assessment for listing Infection with ostreid herpesvirus-1	Annex V
Diseases listed by the OIE (Chapter 1.3.)	Annex VI
Import risk analysis (Chapter 2.2.)	Annex VII
Communication (new Chapter 3.2.)	Annex VIII
Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals (new Chapter 6.4.)	Annex IX
Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals (new Chapter 6.5.)	Annex X
Welfare of farmed fish during transport (Chapter 7.2.)	Annex XI
Welfare aspects of stunning and killing of farmed fish for human consumption (Chapter 7.3.)	Annex XII
Killing of farmed fish for disease control purposes (new Chapter 7.4.) (Annex 13A with changes tracked; Annex 13B as clean text)	Annex XIII (A and B)
Disinfection of salmonid eggs (Article 10.4.13., Article 10.5.13. and Article 10.9.13.)	Annex XIV
Infectious salmon anaemia (Chapter 10.5.)	Annex XV
Annexes for Members' information	**Annex number**
Aquatic Animal Health Standards Commission Work Plan for 2011/2012	Annex XVI
Report of the *ad hoc* Group on Pathogen Differentiation for Aquatic Animal Diseases	Annex XVII
Report of the *ad hoc* Group on Responsible Use of Antimicrobials in Aquatic Animals	Annex XVIII
Report of the *ad hoc* Group on Veterinary Education	Annex XIX

Meeting with Dr Vallat

Dr Bernad Vallat joined the Commission for a short discussion on the following key points:

1. Disease listing

Noting that the OIE Terrestrial Animal Standards Commission (the Code Commission) is in the process of modifying the disease listing criteria in the OIE *Terrestrial Animal Health Code*, the Aquatic Animals Commission proposed to await the decision of Members on this work before proposing any modifications to the text in the *Aquatic Code*.

2. OIE PVS Pathway

Bearing in mind the central importance of the aquatic animal health professional in the Aquatic Animal Health Services (AAHS) and the fact that the OIE *PVS Tool* needs some further refinement to make it more pertinent to AAHS, the Aquatic Animals Commission proposed a definition of 'aquatic animal health professional', for consideration of Members. Should Members support this proposal, the Commission asked the Director General to consider convening an *ad hoc* group to develop AAHS performance indicators for use in PVS assessments of AAHS.

In addition, the Commission asked the Director General to convene an *ad hoc* group to develop recommendations on the education of aquatic animal health professionals, including veterinarians.

3. Antimicrobial resistance and aquatic animals

The Director General commended the work of the Commission on antimicrobial resistance and noted the Commission's decision not to draft, for the moment, a chapter on risk assessment. The Director General agreed that the Commission and the *ad hoc* Group should take every opportunity to highlight the need for scientific research on the topic of antimicrobial resistance and aquatic animals.

4. Invasive animals

The Director General noted the interest of the Aquatic Animals Commission to be represented at the OIE brainstorming meeting on risk assessment for invasive animal species.

5. Welfare standards for farmed fish

On animal welfare, Dr Barry Hill advised the Director General of the extensive comments submitted by Members on the draft chapter on killing for disease control purposes. Dr Vallat encouraged the Commission to proceed with its work on this topic. He also supported the views of the Commission that the emphasis for the next few years should be on encouraging Members to implement adopted standards, rather than the development of standards on new topics.

6. Disease free compartment (diseases of shrimp)

The Director General noted the Commission's review of a proposal from Indonesia for a disease free compartment in shrimp and agreed that the information provided by Indonesia could be published in the OIE *Bulletin*.

1. Activities and progress of *ad hoc* groups

1.1. Report of the OIE *ad hoc* Group on Pathogen Differentiation for Aquatic Animal Diseases

Dr Franck Berthe gave a summary of progress made at the meeting of the *ad hoc* Group on Pathogen Differentiation for Aquatic Animal Diseases held from 6 to 8 September 2011.

The Aquatic Animals Commission reviewed the *ad hoc* Group report and agreed with the Group's recommendations. The Commission proposed that:

- ISAV be recognised by the OIE as having HPR0 and HPR-deleted variants;
- HPR0 and HPR-deleted variants be reported separately to the OIE; and reporting mechanisms allow separate reporting of HPR0 ISAV and HPR-deleted ISAV;
- relevant amendments be made to the *Aquatic Code* and *Manual of Diagnostic Tests for Aquatic Animals* (*Aquatic Manual*) to accommodate the recognition of the variants.

The Aquatic Animals Commission noted that for the purposes of the *Aquatic Code*, HPR0 is included in the current definition of ISA infection, but the detection of ISAV with RT-PCR alone (since HPR0 does not generally yield positive test results except through molecular testing methods) does not fit the case definition of ISAV positive in the *Aquatic Manual* thus causing confusion for Member Countries with respect to their reporting obligations for ISAV. The Commission recommended that the author of the ISAV chapter in the *Aquatic Manual* be requested to consider the amendments to the chapter suggested by the *ad hoc* Group in order to resolve this problem.

The Aquatic Animals Commission agreed with the amended text in Chapter 10.5. of the *Aquatic Code* proposed by the *ad hoc* Group, and agreed to circulate the amended text for Member comments.

The amended Chapter 10.5. is presented in Annex XV for Member comments.

The Aquatic Animals Commission noted that if Members agreed to this approach, it could be applied in the future to several other listed diseases such as yellow head, viral haemorrhagic septicaemia, infectious hypodermal and haematopoietic necrosis and red sea bream iridoviral disease.

The *ad hoc* Group report is provided for information at Annex XVII.

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

The Aquatic Animals Commission reviewed the report of the *ad hoc* Group on Responsible Use of Antimicrobials in Aquatic Animals, which met on 8–9 September 2011. The Commission addressed the following issues:

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

The Aquatic Animals Commission reviewed the draft Chapter 6.4. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals, developed by the *ad hoc* Group, and proposed that this chapter be considered for inclusion in the *Aquatic Code*.

The draft chapter is presented at Annex IX for Member comments.

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

The Aquatic Animals Commission reviewed the draft Chapter 6.5. Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals, developed by the *ad hoc* Group, and proposed that this chapter be considered for inclusion in the *Aquatic Code*.

The draft chapter is presented at Annex X for Member comments.

Risk assessment for antimicrobial resistance arising from the use of antimicrobials in aquatic animals

a) List of bacteria to be prioritised

The Aquatic Animals Commission noted the advice of the *ad hoc* Group that there are key gaps in scientific knowledge in relation to risk assessment and agreed with the Group's position that it is too soon to develop a chapter for the Code on this topic. The development of methods of antimicrobial resistance testing in aquatic animals is a critical need. The Commission commended the work of the Group in preparing a short paper on the priority bacteria for the development of methods of antimicrobial resistance testing in aquatic animals. The Commission encouraged the *ad hoc* Group to publish an appropriate scientific article on this topic in the September 2012 issue of the OIE *Bulletin* that will be dedicated to aquatic animal topics.

b) Discussion paper on risk assessment for antimicrobial resistance in aquatic animals

The Aquatic Animals Commission commended the *ad hoc* Group's paper on Antimicrobial resistance risk analysis in aquaculture and supported its publication in the September 2012 issue of the OIE *Bulletin* that will be dedicated to aquatic animal topics.

The Commission noted that the issue of antimicrobial resistance in aquatic animals has broad implications. Resistance presents potential risks to human health, aquatic animal health and the environment. The Commission encouraged the members of the *ad hoc* Group to consider presenting papers on this topic in relevant scientific meetings and congresses. Some relevant upcoming meetings and congresses include:

Antibiotic Awareness Day, European Centre for Disease Prevention and Control (18 November 2011); Responsible Use of Antibiotics in Animals (14–16 November 2011, Netherlands); 22nd European Congress of Clinical Microbiology and Infectious Diseases (31 March–03 April 2012, London); ASM Conference on Antimicrobial Resistance in Zoonotic Bacteria and Foodborne Pathogens (2012, Lyon [France]); Inter science Conference on Antimicrobial Agents and Chemotherapy (9–12 September 2012, San Francisco); OIE Global Conference on Antimicrobial Resistance.

The Aquatic Animals Commission endorsed the *ad hoc* Group's outline of a future new chapter in the *Aquatic Code* but considered that this work should not be commenced until after the adoption of Chapters 6.4. and 6.5. (Annexes IX and X). In addition, the Commission considered that the current work on the revision of the *Terrestrial Code* chapters on antimicrobial resistance should be finalised and adopted before drafting a new chapter on risk assessment for the *Aquatic Code*.

The *ad hoc* Group report is provided for information at Annex XVIII.

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 presented the report of the meeting of this *ad hoc* Group, which had been held from 27 to 28 September 2011. She explained that the Group had completed its Terms of Reference: to assess and further develop the draft criteria, which had been appended to the report of the February 2011 meeting of the Commission, including Members' comments, and to develop a worked example using these criteria for Koi herpesvirus disease (KHVD) to aid authors of disease chapters in the *Aquatic Manual* and in the *Aquatic Code* to correctly apply the criteria.

The Commission held an in-depth discussion on the document provided. The Commission noted that the issue was a very complex one that required careful thought and consideration to ensure the utmost clarity, defensibility and utility of the final document. The process of reviewing and refining the criteria and explanatory notes was an on-going one. The Commission provided Dr Haenen with some feedback for the *ad hoc* Group, which it was hoped would assist the Group in further developing and expanding the document.

Japan had submitted the scientific rationale to support its opinion that there was not sufficient evidence to include goldfish (*Carassius auratus*) in the susceptible species list for koi herpesvirus disease. The Aquatic Animals Commission considered this submission, felt it had merit, and requested that the *ad hoc* Group take this into account.

The Aquatic Animals Commission received an in-depth assessment of 104 potentially susceptible species for white spot disease (WSD) from Canada and will forward this to the author of the *Aquatic Manual* chapter on WSD for consideration as to whether there is need to amend the susceptible species list in the revised chapter. The Commission also decided to forward this document to the *ad hoc* Group for information.

The Aquatic Animals Commission recommended that the *ad hoc* Group produce a guidance document, including criteria for listing host species as susceptible, and explanatory text on how to systematically assess and interpret scientific information for use in the decision-making process. The Commission indicated that it would be prepared to recommend publishing such a document on the OIE website.

The Commission undertook to review the *ad hoc* Group's response to the Commission's comments and at the meeting in March 2012.

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

2.1. General comments

The Aquatic Animals Commission welcomed the contribution of Chile, Chinese Taipei, European Union, Mexico, New Zealand, Norway, Philippines, and the United States of America.

2.2. Glossary

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

As agreed at the General Session, the Aquatic Animals Commission reviewed the definition of feed and considered the use of the term throughout the chapter and concluded that the reality of aquaculture throughout the world includes some use of live plant and animal organisms (e.g. *Artemia* spp., rotifers, phytoplankton). The Commission proposed the definition be modified and that the definition for live feed be deleted.

Feed

means any material (single or multiple), ~~whether~~ processed, semi-processed or ~~raw~~ unprocessed plant or animal material as well as live organisms that 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.~~

At the General Session a Member requested that the term 'aquatic animal health professional' be defined. The Aquatic Animals Commission proposed the following definition:

Aquatic animal health professional

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

The Aquatic Animals Commission proposed the following amendment to the definition of 'disease', based on the fact that this term is used throughout the *Aquatic Code* in relation to both OIE listed diseases and in horizontal chapters:

Disease

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

The Aquatic Animals Commission reviewed the definition of 'self-declaration of freedom from disease', amended it and added a note to clarify the process of self-declaration.

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 chapter is presented at Annex III for Member comments.

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

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

In response to a Member comment, the Commission proposed to delete the footnote because the definition of disease includes non-clinical infection and therefore the footnote is redundant.

Noting that the Code Commission is in the process of modifying the disease listing criteria in the *Terrestrial Code*, the Aquatic Animals Commission proposed to await the decision of Members on this work before proposing any significant modifications to the text in the *Aquatic Code*.

The revised chapter is provided at Annex IV for Member comments.

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

As part of its ongoing review of the OIE list of aquatic animal diseases, and in response to Member comments, the Commission considered recent reports of serious mortalities in oysters in several Member Countries and the published evidence for the ostreid herpesvirus-1 being an associated causative agent. An assessment of the scientific information was made to determine whether the required criteria for listing this disease as an emerging disease (Article 1.2.2.) were now met.

Based on this assessment the Aquatic Animals Commission concluded that the disease 'Infection with ostreid herpesvirus-1' meets criteria 2 and 4 of Article 1.2.2. and therefore proposed that the disease be listed in Chapter 1.3. as an emerging disease.

The assessment is presented at Annex 5 for Member comments.

As requested by the Aquatic Animals Commission, Chile provided additional supporting evidence that pancreas disease meets the listing criteria (Chapter 1.3.) in relation to criteria 6 and 7. The Commission decided to forward the information to the *ad hoc* Group on the OIE List of Aquatic Animal Diseases (Finfish Team), which had undertaken the initial assessment, and to ask this group to review the new information. The Aquatic Animals Commission requested that the *ad hoc* Group meet electronically and finalise a report in time for the March 2012 meeting of the Aquatic Animals Commission.

Canada proposed that epizootic ulcerative syndrome be delisted. The Commission invited Canada to provide a full assessment using the disease listing criteria and supporting documentation.

The revised chapter is presented at AnnexVI for Member comments.

2.5. Import risk analysis (Chapter 2.2.)

The Aquatic Animals Commission considered the proposed amendments to the *Terrestrial Code* Chapter 2.1., based on the internationally accepted practice of referring to an 'entry assessment' rather than a 'release assessment' and taking account of the need to harmonise with the terminology in the revised OIE *Handbook on Import Risk Analysis*. The Aquatic Animals Commission made several similar amendments to the text in the *Aquatic Code* Chapter 2.2.

The revised chapter is presented at Annex VII for Member comments.

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

The Aquatic Animals Commission agreed with a Member's proposal to replace the words 'OIE Members' with the words '*Competent Authority'* in paragraph 2 of Articles 10.4.13., 10.5.13., 10.9.13. The Aquatic Animals Commission proposed that, should Members agree to this modification, the same amendment would be made in the last sentence in Article X.9.X. of the disease specific chapters of the *Aquatic Code* (i.e. replace the word 'Members' with '*Competent Authority'*).

The revised chapter is presented at Annex XIV for Member comments.

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

In response to a Member comment, the Aquatic Animals Commission reviewed the chapter and concluded that it could be improved to clarify the issue of food safety risks. The Commission will invite an expert in the field of food safety risks associated with feed to review this chapter and suggest any necessary amendments.

At the General Session in May 2011, several Members had requested that the Aquatic Animals Commission consider the development of a new chapter addressing the hazards associated with feeding live aquatic animals to aquatic animals. In response, the President of the Commission had invited Members to submit proposals for the Commission's consideration. The Aquatic Animals Commission noted that no proposals had yet been received and encouraged Members to submit proposals for consideration at the next Commission meeting.

The Aquatic Animals Commission drew the attention of Members to the proposed changes to the definitions of 'feed' and 'live feed' (see Item 2.2.).

2.8. Principles for responsible and prudent use of antimicrobial agents in aquatic animals (Chapter 6.3.)

In response to a Member's request that the Commission consider expanding the chapter to include antiparasitic agents and other pharmaceuticals used in veterinary medicine, the Aquatic Animals Commission advised that this development may be considered in the future. However, at the present time, the focus is on antimicrobial resistance and the priority is adoption of chapters on this topic.

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

The Aquatic Animals Commission considered Member comments and comments from the OIE Animal Welfare Working Group (AWWG) and made relevant amendments.

In response to a comment from the AWWG regarding concerns about welfare in the capture and transport of wild caught fish, the Aquatic Animals Commission clarified that the OIE *Aquatic Code* only addresses the welfare of farmed fish. Encouraging the implementation of the adopted chapters by Members is the priority in the short to medium term.

In response to a comment from the AWWG if the recommendations in Chapter 7.2. are intended to cover welfare aspects of translocation (e.g. towing fish in net cages to farm locations), the Aquatic Animals Commission clarified that this chapter does not address this practice. If Members request, the Commission may consider other practices of potential welfare concern in future.

The Aquatic Animals Commission considered comments from some Members proposing text amendments but did not accept these as they considered them to be too detailed. The Commission clarified that all the welfare chapters are intended to provide general recommendations/ guidelines to all OIE Member Countries without being prescriptive.

The revised chapter is provided at Annex XI for Member comments.

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

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

The Commission clarified that this chapter recommends methods that produce rapid loss of consciousness.

The Commission made some amendments to the Scope in Article 7.3.1. to clarify that methods listed in Chapter 7.3. can also be used for disease control purposes.

A Member suggested that the second example in point 2 (g) in Article 7.3.5. ' (e.g. to clear the gut or to reduce undesirable organoleptic properties)' be deleted as it was misleading. The Commission disagreed because in reality it was necessary for some species of fish to have a longer period of fasting than to just clear the gut, e.g. the need to remove off-flavours in some freshwater fish species).

The Aquatic Animals Commission did not agree with a Member's recommendation to amend the text in Point 4 of Article 7.3.6. 'Other killing methods', as the Commission did not wish to imply that all methods provide equally acceptable welfare outcomes.

The Aquatic Animals Commission disagreed with a Member's recommendation to add exsanguination as a killing method in Article 7.3.6., because the focus of the article is on stunning rather than describing the killing method *per se*. However, the Commission agreed that exsanguination (or another killing method) should be applied where loss of consciousness is transient.

The revised chapter is presented at Annex XII for Member comments.

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

The Aquatic Animals Commission noted that many Members commented on this chapter. All comments were reviewed and relevant amendments were made.

The Commission did not accept several recommendations from Members on the basis that it considered them to be calling for excessively detailed text. The Commission reminded Members that the chapters on welfare of farmed fish are intended to provide general recommendations and guidelines to OIE Members without being prescriptive.

Several Members requested clarification as to why some killing methods were listed in Chapter 7.3. and not in Chapter 7.4. despite the fact that they could be used for disease control purposes. The Aquatic Animals Commission amended Article 7.4.2. to clarify that methods described in Chapter 7.3. may also be used for killing of fish for disease control purposes where the fish are not intended for human consumption. The Commission reiterated the general principle that fish should be stunned before killing to avoid unnecessary pain and distress, by adding a new point to Article 7.4.2.

Several Members questioned why Point 4 of Article 7.4.3. had been proposed for deletion. After re-consideration, the Aquatic Animals Commission decided to retain this point, with amendment to highlight the importance of killing fish in the shortest time possible and avoiding unnecessary pain or distress.

In response to a Member's request for clarification on the intent of Article 7.4.6., the Commission amended the title of this article to 'Killing by an overdose of an anaesthetic agent' and replaced the word 'pharmacological substance' by 'anaesthetic agent' throughout the article. The Commission drew to the attention of Members to the fact that the intent of this article was to address killing with an overdose of anaesthetic, rather than use of the anaesthetic prior to killing by another method.

Some Members proposed the addition of a new article on the use of carbon dioxide gas as a killing method. The Aquatic Animals Commission did not agree because this method is already referred to in Article 7.3.6 and Point 3 of Article 7.4.2. was also amended to clarify that methods described in Chapter 7.3. could also be used for disease control purposes, where the fish are not intended for human consumption.

The revised chapter is presented at Annex XIIIA for Member comments.

A clean text version is presented at Annex XIIIB.

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

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

3.1.1. Communication chapter

The Aquatic Animals Commission reviewed the recently adopted *Terrestrial Code* Chapter 3.3. 'Communication' and considered that this information was also relevant in the *Aquatic Code*. The Aquatic Animals Commission amended the text of the *Terrestrial Code* Chapter 3.3. to make it appropriate for inclusion in the *Aquatic Code*, noting the importance of effective communication between the Aquatic Animal Health Services (AAHS) and Veterinary Services (VS), particularly where AAHS are separate from, and independent of VS.

The proposed new Chapter 3.2. is provided at Annex VIII for Member comments.

3.1.2. Welfare and transport of laboratory animals

Dr Sarah Kahn updated the Aquatic Animals Commission on the proposed addition to the *Terrestrial Code* of text on the welfare animals used in research and education, including transport between laboratories. Such animals include both terrestrial and aquatic animals – e.g. amphibians and zebra fish. The Aquatic Animals Commission considered 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 some work still needs to be done to finalise relevant chapters and to encourage Members to implement them, it was not appropriate to propose adoption of text on the welfare of aquatic animals used in research and education at this time

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 Member and reviewer comments on draft Chapters

Comments had been received from ten Member Countries (Australia, Canada, People's Republic of China, Cyprus, European Union, Japan, Norway, Romania, Serbia and Switzerland) on the 34 draft chapters for the next edition of the *Aquatic Manual* that had been circulated in August 2011. Those comments that were of a technical nature would be sent to the authors for consideration; the Commission only considered more general comments on policy or procedure.

The European Union had asked for the rationale behind reintroducing chapters on delisted diseases. At its meeting in March 2011, the OIE Council had supported the approach whereby Reference Laboratories can be designated or maintained and *Manual* chapters can be developed or maintained for an important non-listed disease (regardless of whether it is a terrestrial or aquatic animal disease). The Commission consulted electronically and drew up a list of delisted diseases (tetrahedral baculovirosis; spherical baculovirosis, *Oncorhynchus masou* virus disease, viral encephalopathy and retinopathy, infection with *Mikrocytos mackini*) and one non-listed disease (infection with ostreid herpesvirus-1) for which chapters could be drafted. One criterion used in selecting a disease was the availability of authors and reviewers. The Commission was aware that there are other diseases that may merit a chapter and would welcome Member Country proposals.

Australia commented that reviewing the entire *Aquatic Manual* at one time was a demanding task that was well beyond the resources of many OIE Member Countries and proposed that a different approach be adopted, such as identifying, annually, a limited number of chapters for update (e.g. 10–15), such that each year Member Countries would be asked to comment on these chapters only. The Commission agreed to this approach.

A number of comments had been received criticising the limitation placed on the number of references that should be included in the *Aquatic Manual* disease chapters and on the nature of the references (that review articles are often favoured). It was evident those making these comments have misunderstood the purpose of the *Aquatic Manual* – that it is primarily a laboratory manual of diagnostic test methods and was not intended to include comprehensive reviews of the literature. To address this misunderstanding, it was decided that at its meeting in October 2012 (following publication of the seventh edition of the *Aquatic Manual*), the Commission would review the chapter template and the instruction to authors, and explore ways of communicating better the purpose of this laboratory manual.

For a number of chapters, Canada had asked that a reference be included to support each newly listed susceptible species. The Commission agreed to this proposal and extended it to each newly added geographical location (country) where a disease was reported to have occurred. All susceptible species and locations that are already in the *Aquatic Manual* are deemed to have been adopted previously by the Assembly and so no longer require a reference. Text explaining this practice would be added to the chapters introducing the sections on diseases of amphibians, crustaceans, fish and molluscs.

At the February meeting, the Aquatic Animals Commission had identified a number of experts who were asked to work electronically to complete the disinfection chapter, in particular the section on disinfection of fish eggs. The experts, led by the Norwegian component of the OIE Collaborating Centre for Epidemiology and Risk Assessment of Aquatic Animal Diseases, deemed the task was more complex than originally thought and would take more time. They agreed to provide an update by the end of the year. The Commission would review it at its March 2012 meeting, and, if approved, it would be circulated for comments. This meant that the chapter will not be included in the next edition of the *Aquatic Manual*, which will be proposed for adoption in May 2012, but it may be proposed for adoption in May 2013 and, if it is adopted then, it would be added to the web version.

The 34 draft chapters will be amended following the comments received, and those amendments will be highlighted in yellow for ease of reference. After final review by the Commission at its next meeting in March 2012, the chapters will be circulated again to Members as the final version that will be proposed for adoption by the World Assembly of Delegates of the OIE in May 2012, after which the seventh edition of the *Aquatic Manual* will be published.

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

The experts involved were still working on drafting the texts on sampling for the three chapters. It was hoped that the texts would be ready for review by the Commission at its meeting in March 2012.

5. OIE Reference Laboratories and Collaborating Centres

5.1. New Terms of Reference and Internal Rules for OIE Reference Centres

Dr Kazuaki Miyagishima, Head of the OIE Scientific and Technical Department, joined the Commission for a brief discussion on the revision of the OIE Basic Texts. The Commission noted that a number of important modifications to the OIE Organic Texts had been adopted at the General Session 2011. These included membership of elected commissions, declarations of confidentiality, avoidance of conflict of interest, and the arrangements for the approval of OIE Reference Centres. The Commission noted this information.

5.2. Review nominations for replacement experts

The OIE had been notified of the following change of the designated expert at an OIE Reference Laboratory for spring viraemia of carp:

Dr David Stone to replace Dr Peter Dixon at The Centre for Environment, Fisheries and Aquaculture Science (CEFAS), Weymouth Laboratory, Weymouth, Dorset, UNITED KINGDOM.

The Commission recommended its acceptance.

5.3. Follow-up from the February 2011 meeting – questions on the annual reports of OIE Reference Centre activities in 2010

At its last meeting the Aquatic Animals Commission had carefully reviewed the annual reports received from OIE Reference Centres with respect to activities in 2010. Some experts that had not followed the instructions sent with the report template had been asked to do so, and the edited reports were considered by the Commission. Some laboratories reported little or no activity in several categories in the report template. The laboratories had clarified that this was because of lack of requests, sometimes linked to the cost of packaging and shipment of materials, and was not because of an inability to fulfil their mandate. The Commission noted the responses.

6. Laboratory Twinning Projects

Dr Keith Hamilton, from the OIE Scientific and Technical Department, joined the meeting and presented an update on Laboratory Twinning Projects relevant to aquatic animals. He informed the Aquatic Animals Commission that the application for twinning between Zambia and Thailand on EUS was still pending but close to being formalized.

The Aquatic Animals Commission encouraged Members, especially developing countries, to consider laboratory twinning projects and to explore possible collaboration with Reference Laboratories.

7. Other relevant activities

7.1. Document on OIE standard-setting procedures

Dr Sarah Kahn, Head of the OIE International Trade Department, informed the Aquatic Animals Commission that the Trade Department had drafted a document setting out the OIE procedures for standard setting with a focus on the *Terrestrial* and *Aquatic Codes*. Dr Sarah Kahn indicated that this document could be viewed on the OIE website at: http://www.oie.int/en/international-standard-setting/overview/productionimplementation/.

At a later date, if considered appropriate, OIE Members may be asked to formally adopt these procedures within the official framework governing the OIE's activities.

7.2. 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.

As mentioned in the discussion with the Director General (see above), the Aquatic Animals Commission considered that the time was right to undertake some significant development of the PVS Tool to make it more useful for evaluation of AAHS. With this in mind, the Commission asked the Director General to convene an *ad hoc* Group to develop performance indicators for use in PVS assessments of AAHS, using the experience gained from the evaluations of AAHS conducted to date.

Noting the central importance of professional staff in AAHS, the Aquatic Animals Commission proposed a definition of 'aquatic animal health professional', for consideration of Members. Should Members support this proposal, the Commission recommended the development of recommendations on the education of aquatic animal health professionals including veterinarians and suggested that the Director General consider convening an *ad hoc* group on this topic.

The Commission again encouraged Members 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.

7.3. OIE *ad hoc* Group on Veterinary Education

Dr Sarah Kahn updated the Commission on the work of the *ad hoc* Group on Veterinary Education. At its September 2011 meeting, the Code Commission had endorsed the document 'Minimum Competencies expected of Day 1 Veterinary Graduates to assure Delivery of High-Quality National Veterinary Services' and proposed that this document be placed on the OIE website under the rubric 'Support to OIE Members', as one of the tools used in the PVS Pathway.

After some discussion of the relevance of this work to AAHS, the Aquatic Animals Commission decided to ask the *ad hoc* Group on Veterinary Education consider post-graduate competencies for veterinarians working in aquatic animal health.

The Aquatic Animals Commission also requested that the *ad hoc* Group on Veterinary Education be informed of the work underway by the Commission to define an aquatic animal health professional.

The 'Minimum Competencies expected of Day 1 Veterinary Graduates to assure Delivery of High-Quality National Veterinary Services' is at Annex XIX.

7.4. OIE *ad hoc* Group on Veterinary Legislation

As part of its global PVS Pathway initiative to help strengthen Veterinary Services (VS) and aquatic animal health services (AAHS) of Members, the OIE is continuing to publish new standards and recommendations on key elements of good governance. Noting the pressing need for developing countries to modernise their veterinary legislation, the Code Commission will propose for adoption in 2012 a new standard on the topic of veterinary legislation, which is a critically important part of the infrastructure of VS and AAHS.

The Aquatic Animals Commission noted this work.

7.5. Invasive alien species

Dr Sarah Kahn briefed the Aquatic Animals Commission on the discussions that had taken place between the Secretariats of the OIE and the Convention on Biological Diversity (CBD), regarding 'gaps in the coverage by international standards of risks associated with animals that may be invasive'.

The OIE International Trade Department had contributed to the briefing provided by the Secretariat of the CBD to the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) on ''Invasive Alien Species: proposals on ways and means to address gaps in international standards regarding invasive alien species introduced as pets, aquarium and terrarium species, as live bait and live food.''

At the request of the Code Commission, the Director General had undertaken to consider the development of guidance on risk assessment of the invasiveness of animals, noting that this should take the form of guidelines on the OIE website, not a standard in the *Terrestrial Code*.

The Aquatic Animals Commission noted this information and indicated that a member of the Commission would be pleased to attend meetings on this topic.

8. OIE Conferences and relevant meetings

Members of the Aquatic Animals Commission or other OIE representatives attended the following OIE conferences and meetings and delivered a presentation on the work of the Aquatic Animals Commission:

- 19th Conference of the OIE Regional Commission for Africa (Kigali, Rwanda, 14−18 February 2011);
- OIE Global Conference on Wildlife: animal health and biodiversity – Preparing the future **(**Paris, France, 23−25 February 2011);
- 15th International Conference of the European Association of Fish Pathologists (Split, Croatia, 12−16 September 2011).

9. OIE Global Conference on Aquatic Animal Health: 'Aquatic Animal Health Programmes: their benefit to global food security', 28−30 June 2011, Panama

The Aquatic Animals Commission was pleased the success of this conference which was attended by 228 participants from 118 countries, and took note of the recommendations, which are available at:

http://www.oie.int/fileadmin/Home/eng/Conferences_Events/docs/pdf/recommendations/A_Declaration.pdf

The Aquatic Animals Commission noted that the abstracts and the presentations are all available on the OIE website at:

http://www.oie.int/eng/A_aquatic/en_presentations.htm

The Aquatic Animals Commission also noted that subsequent to the conference, the OIE posted a video interview with Dr Vallat in which he emphasised the importance of aquatic animal health programmes for global food security. This is available on the OIE website at:

http://www.oie.int/en/for-the-media/multimedia/webcasting/aquatic-animals/

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

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

11. Date of the next meeting

The next meeting of the Aquatic Animals Commission is scheduled for 5–9 March 2012.

.../Annexes

Annex I

MEETING OF THE OIE
AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 3–7 October 2011

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Annex I (contd)

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Annex II

MEETING OF THE OIE
AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 3–7 October 2011

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Adopted agenda

1. Activities and progress of *ad hoc* groups

1.1. Report of the OIE *ad hoc* Group on Pathogen Differentiation for Aquatic Animal Diseases

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 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.)

2.5. Import risk analysis (Chapter 2.2.)

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

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

2.8. Principles for responsible and prudent use of antimicrobial agents in aquatic animals (Chapter 6.3.)

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

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

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

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

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

3.1.1. Communication chapter

3.1.2. Welfare and transport of laboratory animals

Annex II (contd)

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

4.1. Review Member and reviewer comments on draft Chapters

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

5. OIE Reference Laboratories and Collaborating Centres

5.1. New Terms of Reference and Internal Rules for OIE Reference Centres

5.2. Review nominations for replacement experts

5.3. Follow-up from the February 2011 meeting – questions on the annual reports of OIE Reference Centre activities in 2010

6. Laboratory Twinning Projects

7. Other relevant activities

7.1. Draft document on OIE standard-setting procedures

7.2. OIE PVS Tool: Application to Aquatic Animal Health Services

7.3. OIE *ad hoc* Group on Veterinary Education

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

7.5. Invasive alien species

8. OIE Conferences and relevant meetings

9. OIE Global Conference on Aquatic Animal Health: 'Aquatic Animal Health Programmes: their benefit to global food security', 28−30 June 2011, Panama

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

11. Date of the next meeting

Annex III

GLOSSARY

Feed

means any ~~material~~ product (single or multiple) of ~~whether~~ processed, semi-processed or ~~raw~~ unprocessed plant or animal material, as well as live organisms, that 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.~~

Aquatic animal health professional

means an individual holding a tertiary (university) level qualification in animal sciences 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*~~.

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.~~

— Text deleted.

Annex IV

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, 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	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*~~+~~ *species*, and that morbidity or mortality are related primarily to the agent and not management or environmental factors. (Morbidity includes, for example, loss of production due to spawning failure.) The direct economic impact of the disease is linked to its morbidity, mortality and effect on product quality.
2.	Or	The disease has been shown to or scientific evidence indicates that it is likely to 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.	

Annex IV (contd)

No.	Criteria (A-C)	Parameters that support a listing	Explanatory notes
5.	Or	An infectious agent is strongly associated with the disease, but the aetiology is not yet known.	Infectious diseases of unknown aetiology can have equally high-risk implications as those diseases where the infectious aetiology is proven. Whilst disease occurrence data are gathered, research should be conducted to elucidate the aetiology of the disease and the results be made available within a reasonable period of time.
No.	**Criteria (A-C)**	**Parameters that support a 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.

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— Text deleted.

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

Annex V

Assessment for listing of Infection with ostreid herpesvirus-1 (including OsHV-1 µvar) as an emerging disease

Infection with ostreid herpesvirus-1 (including OsHV-1 µvar) was assessed against the criteria for listing an emerging aquatic animal disease in Article 1.2.2. of the *Aquatic Code.*

Case definition

An increased mortality in Pacific oysters associated with the presence of OsHV-1 or OsHV-1 µvar in affected animals.

Criterion 2: An infectious agent is strongly associated with the disease, but the aetiology is not yet known

OsHV-1, including µvar (Segarra *et al*., 2010), has been predominantly associated with increased mortality of Pacific oysters. This suggests that OsHV-1 infection is one of the causative factors. However, it may not be sufficient by itself as other factors appear to be important (EFSA, 2010; Garcia *et al*., 2011). OsHV-1 µvar has not been sufficiently characterised to be defined as a new genotype but may be considered as a different strain. OsHV-1 µvar seems to be the dominant viral strain in the 2008-2010 increased mortality events, but it is not clear if this is a result of increased virulence or other epidemiological factors (EFSA, 2010). There are observations indicating emergence of different OsHV-1 variants (Martenot *et al*., 2011).

Criterion 4: Significant spread in naive populations of wild or cultured aquatic animals

Since 2008, severe mortality events in cultured Pacific oyster were reported from the main European producing countries. Information provided to OIE (WAHIS) shows that in 2009, Ireland and France experienced mortality rates ranging between 15-95% and 50-75% respectively. In 2010, United Kingdom reported mortalities of 60%. New Zealand also reported increased mortality ranging between 50-80%. In 2011, reports were received from the Netherlands and Australia. In Australia, mortality has been 100% for spat and 95% for market sized stock.

Conclusion

Infection with ostreid herpesvirus-1 including OsHV-1 µvar is eligible for listing as an emerging disease because it meets the criteria 2 and 4.

Note

Diagnostic methods are listed in the draft *Aquatic Manual* chapter Infection with ostreid herpesvirus-1. Definition of a confirmed case should require the identification of the variants involved.

References

MARTENOT C., ODEN E. TRAVAILLÉ J.P. MALAS & M. HOUSSIN, 2011. Detection of different variants of Ostreid Herpesvirus 1 in the Pacific oyster, *Crassostrea gigas* between 2008 and 2010. Virus Research, 160, 25–31.

EFSA PANEL ON ANIMAL HEALTH AND WELFARE (AHAW); Scientific Opinion on the increased mortality events in Pacific oyster (*Crassostrea gigas*). EFSA Journal 2010;8(11):1894. [60 pp.]

Annex V (contd)

GARCIA C., THEBAULT A., DEGREMONT L., ARZUL I., MIOSSEC L., ROBERT M., CHOLLET B., FRANÇOIS C., JOLY J.P., FERRAND S., KERDUDOU N. & RENAULT T. (2011). Ostreid herpesvirus 1 detection and relationship with *Crassostrea gigas* spat mortality in France between 1998 and 2006. Vet Res, 42, 73.

SEGARRA A., PÉPIN J.F., ARZUL I., MORGA B., FAURY N. & RENAULT T. (2010). Detection and description of a particular Ostreid herpesvirus 1 genotype associated with massive mortality outbreaks of Pacific oysters, *Crassostrea gigas*, in France in 2008. Virus Res, 153, 92–99.

Annex VI

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, 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

– Koi herpesvirus disease

– Red sea bream iridoviral disease

– Spring viraemia of carp

– Viral haemorrhagic septicaemia.

Article 1.3.2.

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

– Infection with abalone herpes-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-1[1].

Annex VI (contd)

Article 1.3.3.

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

– Crayfish plague (*Aphanomyces astaci*)

– Infectious hypodermal and haematopoietic necrosis

– Infectious myonecrosis

– Necrotising hepatopancreatitis

– Taura syndrome

– White spot disease

– White tail disease

– Yellow head disease.

Article 1.3.4.

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

– Infection with Batrachochytrium dendrobatidis

– Infection with ranavirus.

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— Text deleted.

[1]Listed according to Article 1.2.2.

Annex VII

CHAPTER 2.2.

IMPORT RISK ANALYSIS

Article 2.2.1.

Introduction

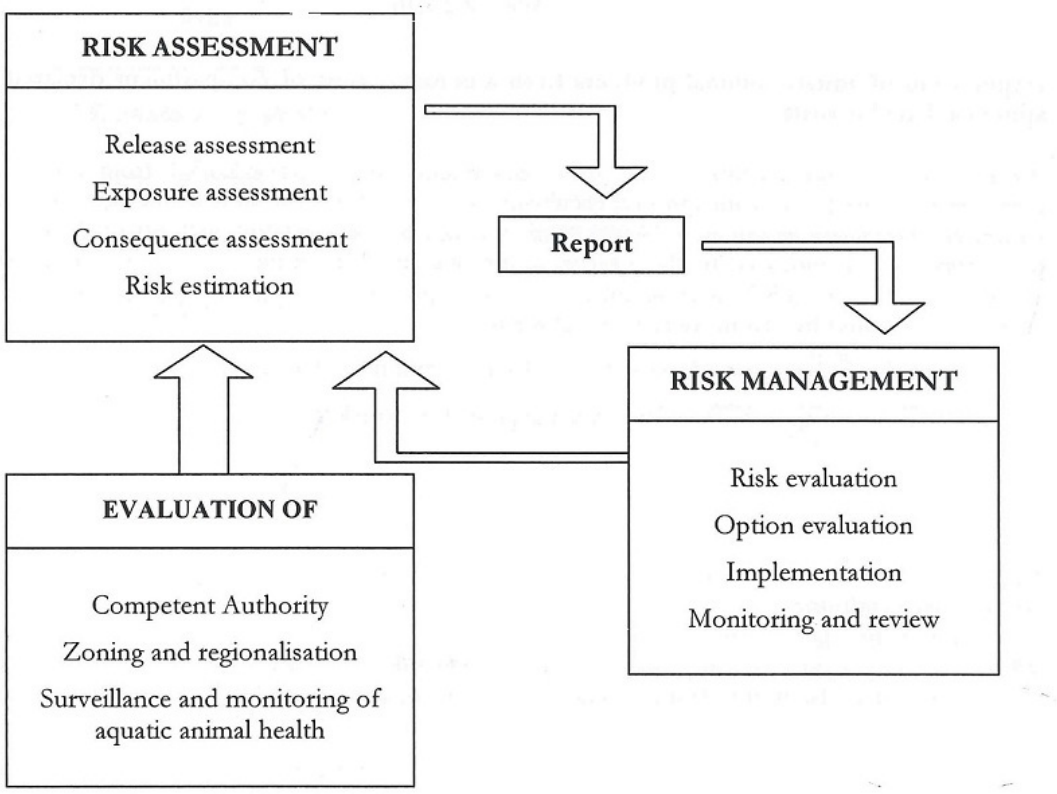
An import *risk analysis* begins with a description of the *commodity* proposed for import and the likely annual quantity of trade. It should be recognised that whilst an accurate estimate of the anticipated quantity of trade is desirable to incorporate into the *risk* estimate, it may not be readily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

Annex VII (contd)

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.

Annex VII (contd)

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

a) Biological factors

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

b) Country factors

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

c) Commodity factors

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

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

3. Consequence assessment

Consequence assessment consists of identifying the potential biological, environmental and economic consequences. A causal process 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.

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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.

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 VIII

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 expertises 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 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*.

Annex VIII (contd)

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

Crisis communication: means the process of communicating information 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 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 (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 premise/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

        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*

vi) 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 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 strategic plan for communication should consider the different types of communication: routinecommunication, *risk communication*, outbreak communication and crisis communication, to allow individuals, affected and/or interested parties, an entire community or the general public to make 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.

Annex IX

CHAPTER 6.4.

MONITORING OF THE QUANTITIES AND USAGE PATTERNS OF ANTIMICROBIALS 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 collect objective and quantitative information to evaluate usage patterns by antimicrobial class, route of administration-and animal species in order to evaluate exposure 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 labeled products and poorly understood distribution channels. 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. 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 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.

Development and standardisation of monitoring systems for antimicrobial agents

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

1. Sources of data on antimicrobial agents

   a) Basic sources

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

Annex IX (contd)

b) Direct sources

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 authorization (registration of the antimicrobial agent).

c) End-use sources (veterinarians, aquatic animal health professionals and 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 source may be useful when more accurate and locally specific information is needed (such as extra-/off-label use).

Because collection of this type of information can be resource intensive, 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 and 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 could be collected where available.

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. 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) 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.

   The total number of *aquatic animals* cultured and their weight in kilograms is important basic information.

b) Subdivision of antimicrobial use into species of finfish, crustacean, or mollusc treated.

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

d) 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, volume of water treated).

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.

Nomenclature of antimicrobials should comply with international standards where available.

3. Considerations for data collection

Antimicrobial usage data 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 temperature, disease conditions (epizootiology), species and age affected, aquacultural systems (i.e. intensive / extensive), dosage and duration of treatment with antimicrobial agents.

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 6.4.4.

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, when available, aid in the 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;

Annex IX (contd)

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

e) geographical location, specific rearing units;

f) dosage regimes and duration of treatment with antimicrobial agents.

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.

Annex X

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*, products of aquatic 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 should conduct active antimicrobial resistance surveillance and monitoring programmes.

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.

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

Annex X (contd)

Article 6.5.3.

Design of surveillance and monitoring programmes

Surveillance of antimicrobial resistance at targeted intervals or ongoing monitoring of the prevalence of resistance in microorganisms from animals, food, environment and humans constitutes a critical part of 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 animal* and microorganisms 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 resistence determinants in the environment.

Article 6.5.4.

Design of surveillance and monitoring programmes for micro organisms that infect aquatic animals

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 overrepresentation 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 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 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 and on-going validation studies.

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

Article 6.5.5.

Design of surveillance and monitoring programmes for microorganisms in or on food derived from aquatic animals

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 origin intended for human consumption, the relevant section of the *Terrestrial Animal Health Code* should be consulted.

It is important to note that the word 'commensal' as used in the *Terrestrial Animal Health Code* has less relevance due to the transient nature of the intestinal microflora of *aquatic animals*. Therefore commensal bacteria should not be included in surveillance and monitoring programmes.

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 microorganisms of *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 programme:

a) *Salmonella* spp.;

b) *Vibrio parahaemolyticus*;

c) *Listeria monocytogenes*.

Article 6.5.6.

Surveillance and monitoring for antimicrobial resistance in microorganisms present in 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.

Annex X (contd)

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.

Annex XI

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. Transport 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:

Annex XI (contd)

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;

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) need for care of the fish during the transport;

e) emergency response procedures related to fish welfare;

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

2. Vehicle design and maintenance

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.

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 XI (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 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 XI (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 XII

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.

Annex XII (contd)

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

4. The following recommendations may help to achieve this:

   a) nets and tanks should be designed and maintained to minimise 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 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 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 were 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.

Annex XII (contd)

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.

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.

Stunning/ killing method	Specific method	Key fish welfare concerns/requirements	Advantages	Disadvantages
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.
Electrical	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 XIIIA

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 stunning and killing of fish for human consumption is covered in Chapter 7.3.~~

The ~~killing~~ ~~death~~ 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. ~~Contingency plans for disease control should be in place at a national level and should contain details of disease control strategies, managerial structure, and operational procedures.~~ Fish welfare considerations should be addressed within contingency plans for disease control (refer to Chapter 4.4.).

~~2. Depending on the situation, emergency killing of fish may be carried out on site or after fish are transported to an approved killing facility.~~

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.

~~2. Depending on the situation, emergency killing of fish may be carried~~ out ~~on site or after fish are transported to an approved killing facility.~~

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

Annex XIIIA (contd)

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. ~~Fish not suitable for human consumption may be killed by specific methods (e.g. chemical, mechanical.~~

~~4. Fish suitable for human consumption should be killed following according to the provisions provided in Chapter 7.3. Welfare aspects of stunning and killing of farmed fish for human consumption.~~

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

The following ~~principles~~ should apply when killing fish:

1. Operational procedures should be adapted to the specific ~~operating~~ circumstances on the premises and should address biosecurity and fish welfare 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. ~~The h~~Handling of fish should be kept to a minimum to avoid stress and ~~minimised~~ to prevent spread of *disease*.~~and when done, it~~ This should be done in accordance with the Articles described below.

4. ~~Methods used to kill the fish should result in immediate death or loss of consciousness lasting until death.~~ Methods used to kill the fish should render them unconscious 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.

~~Article 7.4.4.~~

~~**Operational guidelines for affected premises**~~

A protocol ~~plan~~ for the killing of fish on affected premises ~~due~~ for ~~to~~ disease control ~~issues~~ 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:

~~Considerations should include:~~

1. ~~minimising~~ handling and movement of fish;

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

3. methods for killing the fish;

4. availability of ~~pharmacological substances~~ anaesthetic agents ~~chemicals/equipment needed to kill the fish~~ suitable to kill the fish;

5. equipment needed to kill the fish;

~~6. biosecurity issues;~~

6. any legal issues ~~that may be involved, for example,~~ (e.g. the use of anaesthetic ~~pharmacological substances~~ agents suitable for killing fish) ~~controlled drugs or chemicals~~;

7. presence of other nearby aquaculture premises;

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

Article 7.4.~~5~~4.

Competencies and responsibilites of the operational team

The operational team is responsible for ~~the~~ planning, implementation of, and reporting ~~from~~ 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 outcome on time;

      iv) awareness of the emotional 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 ~~which balance~~ 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;

Annex XIIIA (contd)

vii) report upwards on progress and problems;

viii) provide a written report summarising the killing~~,~~ practices utilised in the operation and their effect on ~~aquatic animal~~ 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-~~farm~~site personnel responsible for killing of fish

a) Competencies

i) specific knowledge of fish, ~~and~~ 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 ~~humane~~ 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.

Article 7.4.~~6~~5.

~~Chemical~~ ~~Pharmacological k~~Killing ~~methods~~ by an overdose of an anaesthetic agent

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

1. Use of ~~chemicals pharmacological substances~~ anaesthetic agents

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

b) when using ~~such chemicals pharmacological substances~~ anaesthetic agents, the operating personnel should ensure that the solution has the correct concentration, and that sea water is used for marine fish species and freshwater for freshwater species;

c) fish should be kept in the ~~pharmacological substance~~ anaesthetic solution ~~chemical solution~~ until they are dead. ~~Fish that are merely anaesthetised should be killed before they regain consciousness by another method such as bleeding, decapitation or another appropriate killing method.~~

2. Advantages

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

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

c) use of ~~chemicals~~ ~~pharmacological substances~~ anaesthetic agents is a non-invasive technique and thus reduces ~~minimises~~ biosecurity risks.

3. Disadvantages

a) m~~M~~ay need to be followed by killing if fish are only anaesthetised;

b) some ~~chemicals~~ ~~pharmacological substances~~ anaesthetic agents may induce a transient aversive ~~panic~~ 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 ~~anaesthetic agents~~ ~~pharmacological substances~~.

Article 7.4.~~7~~6.

Mechanical killing methods

~~The following mechanical killing methods should only be used for killing fish following stunning.~~

1. Decapitation

a) Decapitation, using a sharp device such as a guillotine or knife~~,~~ may be used ~~for killing fish but only following anaesthesia~~;

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

c) contamination of the working area by blood ~~due to bleeding and,~~ 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 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) large fish should be introduced head first into the device;~~

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

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Annex XIIIB

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

The following should apply when killing fish:

1. Operational procedures should be adapted to the specific circumstances on the premises and should address biosecurity and fish welfare 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 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.

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;

Annex XIIIB (contd)

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 outcome on time;

      iv) awareness of the emotional 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.

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, and that sea water 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 anaesthetised;

Annex XIIIB (contd)

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

3. Disadvantages

a) 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;

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 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.

Annex XIV

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 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 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.

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 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 XV

CHAPTER 10.5.

INFECTIOUS SALMON ANAEMIA

Article 10.5.1.

For the purposes of the *Aquatic Code*, infectious salmon anaemia (ISA) means *infection* with HPR0 ISA virus or with ISA virus (ISAV) having deletions in the HPR region (hereafter named HPR-deleted ISA virus) ~~(ISAV)~~ of the genus *Isavirus* of the family Orthomyxoviridae.

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*.

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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.

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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.

Article 10.5.~~5.~~6.

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.

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.

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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.

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

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~~.12

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~~.13

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:

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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~~.14

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~~ 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~~.15

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~~.16

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~~16. have been fulfilled.

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Annex XVI

AQUATIC ANIMALS COMMISSION WORK PLAN FOR 2012

OIE *Aquatic Animal Health Code*
• Assess pancreas disease for listing against the criteria for listing aquatic animal diseases (Ch 1.2.) • On going review of the list of diseases • Review of emerging diseases
• On going review of the Glossary
• Harmonise horizontal chapters with those in the *Terrestrial Code*
• Develop disease specific surveillance model chapters (1 fish, 1 mollusc, 1 crustacean)
• Develop 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 *Code*
OIE *Manual of Diagnostic Tests for Aquatic Animals*
• Revise template for disease-specific chapters (on hold)
• Finalise disease specific chapters for 2012 edition
• Continue to develop guidance with criteria for susceptible species
• Consider new candidates for OIE Reference Laboratories for listed diseases
Meetings
• Make presentations on the activities of the Aquatic Animals Commission at the conferences of the OIE Regional Commissions
• Be proactive in presenting the activities of the Aquatic Animals Commission at scientific conferences
• Contribute to OIE Aquatic Animal Focal Point seminars
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 XVII

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

Original: English

September 2011

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON PATHOGEN DIFFERENTIATION FOR AQUATIC ANIMAL DISEASES

Paris (France), 6–8 September 2011

The OIE *ad hoc* Group on Pathogen Differentiation for Aquatic Animal Diseases (the *ad hoc* Group) met at the OIE Headquarters in Paris from 6 to 8 September 2011.

The members of the *ad hoc* Group are listed at Annex I. The Terms of Reference adopted are given at Annex II.

On behalf of the Dr Bernard Vallat, Director General of the OIE, Dr Sarah Kahn, Head of the International Trade Department, welcomed the *ad hoc* Group members, and thanked them for their continued work on this important new area. Dr Sarah Kahn highlighted that the aquatic work is of increasing profile for the OIE, recognizing the importance of aquatic animals for global food security and the use of detailed disease information to support trade.

Below is a summary of discussions and key recommendations proposed by the *ad hoc* Group.

1. Background

At a previous meeting in January 2011, the *ad hoc* Group explored broad concepts for differentiating pathogens recognizing that there were some inconsistencies in reporting by Member Countries. The *ad hoc* Group recommended to the OIE Aquatic Animal Health Standards Commission (Aquatic Animals Commission) that the approach might be useful for OIE listed diseases which are amenable to such differential reporting strategies. Selected from a number of potential candidate pathogens, infectious salmon anaemia virus (ISAV) was chosen by the Aquatic Animals Commission as the most appropriate pathogen to review the potential for this approach. ISA experts were invited to join this second meeting of the *ad hoc* Group to address technical details of ISAV differentiation.

2. Introduction

When the *ad hoc* Group considered the applicability of pathogen differentiation, three main criteria were the focus for decisions regarding appropriate candidates for changes to the standard approach. These criteria are:

1. Variants of the pathogen are clearly recognized in the scientific literature and have different disease characteristics;

2. there are robust, readily available methods for consistently differentiating (typing) the variants; and

3. there is, or there is potential for, different management of variants within or between countries.

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Based on these criteria, the *ad hoc* Group considered the request by the Aquatic Animals Commission to develop a comprehensive theoretical framework for all pathogens, but decided that since very few listed pathogens are likely to fulfill these criteria, it was more efficient to address the selected pathogens on a case by case basis. The *ad hoc* Group considered this approach would more likely lead to a timely consideration of potential changes by Member Countries.

3. Assessment of ISAV against criteria

1. Variants of the pathogen are clearly recognized in the scientific literature and have different disease characteristics

Variants of ISAV have been primarily differentiated on the basis of the sequence of a highly polymorphic region (HPR) of genomic segment 6 which encodes the Haemagglutinin-Esterase (HE) protein (e.g. Kibenge *et al*., 2009). This is a consistent trait which shows a robust association with pathogenicity. HPR deletion variants (HPR-deleted) associated with ISA disease outbreaks are believed to have arisen within aquaculture following deletions within the HPR region of segment 6 with respect to a putative full-length ancestral progenitor designated HPR0 (Mjaaland *et al*., 2002). The presence of the HPR0 variant has been reported in all countries where ISA disease has occurred including Norway (Nylund *et al*., 2007), Scotland (Cunningham *et al*., 2002; Anonymous, 2005); McBeath *et al*., 2009), Canada (Cook-Versloot *et al*., 2004, the Faroes (Christiansen *et al*., 2011) and Chile (Kibenge *et al*., 2009). The presence of the HPR0 variant has been reported mostly in apparently healthy fish and to date has never been associated with clinical ISA disease. As such the presence of HPR0 variants represent a significantly lower risk of disease development than the presence of an ISAV variant with any deletion within the HPR region. A large number of HPR-deleted variants have been reported worldwide, all of which have been associated with varying degrees of clinical ISA disease.

Although the pathogenic determinants of ISAV are not well understood, the presence of any deletion within the HPR region appears to be a consistent indicator of pathogenicity and as such allows the discrimination of two distinct ISAV groups which clearly represent different probabilities of clinical ISA disease occurrence. In addition to not being associated with disease outbreaks, HPR0 (low risk) viruses differ phenotypically from HPR-deleted variants (high risk), since they have mainly been detected in gills, show a transient infection pattern and remain non-culturable in permissive cell lines (Christiansen *et al*., 2011).

2. There are robust, readily available methods for consistently differentiating the variants

Existing RT-PCR methodologies based on segments other than segment 6 allow the detection of HPR0 and HPR-deleted ISAV variants. Characterisation of the HPR region is dependent on independent amplification of segment 6 and subsequent sequencing. At present, this is a robust method for discrimination between HPR0 and HPR-deleted variants, although there is the potential for other discriminatory methods to be developed and validated.

3. There is, or there is potential for, different management of variants within or between countries

The presence of HPR0 and HPR-deleted variants pose a clearly different risk to the development of ISA disease. Indeed, HPR0 variants are known to be in widespread circulation in areas which do not experience recurring ISA outbreaks. The presence of HPR0 variants may represent some risk for the development of ISA disease, should mutation to pathogenic (HPR-deleted) forms occur. Based on evidence from countries which are free from recurrent ISA disease despite a high prevalence of HPR0 variants, this risk is believed to be low and can be reduced further through adoption of good management practice. Different countries have adopted different internal management strategies in an attempt to limit the risk of disease emergence resulting from HPR0 presence. These have included:

a) Focusing on reducing the opportunity for long term maintenance and thus evolution of pathogens in aquaculture systems (e.g. synchronous fallowing within discrete management areas).

b) Attempting to reduce prevalence, and thus the potential for mutation, of HPR0 through destruction of progeny from HPR0 positive parents.

c) Restricting movement of HPR0 positive fish.

Conclusion

The *ad hoc* Group concluded that ISAV fulfilled all three criteria and progressed to consider the case for pathogen differentiation for ISAV, and its implications.

4. Current status of ISAV detection, management and reporting

1. International reporting of HPR0 to the OIE is currently different than HPR-deleted. The detection of ISAV with RT-PCR alone (since HPR0 does not generally yield positive test results except through molecular testing methods) does not fit the case definition of ISAV positive in the *Manual of Diagnostic Tests for Aquatic Animals (Aquatic Manual*). It is important to note that for the purposes of the *Aquatic Animal Health Code* (*Aquatic Code*), HPR0 is included in the current definition of ISA infection, thus creating a conflict between the *Aquatic Code* and the *Aquatic Manual*.
2. HPR0 is not related to clinical disease and so detections are associated with routine testing in the absence of elevated mortality rates.
3. Some Member Countries are managing HPR0 as non-pathogenic, meaning no action (except perhaps increased surveillance), but may manage areas within their country that are defined as HPR0-negative (and also negative for HPR-deleted) in an attempt to prevent the introduction of HPR0.
4. In conclusion, HPR0 occurs in more countries and more frequently than is currently reported to the OIE.

5. Justification for change

The reason that ISAV requires a change to current reporting was driven by the fact that there is a false perception that Member Countries report all ISAV, including the low (or non-) pathogenic genotype, HPR0. However, HPR0 does not currently have confirmatory testing so will never be reported. The *ad hoc* Group recognised some Member Countries may benefit from information on the distribution of HPR0, either from a trade or internal control basis, and that this difference in reporting should be corrected.

The *ad hoc* Group considered the implications of three potential options for revising the reporting structure for ISA with respect to HPR variants:

1. include HPR0 in the definition of ISA and report all HPR types as a single pathogen

The *ad hoc* Group felt that it was a fairly straightforward exercise to redefine the case definition in the *Aquatic Manual* to include HPR0. However, the consequences of not discriminating between pathogenic and non-pathogenic variants would impose an excessive burden of reporting on Member Countries and significant economic cost, to the potential detriment of ISA disease control.

The *ad hoc* Group did not consider this option viable.

2. exclude HPR0 from the definition of ISA

In practical terms, this represents the least deviation from current ISA reporting practices and maintains focus on management of disease causing ISA variants. Article 10.5.1. of the *Aquatic Code* chapter on ISA would require amendment to explicitly reflect the exclusion of HPR0. However, there is a perceived desire by some Member Countries that there should be some form of continued international reporting of HPR0 status, since i) there may be some Member Countries free of all ISA variants, including HPR0, and ii) whilst HPR0 ISAV carries an extremely low direct risk of ISA disease development, it has the potential to mutate into a pathogenic variant with unknown probability.

On the basis of current knowledge the *ad hoc* Group agreed with this view for the reasons outlined in option 3.

Annex XVII (contd)

3. include HPR0 in the definition of ISA, but create a new designation for HPR0 that is reported separately

This option aligns with the *Aquatic Code* and *Aquatic Manual*, provides greatest transparency in the reporting of pathogenic variants and their potential precursors. This is considered important because whilst HPR0 ISAV carries an extremely low direct risk of ISA disease development, it has the potential to mutate into a pathogenic variant with unknown probability. The main benefits of this approach are:

a) enable Member Countries that are free of HPR-deleted ISA variants to focus their management and trade decisions on the control of the disease causing variants (as per option 2);

b) enable Member Countries that may be free of all ISA variants, including HPR0, to make trade decisions based on best available disease information (additional benefit beyond option 2);

c) facilitate the capture of information to inform future decisions on the feasibility of maintaining controls on HPR0 distribution and the value of this to reducing emergence of ISA disease.

This option should be achievable with minimal additional reporting requirements but may involve increased surveillance requirements especially for self-declaring HPR0 freedom. It should be noted that only in situations where Member Countries wish to self declare freedom from HPR0 would there be any increase in surveillance needs. The reporting regime should not be onerous, involving a simple 2-way split of ISAV into HPR0 and HPR-deleted types, and no change is suggested to the notification regime i.e. immediate notifications are only required on first identification, thereafter reporting would be periodic.

Assuming it is the desire of Member Countries to control HPR0 as a means of reducing the risk of importing the precursor to pathogenic ISAV, the *ad hoc* Group considered option 3 to be the preferred approach, where reporting requirements do not become onerous. With increased knowledge over time it may be appropriate to review the situation every five years and revise this approach when necessary.

6. Implications of option 3

The following implications were noted by the *ad hoc* Group:

1. The definition of ISA in the *Aquatic Code* needs to be clarified to include HPR0 and HPR-deleted variants.

2. Section 7 of the *Aquatic Manual* chapter for ISA needs to be amended to change the case definition for suspect and confirmed cases to reflect the current existence of one independent test for HPR0 variants.

3. The notification and reporting framework of the OIE requires amendment to permit the separate notification and reporting of HPR0 and HPR-deleted variants.

4. The *Aquatic Code* Chapter 10.5. requires revision in particular the articles on gaining and maintaining free status to include specific recommendations on HPR0 variants.

5. Various sections of the chapter on ISA in the *Aquatic Manual* require additional material to reflect knowledge regarding HPR0 variants.

7. Recommendations

The *ad hoc* Group recommends that:

1. The Aquatic Animals Commission endorse that ISAV be recognised by the OIE as having HPR0 and HPR-deleted variants.

Annex XVII (contd)

2. HPR0 and HPR-deleted variants be reported separately to the OIE; and reporting mechanisms allow separate reporting of HPR0 ISAV and HPR-deleted ISAV.

3. The Aquatic Animals Commission recognise changes are necessary to the *Aquatic Code* and *Aquatic Manual* to accommodate the recognition of the variants. The *ad hoc* Group amended the relevant text in Chapter 10.5. of the *Aquatic Code* (see Annex III). The *ad hoc* Group also reviewed the revised *Aquatic Manual* Chapter 2.3.5. and modified text in some sections (particularly section 7, corroborative diagnostic criteria) and noted other sections that would need further revision should this approach be endorsed (see Annex IV).

REFERENCES

Anonymous (2005) Epizootiological investigation into a case of suspicion of infectious salmon anaemia (ISA) in Scotland in November. Fisheries Research Services Internal Report no 11/05.

Christiansen, D.H., Ostergaard, P.S., Snow, M., Dale, O.B., Falk, K. (2011) A low-pathogenic variant of infectious salmon anaemia virus (ISAV-HPR0) is highly prevalent and causes a non-clinical transient infection in farmed Atlantic salmon (*Salmo salar* L.) in the Faroe Islands. *Journal of General Virology*, 92, 909–918.

Cook-Versloot, M., Griffith, S., Cusack, R., McGeachy, S. & Ritchie, R. (2004). Identification and characterisation of infectious salmon anaemia virus (ISAV) haemagglutinin gene highly polymorphic region (HPR) type 0 in North America. *Bulletin of the European Association of Fish Pathologists*, 24, 203–208.

Cunningham, C. O., Gregory, A., Black, J., Simpson, I. & Raynard, R. S. (2002a). A novel variant of the infectious salmon anaemia virus (ISAV) haemagglutinin gene suggests mechanisms for virus diversity. *Bulletin of the European Association of Fish Pathologists*, 22, 366–374.

Kibenge, F. S., Godoy, M. G., Wang, Y., Kibenge, M. J., Gherardelli, V., Mansilla, S., Lisperger, A., Jarpa, M., Larroquete, G. & other authors (2009). Infectious salmon anaemia virus (ISAV) isolated from the ISA disease outbreaks in Chile diverged from ISAV isolates from Norway around 1996 and was disseminated around 2005, based on surface glycoprotein gene sequences. *Virology Journal*, 6, 88.

McBeath, A. J., Bain, N. & Snow, M. (2009). Surveillance for infectious salmon anaemia virus HPR0 in marine Atlantic salmon farms across Scotland. *Diseases of Aquatic Organisms*, 87, 161–169.

Mjaaland, S., Hungnes, O., Teig, A., Dannevig, B. H., Thorud, K. & Rimstad, E. (2002). Polymorphism in the infectious salmon anemia virus hemagglutinin gene: importance and possible implications for evolution and ecology of infectious salmon anemia disease. *Virology*, 304, 379–391.

Nylund, A., Plarre, H., Karlsen, M., Fridell, F., Ottem, K. F., Bratland, A. & Saether, P. A. (2007). Transmission of infectious salmon anaemia virus (ISAV) in farmed populations of Atlantic salmon (*Salmo salar*). *Archives of Virology*, 152, 151–179.

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Annex I

OIE *AD HOC GROUP* ON PATHOGEN DIFFERENTIATION FOR AQUATIC ANIMAL DISEASES

Paris (France), 6–8 September 2011

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Annex II

TERMS OF REFERENCE

1. Review output from the first meeting of the *ad hoc* Group on Pathogen differentiation and consider any feedback from Member Countries and the OIE Aquatic Animal Health Standards Commission

2. Assess applicability of generic differentiation principles, elucidate practical and effective criteria for OIE listed diseases and examine the utility of developing comprehensive differentiation guidelines

3. Assess ISAV for suitability for recognition of differentiation and applicability of criteria developed above

4. Develop recommendations with respect to ISAV from the OIE *Aquatic Animal Health Code* and the OIE *Manual of Diagnostic Tests for Aquatic Animals* perspective (plus any other recommendations considered appropriate) for submission to the OIE Aquatic Animal Health Standards Commission

5. Produce a report for the October meeting of the OIE Aquatic Animal Health Standards Commission

Annex XVII (contd)

Annex III

CHAPTER 10.5.

INFECTIOUS SALMON ANAEMIA

Article 10.5.1.

For the purposes of the *Aquatic Code*, infectious salmon anaemia (ISA) means *infection* with HPR0 ISA virus or with ISA virus (ISAV) having deletions in the HPR region (hereafter named HPR-deleted ISA virus) ~~(ISAV)~~ of the genus *Isavirus* of the family Orthomyxoviridae.

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*.

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.

Annex XVII (contd)

Annex III (contd)

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.

Annex XVII (contd)

Annex III (contd)

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 XVII (contd)

Annex III (contd)

Article 10.5.~~5.~~6.

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.

Annex XVII (contd)

Annex III (contd)

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) t*argeted 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.

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 XVII (contd)

Annex III (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.

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.

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:

Annex XVII (contd)

Annex III (contd)

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~~.12.

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:

3 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

4 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~~.13.

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 XVII (contd)

Annex III (contd)

3 the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the *Competent Authority*; and

4 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~~.14.

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~~ 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~~.15.

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~~.16.

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;

Annex XVII (contd)

Annex III (contd)

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~~16. have been fulfilled.

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Annex XVII (contd)

Annex IV

PROPOSED AMENDMENTS TO CHAPTER 2.3.5. OF THE
MANUAL OF DIAGNOSTIC TESTS FOR AQUATIC ANIMALS

7. Corroborative diagnostic criteria

Reasonable grounds to suspect fish of being infected with ISAV (HPR0 or HPR-deleted) are outlined below. The Competent Authority should ensure that, following the suspicion of fish infected with ISAV on a farm, an official investigation to confirm or rule out the presence of the disease will be carried out as quickly as possible, applying inspection and clinical examination, as well as collection and selection of samples and using the methods for laboratory examination as described in Section 4.

7.1. Definition of suspect case (HPR-deleted)

ISA or infection with ISAV would be suspected if at least one of the following criteria is met:

i) Clinical signs consistent with ISA or pathological changes consistent with ISA (Section 4.2) whether or not the pathological changes are associated with clinical signs of disease;

ii) Isolation and identification of ISAV in cell culture from a single sample (targeted or routine) from any fish on the farm, as described in Section 4.3.1.2.1;

iii) Evidence for the presence of ISAV from two independent laboratory tests such as RT-PCR (not followed by sequence data indicating HPR0) (Section 4.3.1.2.3) and IFAT on tissue imprints (Section 4.3.1.1.2.1) or IHC (Section 4.3.1. 1.3.1)

7.2. Definition of confirmed case (HPR-deleted)

7.2.1. Definition of confirmed ISA

The following criteria in should be met for confirmation of ISA.

Mortality, clinical signs and pathological changes consistent with ISA (Section 4.2), and detection of ISAV in tissue preparations by means of specific antibodies against ISAV (IFAT on tissue imprints [Section 4.3.1.1.2] or fixed sections as described in Section 4.3.1.1.3) in addition to either:

a) isolation and identification of ISAV in cell culture from at least one sample from any fish on the farm, as described in Section 4.3.1.2.1

or

b) detection of ISAV by RT-PCR by the methods described in Section 4.3.1.2.3;

7.2.2. Definition of confirmed ISAV infection (HPR-deleted)

The criteria given in i) or ii) should be met for the confirmation of ISAV infection.

i) Isolation and identification of ISAV in cell culture from at least two independent samples (targeted or routine) from any fish on the farm tested on separate occasions as described in Section 4.3.1.2.1.

ii) Isolation and identification of ISAV in cell culture from at least one sample from any fish on the farm with corroborating evidence of ISAV in tissue preparations using either RT-PCR (Section 4.3.1.2.3) or IFAT/IHC (Sections 4.3.1.1.2 and 4.3.1.1.3).

Annex XVII (contd)

Annex IV (contd)

7.2.3. Definition of confirmed ISAV infection (HPR0)

The criteria given in i) and ii) should be met for the confirmation of ISAV infection with low path (HPR0).

i) An absence of clinical signs consistent with ISA disease or mortality (= apparently healthy fish).

ii) Detection of ISAV by RT-PCR followed by independent amplification and sequencing of the HPR region of segment 6 to confirm the presence of HPR0 only.

Comments on additional changes required in other sections:

1. Scope

Infectious salmon anaemia (ISA) is a disease of sea-farmed Atlantic salmon (*Salmo salar*) caused by infection with Infectious salmon anaemia virus (ISAV). The infection induces a systemic and lethal condition characterised by severe anaemia and variable haemorrhages and necrosis in several organs. The disease course is prolonged with low daily mortality (0.05–0.1%) typically only in a few cages, but cumulative mortality may become very high. (Thorud & Djupvik, 1988; Rimstad *et al*., 2011). A variant of ISAV is known to exist (designated HPR0) which is believed to be a precursor of virulent forms of the virus which are distinguished by the presence of a deletion within the so-called highly polymorphic region (HPR) of genomic segment 6. All ISAV isolates responsible for disease in Atlantic salmon have a deletion in this region. These two distinguishable variants (high and low path) of ISAV pose a recognised different level of risk with respect to development of ISA disease and as such require different management strategies.

For the purpose of this chapter, ISAV means HPR0 or HPR-deleted ISA virus (ISAV) of the genus Isavirus of the family Orthomyxoviridae.

2. In addition, changes will be required in the following areas of Chapter 2.3.5 of the Manual, to reflect differences between HPR0 and HPR-deleted variants of ISAV.

2.1.1 Aetiological agent, agent strains to clarify that HPR deletions are indicators of virulence and not necessarily causative.

2.1.4 Life cycle to reflect difference in infection route for HPR0.

2.2.4 Target organs and infected tissue to reflect changes in tissue tropism, and hence sampling locations.

2.3.1 Transmission mechanisms to reflect that transmission mechanisms for HPR0 are less understood.

2.3.2 Prevalence to reflect the transient nature of HPR0 infection.

2.3.3 Geographical distribution to reflect the known distribution of HPR0.

2.3.4 Mortality and morbidity to reflect that HPR0 infection does not result in mortality or morbidity.

2.3.5 Environmental factors to reflect that HPR0 infection may be seasonal.

Annex XVII (contd)

Annex IV (contd)

2.4.8 General husbandry practices to reflect that these may be important for HPR0 also.

4.3.1.2.1 Cell culture to reflect that HPR0 cannot, to date, be cultured on cell lines.

4.3.1.2.3.1 Reverse-transcription polymerase chain reaction (RT-PCR) to include segment 6 PCR and sequencing for variant characterisation, including consideration of procedure in the event of insufficient PCR product for sequencing often found in low infection intensities.

Table 5.1 to take into consideration changes in Section 7.

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

Annex XVIII

Original: English
September 2011

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON THE RESPONSIBLE USE OF ANTIMICROBIALS IN AQUATIC ANIMALS

Paris, 8–9 September 2011

The OIE *ad hoc* Group on the Responsible Use of Antimicrobials in Aquatic Animals (the *ad hoc* Group) met at OIE Headquarters in Paris from 8 to 9 September 2011.

The members of the *ad hoc* Group and other participants at the meeting are listed at Appendix I. The adopted agenda is at Appendix II. The following documents were given to the members of the *ad hoc* Group prior to the meeting:

- List of participants and draft agenda;
- Draft Chapter 6.X. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals;
- Draft Chapter 6.X. Harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals – List of priority bacteria;
- Draft document on risk analysis for antimicrobial resistance in aquaculture;
- Advisory document on the responsible and prudent use of antimicrobial agents in aquatic animals;
- Presentation made by Dr Peter Smith at the Panama Conference: Veterinary products and aquatic animals: towards the responsible and prudent use of antibiotics;
- Codex Alimentarius Commission Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL 77 – 2011);
- Minutes of the 21/4/2011 teleconference on the Responsible Use of Antimicrobials in Aquatic Animals.

1. Welcome and introduction

Peter Smith, the chair of the *ad hoc* Group, welcomed all members and reminded them of the OIE's on-going work on antimicrobial resistance (AMR) in the field of both terrestrial and aquatic animals. Dr Smith mentioned the adoption by the World Assembly of National Delegates of the first chapter developed by the Group 'Principles for responsible and prudent use of antimicrobial agents in aquatic animals' and the successful conference in Panama on Aquatic Animal Health Programmes.

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On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Sarah Kahn, Head of the OIE International Trade Department, welcomed all members and thanked them for their participation. Members discussed the draft agenda and clarified some points.

2. Chapter 6.X. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals

The *ad hoc* Group reviewed the draft document developed at its meeting in October 2010 (see Annex 24 to the report of February 2011 meeting of the Aquatic Animal Health Standards Commission (the Aquatic Animals Commission): http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/Aquatic_Commission/A_AAC_Feb_2011.pdf). The *ad hoc* Group also reviewed relevant sections of *Terrestrial Animal Health Code* (*Terrestrial Code*) and the recently adopted Codex Alimentarius Commission (CAC) Guidelines for Risk Analysis of Food Born Antimicrobial Resistance (CAC/GL77-2011): http://www.codexalimentarius.net/download/standards/11776/CXG_077e.pdf).

The *ad hoc* Group took note of the ongoing work of the OIE *ad hoc* Group that is updating the chapters on AMR in the *Terrestrial Code* and of OIE Members' comments on this work.

The *ad hoc* Group made minor revisions and finalised the draft chapter (Appendix III).

3. Chapter 6.X. Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals

The *ad hoc* Group reviewed the draft document developed at its meeting in October 2010 (see Annex 24 to the report of the February 2011 meeting of the Aquatic Animals Commission: http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/Aquatic_Commission/A_AAC_Feb_2011.pdf) with reference to relevant sections of *Terrestrial Code* and the recently adopted Codex Alimentarius Commission (CAC) Guidelines for Risk Analysis of Food Born Antimicrobial Resistance (CAC/GL77-2011) : http://www.codexalimentarius.net/download/standards/11776/CXG_077e.pdf .

Noting that criteria for interpreting susceptibility test data are lacking for many bacteria that infect aquatic animals, the *ad hoc* Group highlighted the need to disseminate and publish raw data on susceptibility rather than data indicating frequencies of resistance.

In the section of the document that deals with microorganisms and food safety, the Group discussed a minimum list of bacteria to be included in a monitoring programme, based on the criteria: (1) food safety and (2) prevalence of human infection. The Group considered that OIE Members may add to this list.

The Group considered that it was important to design sampling and monitoring programmes in a manner to facilitate the identification of resistant bacteria derived from sources outside the aquaculture operation.

The subject of antimicrobial resistance determinants in the environment was discussed. Although many challenges exist, the Group identified key components of programmes to facilitate surveillance for resistance determinants in the environment.

The *ad hoc* Group finalized the draft chapter (Appendix IV).

4. List of priority pathogens

Dr Smith, together with other experts, including Ron Miller of the Clinical and Laboratory Standards Institute (CSI), made an alphabetical list of bacteria to be prioritised for the development of methods of antimicrobial resistance testing in aquatic animals (Appendix V).

The Group proposed to publish this list, with an explanatory article, in the issue of the OIE *Bulletin* that would be dedicated to aquaculture in 2012.

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5. Risk analysis for antimicrobial resistance in aquaculture

The *ad hoc* Group discussed and finalised this discussion paper. An outline of a possible future chapter of the OIE *Aquatic Animal Health Code* (*Aquatic Code*) was developed (see Appendix VI). The *ad hoc* Group discussed the possibility of publishing a paper on this topic in the OIE *Bulletin* and requested feedback from the Aquatic Animals Commission on this work.

6. Advisory document on the responsible and prudent use of antimicrobial agents in aquatic animals

The *ad hoc* Group reviewed an advisory document (developed at a previous meeting) that contained more detailed information than the adopted *Aquatic Code* chapter on the responsible and prudent use of antimicrobial agents in aquatic animals. The Group decided that this document should not, for the moment, be published on the OIE website because this could lead to confusion between the advisory document and the adopted *Code* chapter. However, the Group agreed that the document contains useful information and that it should be reconsidered in future, once OIE Members have experience in the application of the adopted chapter.

The advisory document is at Appendix VII.

7. Future work

Assuming that the Aquatic Animals Commission sends the two draft chapters to OIE Members for comment, the Group considered that it could be beneficial to hold a next meeting in early 2012 to address Members' comments.

…/Appendices

Annex XVIII (contd)

Appendix I

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP
ON THE RESPONSIBLE USE OF ANTIMICROBIALS IN AQUATIC ANIMALS

Paris, 8–9 September 2011

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List of participants

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Appendix II

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP
ON THE RESPONSIBLE USE OF ANTIMICROBIALS IN AQUATIC ANIMALS

Paris, 8–9 September 2011

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Adopted agenda

1. Welcome and introduction

2. Discussion on the agenda

It was decided to discuss agenda items in the following order:

a) Chapter 6.X. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals

b) List of priority bacteria

c) Risk analysis for antimicrobial resistance in aquaculture

d) Chapter 6.X. Harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals

e) Key points on the advisory document on the responsible and prudent use of antimicrobial agents in aquatic animals

3. Finalisation of the report

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Appendix III

CHAPTER 6.X.

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

Article 6.X.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 collect objective and quantitative information to evaluate usage patterns by antimicrobial class, route of administration-and animal species in order to evaluate exposure 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 labeled products and poorly understood distribution channels. 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.X.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. 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 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.X.3.

Development and standardisation of monitoring systems for antimicrobial agents

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

1. Sources of data on antimicrobial agents

   a) Basic sources

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

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Appendix III (contd)

b) Direct sources

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 authorization (registration of the antimicrobial agent).

c) End-use sources (veterinarians, aquatic animal health professionals and 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 source may be useful when more accurate and locally specific information is needed (such as extra-/off-label use).

Because collection of this type of information can be resource intensive, 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 and 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 could be collected where available.

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. 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) 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.

Annex XVIII (contd)

Appendix III (contd)

The total number of aquatic animals cultured and their weight in kilograms is important basic information.

b) Subdivision of antimicrobial use into species of finfish, crustacean, or mollusk treated.

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

d) 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, volume of water treated)

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.

Nomenclature of antimicrobials should comply with international standards where available.

3. Considerations for data collection

Antimicrobial usage data 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 temperature, disease conditions (epizootiology), species and age affected, aquacultural systems (i,e. intensive / extensive), dosage and duration of treatment with antimicrobial agents.

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.X.4.

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, when available, aid in the 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;

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

e) geographical location, specific rearing units;

f) dosage regimes and duration of treatment with antimicrobial agents.

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.

Annex XVIII (contd)

Appendix III (contd)

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.

Annex XVIII (contd)

Appendix IV

CHAPTER 6.X.

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

Article 6.X.1.

Purpose

This chapter provides criteria relevant to aquatic animals, products of aquatic 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.X.2.

Objective of surveillance and monitoring programmes

Countries should conduct active antimicrobial resistance surveillance and monitoring programmes.

Surveillance and monitoring of antimicrobial resistance is necessary to:

a) establish baseline data on the prevalence of antimicrobial resistant microorganisms and determinants;

b) collect information on antimicrobial resistance trends in relevant microorganisms;

c) explore the potential relationship between antimicrobial resistance in aquatic animal microorganisms and the use of antimicrobial agents;

d) detect the emergence of antimicrobial resistance mechanisms;

e) conduct risk analyses as relevant to aquatic animal and human health;

f) provide recommendations on human health and aquatic animal health policies and programmes;

g) 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.

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

Annex XVIII (contd)

Appendix IV (contd)

Article 6.X.3.

Design of surveillance and monitoring programmes

Surveillance of antimicrobial resistance at targeted intervals or ongoing monitoring of the prevalence of resistance in microorganisms from animals, food, environment and humans constitutes a critical part of 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 animal and microorganisms 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 resistence determinants in the environment.

Article 6.X.4.

Design of surveillance and monitoring programmes for micro organisms that infect aquatic animals

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 overrepresentation 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 micoorganism susceptibility to antimicrobial agents

   Participating laboratories may perform disc diffusion, minimum inhibitory concentration 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 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 and on-going validation studies.

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.

Annex XVIII (contd)

Appendix IV (contd)

5. Reporting of results

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

Article 6.X.5.

Design of surveillance and monitoring programmes for microorganisms in or on food derived from aquatic animals

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 origin intended for human consumption, the relevant section of the *Terrestrial Animal Health Code* should be consulted.

It is important to note that the word 'commensal' as used in the *Terrestrial Animal Health Code* has less relevance due to the transient nature of the intestinal microflora of aquatic animals. Therefore commensal bacteria should not be included in surveillance and monitoring programmes.

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 microorganisms of 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 programme:

a) *Salmonella* spp.;

b) *Vibrio parahaemolyticus*;

c) *Listeria monocytogenes*.

Article 6.X.6.

Surveillance and monitoring for antimicrobial resistance in microorganisms present in 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.

Annex XVIII (contd)

Appendix IV (contd)

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.

Annex XVIII (contd)

Appendix V

LIST OF PRIORITY PATHOGENS

Background

Standardized and internationally harmonized protocols for determining the antibiotic susceptibility of bacteria associated with aquatic animal disease are urgently required.

As they are the most developed, it is suggested that all efforts in this regard should concentrate on the further development of the protocols published by CLSI (1, 2, 3).

For each of the bacterial groups of relevance to global aquaculture protocols are required that specify the conditions to be used in in-vitro laboratory tests (test conditions) and the criteria to be used to interpret the data generated by these tests (interpretive criteria).

It is important to note that test conditions, and their interpretive criteria, can be developed for any bacterial group independently of the progress in establishing these parameters for any other group.

Significant progress has been made in standardizing the necessary conditions for susceptibility testing but, as yet, the data required to establish interpretive criteria have not been generated. The major need is, therefore, the generation of data sets that would allow the setting of interpretive criteria.

The priorities

In order to facilitate the further development of standardized and internationally harmonized protocols a provisional list (Table 1) of the most important bacterial groups for which standardized antibiotic testing is required by global aquaculture has been drawn up. This priority list was drawn up after consultation with Dr Ron Miller the chair of the Aquaculture Working Group of CLSI and his colleagues. Opinions were also received from Prof. Brian Austin, and Drs Inger Dalsgaard and Craig Shoemaker. In drawing up the list the rationale for inclusion of any bacterial group was that infections by its members were responsible for significant use of antimicrobial agents in some compartment of global aquaculture. The relevance of bacterial groups to any national or regional authority will vary depending on the dominant species farmed and environmental conditions encountered. Different national or regional authorities should therefore be able to select, from the list in Table 1, the bacterial groups of greatest significance in their area.

Table 1: List of bacterial groups for which should be prioritised in developing standardized and internationally harmonized protocols for determining the antibiotic susceptibility. The Table also provides a summary of the current progress in susceptibility testing using the relevant CLSI protocols with respect to those bacterial groups.

Bacterial groups	Test conditions[a]	Interpretive criteria
Aeromonas salmonicida	Accepted	Set
***Aeromonas* spp.**	Accepted	Not set
***Edwardsiella* spp.**	Accepted	Not set
***Flavobacterium* spp.**	Accepted (for broth MIC tests only)	Not set
***Francisella* spp.** [a]	Suggested	Not set
***Photobacterium* spp.**	Suggested	Not set
Piscirickettsia salmonis [a]	No conditions proposed	Not set
***Streptococcus* spp.**	Suggested	Not set
***Vibrio* spp.**	Suggested	Not set
***Yersinia* spp.**	Accepted	Not set

[a] To the extent that infections by these organisms are intracellular they present unique problems for setting interpretive criteria.

Annex XVIII (contd)

Appendix V (contd)

Note:

In drawing up Table 1 it has been assumed that interpretive criteria can be developed with acceptable precision for multi-species (generic) groups. If evidence proves this not to be the case, species-specific criteria may be required.

1. CLSI (2006). - Methods for antimicrobial disk susceptibility testing of bacteria isolated from aquatic animals. Approved guideline M42-A. Clinical and Laboratory Standards Institute, Wayne, Pennsylvania.

2. CLSI (2006). - Methods for broth dilution susceptibility testing of bacteria isolated from aquatic animals. Approved guideline M49-A. Clinical and Laboratory Standards Institute, Wayne, Pennsylvania.

3. CLSI (2010). 'Performance standards for antimicrobial susceptibility testing of bacteria isolated from aquatic animals; first informational supplement'. CLSI document M42/49-S1, Clinical and Laboratory Standards Institute, Wayne, Pennsylvania.

Annex XVIII (contd)

Appendix VI

ANTIMICROBIAL RESISTANCE RISK ANALYSIS IN AQUACULTURE

Introduction

Antimicrobial resistance (AMR) risk analysis in aquaculture is challenged by a variety of factors that impact both risk assessment and risk management, including the diversity of aquaculture, lack of methods for culture and antimicrobial susceptibility testing (AST), lack of approved drugs, and potential for the development of a reservoir of resistant microorganisms and resistance determinants with a potential for horizontal transmission.

Nevertheless, the fundamental principles of risk analysis (risk assessment, risk management, risk communication) provide a framework just as valuable for aquaculture as for terrestrial animal agriculture.

The applicability of these principles, together with the challenges inherent in applying them to aquaculture has been reviewed in several venues, most notably the Joint FAO/OIE/WHO Expert Consultation on Antimicrobial Use in Aquaculture and Antimicrobial Resistance, Seoul, Republic of Korea, 13–16 June 2006.

Recommendations from that Consultation included the need for the Codex Alimentarius Commission and OIE to further develop risk analysis guidelines for aquaculture taking into account inherent challenges and gaps that currently exist in data and methods.

With respect to risk assessment, the OIE *Terrestrial Animal Health Code* (*Terrestrial Code*) contains recommendations for assessment of the risks to human and animal health.

With respect to risk management, the Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) and the Codex Code of Practice for Fish and Fishery Products (Section 6 – Aquaculture Production) (CAC/RCP 52-2003) contain recommendations for the identification and selection and monitoring of risk management options.

Furthermore, OIE Chapters on surveillance and monitoring contain important elements for the collection and analysis of data and information to help establish the link between the use of antimicrobial agents and the selection and dissemination of resistant microorganisms and resistance determinants.

Finally, the Codex Alimentarius Commission recently adopted comprehensive Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance in July 2011.

However, despite all the work of the last decade on development of risk analysis techniques, more needs to be done to apply these principles to aquaculture and understand their limitations given the diversity of aquaculture and the gaps that currently exist in data and methods.

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Appendix VI (contd)

Defining the risks

To obtain meaningful results (accurate risk estimates, effective risk management options) it is important to adequately define the scope of the risk analysis. What are the hazards? Who/what is the target of the adverse consequences? Most of the discussions to date have focused on risks to human health, risks to animal health, and risks to the environment – which ultimately have consequences for human and animal health. Owing to the mechanism for selection of resistant bacteria resulting from the administration of antimicrobial agent and the need for the use of therapeutic agents in food animal production, the discussion has generally narrowed to focus on those risks associated with the use of antimicrobial agents. The context of the discussion has also sometimes been narrowed to focus on risks associated with the consequences of resistant bacteria (vs. risks associated with antimicrobial residues – which arguably have some overlap in the area of impact on human gut flora) through consumption of food (vs. risks associated with food handling and preparation).

While many of these factors defining the scope of the risk analysis have parallels in terrestrial animal agriculture several have unique implications in aquaculture.

Diversity of aquaculture

The range of species under culture, the number and type of different culture systems, and the range of antimicrobial agents and their routes of administration impact elements of the risk assessment, particularly the release assessment, making it difficult to group seemingly similar sectors of the aquaculture industry. Further, the range of products (cooked, raw, ready-to-eat) and processing techniques in aquaculture impacts elements of the exposure pathway for humans again making it difficult to group aquaculture operations and emphasizing the need to narrow and focus the scope of the risk assessment. With respect to risks for animal health, the diversity of aquaculture, particularly the interface of cultured and wild populations in open systems, has considerable impact on the exposure assessment and may require more careful examination than its terrestrial animal counterpart.

Identification and selection of risk management options are influenced by the diversity of aquaculture. Various control measures (husbandry and biosecurity, premarket authorization, obligatory prescription use, treatment guidelines) will have different levels of effectiveness, including unintended consequences, and should be developed, implemented, and monitored with careful consideration for the types of systems, species and target pathogens. The challenge of determining meaningful endpoints for monitoring and surveillance programmes in order to assess the effectiveness of the risk management options and the need for further modification may require collection and stratification of data on a much larger scale than for terrestrial animal operations.

Lack of methods for culture and AST

Accurate assessment of risks associated with the selection and dissemination of resistant microorganisms and resistance determinants is underpinned by the ability to culture microorganisms and evaluate their susceptibility (conversely resistance) to antimicrobial agents. When and to what extent does the acquisition of a resistance determinant result in loss of susceptibility to an antimicrobial agent? The answer to this question is crucial to assessing the consequences (increased numbers of infections, duration and severity of illness, loss of therapeutic options) of the hazard (resistant bacteria and resistance determinants) to humans and aquatic animals. Unfortunately, the situation in aquaculture is that adequate techniques for culturing a wide range of microorganisms and standardized methods for antimicrobial susceptibility testing are lacking. The impact of the lack of methods is a loss in the ability to quantify specific risks and an increase in attendant uncertainty. As a result, the importance of describing uncertainty in the risk assessment for AMR in aquaculture is relatively more important than for AMR in terrestrial animals. Again, considering the diversity of aquaculture and constraints of resources, the need for prioritization in methods development for aquatic microorganisms is underscored.

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Appendix VI (contd)

Lack of approved drugs

A lack of approved antimicrobial agents for use aquaculture also hampers risk analysis, both in terms of risk assessment and risk management. The reason for the lack of approved drugs once again harkens back to the diversity of aquaculture. The framework for premarket review of safety and effectiveness hinges on very specific conditions of use, a particular agent intended for use in a certain species of animal at a particular dose and duration for treatment of a particular disease (pathogen) or condition. Due to the large number of species under culture, considerable variation in culture conditions and a wide range of pathogens, approval of antimicrobial agents is not possible, except for only a few animal species/disease combinations that are economically valuable to sponsors and producers. The result is an increased need for legal extra-/off-label use and also illegal use of agents to treat species where no approved drug exists.

For risk assessment, this means that additional biological pathways need to be considered in the release assessment. When considering the quantities of antimicrobials used and their relative contribution to selection pressure for an intended microorganism, legal extra-/off-label and illegal uses need to be considered.

For risk management, the lack of approved drugs in combination with a range of regulatory and animal health infrastructure in countries engaged in aquaculture presents additional challenges. Regulatory controls such as legal extra-/off-label use under the supervision aquatic animal health professionals may be effective at minimizing AMR in countries where adequate resources exist for enforcement and access to animal health professionals is available. These same controls in countries where enforcement and access to animal health professionals does not exist are likely to be ineffective. Instead, other risk management options such as requirements for adequate labelling and distribution of antimicrobial agents or inspection of processed product may be more effective.

For monitoring and surveillance programmes, a lack of approved drugs means systems for collection of data and information on quantities of antimicrobial used need to consider not only licensed distribution of approved drugs, but should also strive to incorporate information on the use of unapproved drugs. When examining trends in the emergence of resistant microorganisms, the contribution of unapproved drugs as a source of selection pressure should be included in the analysis.

Potential for development of a reservoir of resistant microorganisms and resistance determinants

The potential for development of a reservoir of resistant microorganisms and resistance determinants has been identified as one of the most significant risks from the use of antimicrobial agents in aquaculture. However, assessment and management of this risk is extremely complex. The biological pathways both for the release assessment and the exposure assessment are myriad. Special considerations for aquaculture include the open nature of the culture systems allowing not only exposure of microorganisms in the aquaculture environment to antimicrobial agents from human and terrestrial animal use, but also dissemination of resistant microorganisms from sources outside the aquaculture environment (i.e. run-off from terrestrial animal agriculture or human wastewater). Determining the relative risk of antimicrobial agent use in the aquaculture facility itself is confounded by the other sources and may require sensitive techniques, specially designed endpoints, and sophisticated analysis to assess the risk.

For example, there are a number of technical problems associated with phenotype-based susceptibility measurements that might be used to map the biological pathways related to the horizontal transmission of resistance determinants. These problems include: innate resistance of some bacteria present in the environment, lack of validated interpretive criteria for many environmental bacteria, and lack of culture methods for environmental bacteria. A solution may be to utilize more sensitive techniques, such as molecular methods (PCR, rtPCR) to focus on resistant determinants located on genetic elements that are capable of inter-species or inter-generic transfer. Quantitative techniques could be helpful in determining the relationship between the use of antimicrobial agents in a culture system and the prevalence of resistance determinants in non-target pathogens.

Annex XVIII (contd)

Appendix VI (contd)

Similarly, risk management measures to control the horizontal transmission of resistance determinants both to humans through consumption or handling of food and to animals through the maintenance or dissemination of endemic populations of resistant microorganisms needs to be carefully considered.

Opportunities to address the special considerations of AMR risk analysis in aquaculture

Previous discussions on AMR risk analysis in aquaculture have highlighted potential risks associated with the use of antimicrobials in aquaculture and the selection and dissemination of resistant microorganisms and resistance determinants. These discussions have also pointed out some of the challenges in conducting adequate risk assessment of AMR in aquaculture and the existence of significant gaps in data and methods upon which to base meaningful risk assessment and risk management measures. Often, the OIE framework (*Terrestrial Code*) is cited as a resource for conducting risk assessment as well as for developing programmes for surveillance and monitoring of AMR.

Despite considerable work in progressing AMR risk analysis guidelines over the past decade, the specific detail needed for countries to assess the risks of AMR in aquaculture and develop effective risk management measures is still lacking. This detail includes both special considerations needed to conduct risk analysis for aquaculture as well as the limitations and uncertainty associated with such analyses given the current state of data, methodologies, and antimicrobial use in aquaculture.

To address this need, OIE has tasked the ad hoc group with drafting important components of an overall approach to AMR in aquaculture as part of the *Aquatic Animal Health Code*. So far, these components have included guidelines on Responsible Use of Antimicrobials (adopted), guidelines for monitoring the quantities of antimicrobials used in aquaculture (draft), and development of surveillance and monitoring programmes (draft). In addition, it appears that a draft chapter on considerations for AMR risk analysis in aquaculture would be important. This chapter would augment the guidance provide in Chapter 6.10. of the *Terrestrial Code* with specific considerations for conducting risk assessment and developing risk management along with important information on understanding and describing the uncertainty associated with the risk assessment. In addition, the chapter could highlight the need for further methods development and data collection and provide the proper context for how/where this information is used in AMR risk analysis for aquaculture.

Outline

1. Introduction

    1.1. Special considerations for conducting AMR risk analysis in aquaculture

    1.2. Diversity of aquaculture

    1.3. Lack of methods for culture and AST

    1.4. Lack of approved drugs

    1.5. Potential for development of a reservoir (horizontal transmission)

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Appendix VI (contd)

2. Assessing the risks to human health

    2.1. Defining the risk

    2.2. Hazard identification

    2.3. Release assessment

    2.4. Exposure assessment

    2.5. Consequence assessment

3. Developing risk management measures for human health

    3.1. Identification, Evaluation, Selection

    3.2. Implementation

    3.3. Monitoring

4. Assessing the risks to animal health

    4.1. Defining the risk

    4.2. Hazard identification

    4.3. Release assessment

    4.4. Exposure assessment

    4.5. Consequence assessment

5. Developing risk management measures for animal health

    5.1. Identification, Evaluation, Selection

    5.2. Implementation

    5.3. Monitoring

6. Assessing the risks in the environment

    6.1. Defining the risk

    6.2. Hazard identification

    6.3. Release assessment

    6.4. Exposure assessment

    6.5. Consequence assessment

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7. Developing risk management measures for the environment

    7.1. Identification, Evaluation, Selection

    7.2. Implementation

    7.3. Monitoring

8. Programmes for surveillance and monitoring

9. Communication of risks associated with AMR in aquaculture

Annex XVIII (contd)

Appendix VII

ADVISORY DOCUMENT ON THE RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN AQUATIC ANIMALS

There is a fundamental lack of knowledge related to the use of antimicrobials in aquatic animals and the implications for the development of antimicrobial resistance. In many countries or territories the involvement of the authorities in and the legal framework of aquatic animal production are less developed then for terrestrial animals. In the light of these considerations the OIE Aquatic Animal Health Standards Commission (Aquatic Animals Commission) decided the develop chapter with general principles on responsible and prudent use of antimicrobial agents in aquatic animals for inclusion in the OIE *Aquatic Animal Health Code* (*Aquatic Code*). This document is under the development and has not been adopted yet.

The recommendations in this advisory document provide more detailed guidance for the responsible and prudent use of antimicrobial agents in aquatic animals, with the aim of protecting both animal and human health.

The Competent Authorities responsible for the registration and control of all groups involved in the production, distribution and use of veterinary antimicrobials have specific obligations. Prudent use is principally determined by the outcome of the marketing authorisation procedure and by the implementation of specifications when antimicrobials are administered to aquatic animals.

1. Objectives of prudent use

Prudent use includes a set of practical measures and recommendations intended to reduce the risk associated with the selection and dissemination of antimicrobial resistant microorganisms and antimicrobial resistance determinants in aquatic animal production to:

a) maintain the efficacy of antimicrobial agents and to ensure the rational use of antimicrobials in aquatic animals with the purpose of optimising both their efficacy and safety;

b) comply with the ethical obligation and economic need to keep aquatic animals in good health;

c) prevent or reduce the transfer of resistant microorganisms or resistance determinants from aquatic animals to humans and terrestrial animals;

d) maintain the efficacy of antimicrobial agents used in human medicine and prolong the usefulness of the antimicrobials;

e) prevent the contamination of animal-derived food with antimicrobial residues that exceed the established maximum residue limit (MRL);

f) protect consumer health by ensuring the safety of food of aquatic animals.

Annex XVIII (contd)

Appendix VII (contd)

2. Responsibilities of the regulatory authorities

Marketing autorisation

1. Marketing authorisation of antimicrobial agents

The national regulatory authorities are responsible for granting marketing authorisation. This should be done in accordance with the provisions of the Aquatic Code (under study). They have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the veterinarian or other aquatic animal health professional.

2. Submission of data for the granting of the marketing authorisation

The pharmaceutical industry has to submit the data requested for the granting of the marketing authorisation. The marketing authorisation is granted only if the criteria of safety, quality and efficacy are met. An assessment of the potential risks and benefits to both animals and humans resulting from the use of antimicrobial agents in food-producing aquatic animals should be carried out. The evaluation should focus on each individual antimicrobial product but take into consideration the class of antimicrobials to which the particular active principle belongs. Guidance on usage should be provided for all dose ranges or different durations or different culture conditions (e.g. temperature, salinity, etc.) of treatment that are proposed.

3. Market approval

Regulatory authorities should attempt to expedite the market approval process of a new antimicrobial in order to address a specific need for the treatment of disease.

4. Registration procedures

Countries lacking the necessary resources to implement an efficient registration procedure for veterinary medicinal products (VMPs), and whose supply principally depends on imports from foreign countries, should undertake the following measures:

a) check the efficacy of administrative controls on the import of these VMPs, including to ensure that the product has an accurate label;

b) check the validity of the registration procedures of the exporting and manufacturing country as appropriate;

c) develop the necessary technical co-operation with experienced authorities to check the quality of imported VMPs as well as the validity of the recommended conditions of use.

Regulatory authorities of importing countries should request the pharmaceutical industry to provide quality certificates prepared by the Competent Authority of the exporting and manufacturing country as appropriate. All countries should make every effort to actively combat the manufacture, advertisement, trade, distribution and use of unlicensed and counterfeit bulk active pharmaceutical ingredients and products.

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Appendix VII (contd)

5. Quality control of antimicrobial agents

Quality controls should be performed:

a) in compliance with the provisions of good manufacturing practices;
b) to ensure that all antimicrobial agents are manufactured to the appropriate quality and purity;
c) to ensure that analysis specifications of antimicrobial agents used as active ingredients comply with the provisions of approved monographs;
d) to ensure that the quality and concentration (stability) of antimicrobial agents in the marketed dosage form(s) are maintained until the expiry date, established under the recommended storage conditions;
e) to ensure the adequate stability of antimicrobials when mixed with feed or administered in water to provide appropriate bioavailability.

6. Assessment of therapeutic efficacy

a) Preclinical trials

i) Preclinical trials should:

- establish the range of activity of antimicrobial agents on both target and non-target microorganisms;
- assess the ability of the antimicrobial agent to select for resistance *in vitro* and *in vivo*, taking into consideration pre-existing resistant strains;
- establish an appropriate dosage regimen necessary to ensure the therapeutic efficacy of the antimicrobial agent and limit the selection of antimicrobial resistance.

ii) The activity of antimicrobial agents towards the targeted microorganism can be established by pharmacodynamics. The following criteria should be taken into account:

- spectrum of activity and mode of action;
- minimum inhibitory and bactericidal concentrations;
- time- or concentration-dependent activity or co-dependency;
- activity at the site of infection.

iii) The dosage regimens allowing maintenance of effective antimicrobial levels can be established by pharmacokinetics. The following criteria should be taken into account:

- bio-availability according to the route of administration;
- concentration of the antimicrobial at the site of infection and its distribution in the treated animal;
- metabolism that may lead to the inactivation of antimicrobials;
- excretion routes.

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b) Clinical trials

Clinical trials should be performed to confirm the validity of the claimed therapeutic indications and dosage regimens established during the preclinical phase. The following criteria should be taken into account:

i) diversity of the clinical cases encountered when performing multi-centre trials;

ii) compliance of protocols with good clinical practice, such as Veterinary International Cooperation on Harmonisation (VICH) guidelines;

iii) eligibility of studied clinical cases, based on appropriate criteria of clinical and bacteriological diagnoses;

iv) parameters for qualitatively and quantitatively assessing the efficacy of the treatment.

7. Assessment of the potential of antimicrobials to select for resistance

Other studies may be requested in support of the assessment of the potential of antimicrobials to select for resistance. The party applying for market authorisation should, where possible, supply data derived in target animal species under the intended conditions of use.

For this the following may be considered:

a) the route and level of human exposure to food-borne or other resistant organisms;

b) the degree of cross-resistance within the class of antimicrobials and between classes of antimicrobials;

c) the pre-existing level of resistance in the pathogens of human health concern (baseline determination) in both animals and humans.

8. Establishment of acceptable daily intake, maximum residue level and withdrawal periods for antimicrobial compounds

a) When setting the acceptable daily intake (ADI) and MRL for an antimicrobial substance, the safety evaluation should also include the potential biological effects on the intestinal flora of humans.

b) The establishment of an ADI for each antimicrobial agent, and an MRL for each animal-derived food, should be undertaken.

c) For each VMP containing antimicrobial agents, withdrawal periods should be established in order to produce food in compliance with the MRL, taking into account:

i) the MRL established for the antimicrobial agent under consideration;

ii) the composition of the product and the pharmaceutical form;

iii) the target aquatic animal species;

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iv) the dosage regimen and the duration of treatment or different culture conditions (e.g. temperature, salinity, etc.);

v) the route of administration.

d) The applicant should provide methods for regulatory testing of residues in food.

9. Protection of the environment

An assessment of the impact of the proposed antimicrobial use on the environment should be conducted. Efforts should be made to ensure that the environmental impact of antimicrobial use is restricted to a minimum.

10. Establishment of a summary of product characteristics for each antimicrobial agent

The summary of product characteristics contains the information necessary for the appropriate use of antimicrobial agents (veterinary antimicrobial product) and constitutes the official reference for their labelling and package insert. This summary should contain the following items:

a) active ingredient and class;

b) pharmacological properties;

c) any potential adverse effects;

d) target animal species and age or production category;

e) therapeutic indications;

f) target microorganisms;

g) dosage and administration route;

h) withdrawal periods;

i) incompatibilities;

j) shelf-life;

k) operator safety;

l) particular precautions before use;

m) particular precautions for the proper disposal of un-used or expired products;

n) information on conditions of use relevant to the potential for selection of resistance.

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Appendix VII (contd)

11. Post-marketing antimicrobial surveillance

The information collected through existing pharmacovigilance programmes, including lack of efficacy, should form part of the comprehensive strategy to minimise antimicrobial resistance.

This information will be important to broader surveillance programmes.

Specific surveillance to assess the impact of the use of a specific antimicrobial may be implemented after the granting of the marketing authorisation. The surveillance programme should evaluate not only resistance development in target animal pathogens, but also in food-borne pathogens. Such surveillance will also contribute to general epidemiological surveillance of antimicrobial resistance.

12. Supply and administration of the antimicrobial agents used in veterinary medicine

The relevant authorities should ensure that all the antimicrobial agents used in aquatic animals are:

a) prescribed by a veterinarian or other aquatic animal health professional or other authorised person;

b) supplied only through licensed/authorised distribution systems;

c) administered to aquatic animals by a veterinarian or under the supervision of a veterinarian or other aquatic animal health professional or by other authorised persons.

The relevant authorities should develop effective procedures for the safe collection and destruction of unused or expired antimicrobial agents.

13. Control of advertising

All advertising of antimicrobials should be controlled by a code of advertising standards, and the relevant authorities must ensure that the advertising of antimicrobial products complies with national regulations and the marketing authorisation granted, in particular regarding the content of the summary of product characteristics.

The veterinary pharmaceutical industry should ensure that the advertising of antimicrobials directly to the food animal producer is discouraged.

Surveillance and monitoring programmes

In order to maintain the efficacy and safety of antimicrobial agents regulatory authorities should implement monitoring programmes that include levels of resistance of target animal pathogens and food born pathogens and quantities of antimicrobials used.

The surveillance of animal microorganisms resistant to antimicrobial agents is essential. It is critical to develop appropriate methods and interpretive criteria for aquatic microorganisms in order that baseline data can be established and trends identified.

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Appendix VII (contd)

Regulatory authorities should implement procedures by which the data on the patterns and trends in antimicrobial resistance in target organisms can be collected. These data may be collected in national during surveillance programmes or from the records submitted by individual veterinarians or other aquatic animal health professionals. They should develop procedures by which these data can be disseminated to veterinarians or other aquatic animal health professionals.

Regulatory authorities should ensure regular monitoring of the performance of laboratories involved in antimicrobial susceptibility testing.

Training of antimicrobial users

The training of users of antimicrobials should involve all the relevant organisations, such as regulatory authorities, pharmaceutical industry, veterinary schools, research institutes, veterinary professional organisations and other approved users such as food-animal owners.

This training should focus on:

a) information on aquatic disease prevention and management strategies to reduce the need to use antimicrobial drugs;

b) the importance of relevant information including results of antimicrobial agent susceptibility testing in enabling the veterinarian or other aquatic animal health professional to use antimicrobial agents prudently;

c) the ability of antimicrobial agents to select for resistant microorganisms and antimicrobial resistance determinants in aquatic animals that may contribute to health problems in those aquatic animals or humans and terrestrial animals;

d) the need to observe responsible use recommendations for the use of antimicrobial agents in animal husbandry in agreement with the provisions of the marketing authorisations.

Research

To address the significant lack of information for the numerous species of aquatic animals the relevant authorities should encourage public- and industry-funded research and efforts that aim to:

a) improve knowledge to optimize management practices, particularly for new species under culture to reduce the need for the use of antimicrobial agents;

b) perform a comparative cost benefit analysis of husbandry and therapeutic based approaches to disease control;

c) develop standardised methods for culturing microorganisms and determining microbial susceptibility, appropriate for identification of resistance in relevant microorganisms;

d) develop breakpoints and interpretive criteria to optimize the use of antimicrobial therapy;

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e) encourage research to develop sufficient capacity for clinical field trials;

f) optimize to dose regimens and their efficacy by increasing the amount and utilization of pharmacokinetic and pharmacodynamic data and information on the use of antimicrobials in aquatic animals;

g) to develop information to support extrapolation of appropriate dose regimens and withdrawal periods across multiple aquatic animal species;

h) develop practical models for applying the concept of risk analysis to assess and address the potential public health impact associated with the use of antimicrobial agents in aquaculture.

3. Responsibilities of the veterinary pharmaceutical industry

1. Marketing authorisation of antimicrobial agents

The veterinary pharmaceutical industry has responsibilities to:

a) supply all the information requested by the national regulatory authorities;

b) guarantee the quality of this information in compliance with the provisions of good manufacturing, laboratory and clinical practices;

c) implement a pharmacovigilance programme and on request, specific surveillance for bacterial susceptibility and resistance.

2. Marketing and export of antimicrobial agents

For the marketing and export of antimicrobial agents

a) only licensed and officially approved antimicrobial agents should be sold and supplied, and then only through licensed/authorised distribution systems;

b) the pharmaceutical industry should provide quality certificates prepared by the Competent Authority of the exporting and/or manufacturing countries to the importing country;

c) ensure that the exported antimicrobial agents contain the approved labelling;

d) the national regulatory authority should be provided with the information necessary to evaluate the amount of antimicrobial agents marketed.

3. Advertising

The veterinary pharmaceutical industry should:

a) disseminate information in compliance with the provisions of the granted authorisation;

b) ensure that the advertising of antimicrobials directly to the aquatic animal producer is discouraged.

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Appendix VII (contd)

4. Training

The veterinary pharmaceutical industry should participate in training programmes as defined in 3C.

5. Research

The veterinary pharmaceutical industry should contribute to research as defined in.3.D.

4. Responsibilities of wholesale and retail distributors

1. Retailers distributing antimicrobial agents should only do so on the prescription of a veterinarian or other aquatic animal health professional or other suitably trained person authorised in accordance with the national legislation, and all products and packaging should be appropriately labelled.

2. The recommendations on the responsible use of antimicrobials should be reinforced by retail distributors who should keep detailed records of:

   a) date of supply;

   b) name of prescriber;

   c) name of user;

   d) name of product;

   e) batch number;

   f) quantity supplied.

3. Distributors should be responsible for safe collection and destruction of unused or out of date antimicrobial agents.

4. Distributors should ensure that information for the appropriate use of the antimicrobial agent preparation should accompany all distributed retailed products.

5. Distributors should also be involved in training programmes on the responsible use of antimicrobials, as defined in 3.C.

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

Annex XIX

Original: English

August 2011

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON VETERINARY EDUCATION

Paris, 2–4 August 2011

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 2 to 4 of August 2011. A list of participants to the meeting may be found at Annex I and the adopted agenda at Annex II.

Dr Ron DeHaven asked all members to briefly present themselves and to make a short update on their activities relevant to the work of the *ad hoc* Group for the benefit of all members.

Several members had attended the Second Global Conference on Veterinary Education at Lyon (France) from 13 to 15 May 2011. Drs DeHaven and Timothy Ogilvie both commended the organisation of this conference, which was an excellent event within the overall framework of Vet2011, celebrating 250 years of the veterinary profession.

Dr Tjeerd Jorna presented an overview of the work of the World Veterinary Association (WVA), in the context of Vet2011, including the final event – the WVA Conference, which will be held in Cape Town (South Africa) in October 2011, at which time Dr Jorna will conclude his term as President of the WVA. He commented that the WVA has produced a Policy Paper on Veterinary Education and noted that several other organisations are working on similar statements. Dr Jorna advised that some planning was underway by the WVA for a global conference of veterinary statutory bodies, which would be done in collaboration with the OIE in 2012. He also commented on the WVA planning for a 3rd global conference on veterinary education to be held in 2013 in Asia. This will also be done in collaboration with the OIE.

Dr Alejandro Thiermann, President of the OIE Terrestrial Animal Health Standards Commission (Code Commission), was invited to the opening discussions in order to provide comments and advice on how strengthen the reference to the importance of veterinary education in the OIE *Terrestrial Animal Health Code* (*Terrestrial Code*), taking into account comments received from Members and Academic institutions. He also suggested that the *ad hoc* Group re-examine the list day 1 competencies and consider separating essential day 1 competencies from those that could be addressed post-graduation.

Noting that the OIE had received comments from several Members on the subject of the education of veterinarians in aquatic animal health, Dr DeHaven recommended that the Group's report be provided to both the Code Commission and the Aquatic Animal Health Standards Commission (Aquatic Animals Commission).

Annex XIX (contd)

Meeting with Dr Vallat, Director General

Dr Bernard Vallat held a short introductory meeting with the *ad hoc* Group.

Reflecting on the 79th OIE General Session, Dr Vallat stated that there is a strong consensus on the part of OIE Members to work on improving veterinary education globally. This objective is strongly supported by all countries. The celebration of Vet 2011 has given this work a good momentum, enabling the OIE with its partners, notably WVA, to raise awareness of this important work and secure support of Member Countries and international organisations. The work of the *ad hoc* Group is key to the OIE global initiative on improving veterinary education.

Dr Vallat noted that the recommendations of the *ad hoc* Group had been well received by the World Assembly of Delegates in May 2011. He advised that the objective is to have guidelines supported by the World Assembly. It is important to make appropriate reference to this work in the *Terrestrial Code* but not necessary for the guidelines to be incorporated in the *Terrestrial Code*. Some Members have expressed concerns about the proposed role of the OIE but it is clear that the OIE has no plan or intention to enforce standards for veterinary education in countries or regions.

Dr Vallat advised members of the *ad hoc* Group that there are now new and important challenges, such as the topic of aquatic animal health and production. The OIE held a first Global Conference on the contribution of aquatic animal health programmes to global food security in June 2011. Resolutions made at the conference recognised the key role of aquatic animal production to meet the growing global demand for food and that aquatic animal health programmes must be strengthened. Veterinarians are not currently the leading profession in aquatic animal health. This subject should be addressed by the *ad hoc* Group.

Animal welfare is also an important issue, now and in future. Given the links between animal health and animal welfare, the veterinary profession is well placed to take a leadership role and the OIE is taking steps to encourage a proactive approach to animal welfare by Veterinary Services. Dr Vallat asked the *ad hoc* Group to ensure that the "Day 1 competencies" document provide a basis for the profession to take a leading role in improving animal welfare.

Dr Vallat informed the *ad hoc* Group that the OIE, at the request of some Members, is launching an initiative for twinning between veterinary education establishments, based on the successful model established for veterinary laboratory twinning. The Group's recommendations on day 1 competencies would be a central element in defining the objectives of twinning programmes on veterinary education. Dr Sarah Kahn undertook to provide a progress report on this item at the next meeting of the *ad hoc* Group.

1. Discussion on the May 2011 General Session

Dr DeHaven drew to the attention of members the discussion on *Terrestrial Code* Chapters 3.1. and 3.2. at the General Session held in May 2011. He noted that animal welfare has been the subject of discussion, both as to the definitions of 'animal welfare' and the appropriate references to include in the *Terrestrial Code*.

Dr Jorna commented that animal welfare is now addressed in veterinary education to a much greater extent than was previously the case.

Dr DeHaven commented that the subjects to be addressed in the Day 1 competencies should include not only basic knowledge of relevant animal welfare but also the capacity to advocate for humane treatment of animals, whether these are livestock, companion animals, or animals used in veterinary or medical research. The veterinary profession should be a leading advocate for animal welfare.

Annex XIX (contd)

Dr DeHaven drew members' attention to the recommendation made by several OIE Members for the Group to address aquatic animal health in the Day 1 competencies. He noted that aquatic animal production would make an increasingly important contribution in future to the production of high quality protein and to food security in developing countries. While it may be beyond the scope of the Group to make specific recommendations on Aquatic Animal Health competencies, at least the topic of aquatic animal health should be mentioned in the Day 1 competencies document.

Dr DeHaven considered that the need for linkages between veterinary education establishments and regulatory veterinary medicine should be more clearly stated in the competencies document, ideally in the Executive Summary.

Dr Ogilvie identified a possible need for inclusion of a glossary of terms. It was agreed that where terms are defined in the *Terrestrial Code* glossary, the same definitions are used in this document. For terms that are not defined in the *Terrestrial Code*, the Group may need to develop definitions. The *ad hoc* Group decided to repeat some definitions for the sake of clarity, as the document should be clear on a 'stand alone' basis, for the reader who does not have a good knowledge of the *Terrestrial* and *Aquatic Codes*.

Dr DeHaven also noted the comment made by the Delegate for China (People's Republic) at the General Session and agreed that the *ad hoc* Group should address the topic of continuing education at this meeting.

The *ad hoc* Group made several modifications to the text to address the concern expressed by some Members that the OIE had made too many recommendations and/ or had included too much detail in its recommendations.

Dr Etienne Bonbon suggested that the recommendations on Day 1 competencies needed to be revised to highlight the distinction between Day 1 basic competencies and advanced competencies. This view was generally agreed.

Dr Sarah Kahn indicated that the main discussion at the General Session, reflecting Members' concerns, had concerned the proposal to include a reference in the *Terrestrial Code* [Article 3.2.14. sub-point 2 a (vi)] to the Day 1 competencies elaborated by the *ad hoc* Group. The OIE's approach to this work falls within the scope of the OIE PVS Pathway, a global initiative to improve good governance of Veterinary Services. The legal base for the OIE *PVS Tool for the Evaluation of Veterinary Services* (the OIE *PVS Tool*) is the *Terrestrial Code*. Dr Kahn explained that this was the basis for the Code Commission's proposal to add the reference in the *Terrestrial Code* to the Day 1 competencies. Resolution 34, which was finally adopted at the General Session, reflected a compromise to provide for continuation of the work of the OIE on Day 1 competencies, leaving the way open for appropriate references to be included in the *Terrestrial Code*. Dr Sarah Kahn indicated that the OIE would consider the best way to present the Day 1 competencies – perhaps a publication (in the form of a booklet) could be placed on the internet, available for downloading, as a means to help disseminate the information.

Dr DeHaven summarised his view that it is the Group's job to produce the best document possible, and that the Code Commission, in collaboration with the OIE Headquarters, should decide on the manner of presenting recommendations to National Delegates.

Dr Pierre Lekeux outlined the concerns of many academic staff, as follows: the veterinary graduate of today is under pressure to become competent on a tremendous number of topics. New topics are continually being added to the veterinary curriculum, but no topics are being removed. Day 1 veterinary graduates cannot be experts on all topics. Rather, they should have fundamental skills and knowledge and, importantly, an understanding and capacity to access appropriate and up to date sources of information. Group members generally agreed with this perspective.

Annex XIX (contd)

The *ad hoc* Group noted the valuable contributions to this meeting, including the Draft Report of the American Veterinary Medical Colleges (AAVMC) Board 'Roadmap for Veterinary Medical Education in the 21st Century: Responsive, Collaborative, Flexible' (draft 31 October 2010) and the document provided by Prof. A.S. Mweene, on behalf of the Deans of veterinary establishments of southern and eastern Africa.

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 submitted by Members. Comments were received from Switzerland, the United States of America and the European Union. The *ad hoc* Group also considered comments from the Code and Aquatic Animals Commissions, the OIE Animal Welfare Working Group and the *ad hoc* Group on the Welfare of Laboratory Animals, as well as comments made by Members at the General Session in May.

Distinction between basic and advanced competencies

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.

The *ad hoc* Group drafted new text on the importance of aquatic animal production to global food security and the need to ensure that Day 1 veterinarians possess relevant competencies, as appropriate to the importance of the aquaculture sector in the country or region.

The *ad hoc* Group considered that the need expressed by a Member for greater clarity regarding the role of veterinarians had already been addressed in paragraph 3, which states that veterinarians in the private sector and in government make a contribution towards achieving the goals of the national veterinary services.

The list containing the competencies (i.e. knowledge, skills, attitude and aptitude) was reordered to reflect a more logical sequence.

Annex XIX (contd)

In response to Members' comments, the *ad hoc* Group agreed that the disciplines taught under 'basic veterinary sciences' would normally include subjects such as anatomy, physiology, biochemistry and pharmacology. The disciplines taught under clinical veterinary sciences would normally include subjects such as pathology, clinical medicine and surgery. However, the *ad hoc* Group did not wish to list the relevant disciplines because 1) it would not be possible in the time given to make a complete listing; 2) this could be seen as a prescriptive approach that would not be appropriate to all OIE Members, and 3) it is not the mandate of the Group to advise on the general teaching of veterinarians. Instead, the Group added two sentences, as follows 'Basic veterinary sciences are normally taught early in the curriculum and are prerequisite to clinical studies' and 'clinical veterinary sciences provide the competencies necessary to diagnose, treat and prevent animal diseases.'

The *ad hoc* Group decided that, according to the definitions proposed, the competencies relating to 1) animal identification and traceability; 2) animal welfare; and 3) food hygiene and safety should be included under 'specific competencies' , because these subjects are specifically addressed in the OIE *Terrestrial* and *Aquatic Codes*. Accordingly, the *ad hoc* Group modified the 'general competencies' so that it covered only three sub-points – i.e. basic veterinary sciences, clinical veterinary sciences, and animal production.

The *ad hoc* Group also re-ordered the 'specific competencies' along more logical lines, as follows:

- epidemiology;
- transboundary animal diseases;
- zoonoses;
- emerging and re-emerging diseases;
- disease prevention and control;
- food hygiene and safety;
- veterinary products;
- animal welfare;
- veterinary legislation and ethics;
- certification procedures;
- communication skills.

The *ad hoc* Group discussed the issue of selection of undergraduates. Although a topic of major importance, the Group considered that it is beyond its scope to make any recommendations.

Throughout the document, phrases such as 'as defined by the *ad hoc* Group' were removed, to ensure a presentation consistent with OIE recommendations, rather than a record of the discussion of the *ad hoc* Group. The document was extensively modified, including re-ordering of many points, meaning that it was not feasible to show all modifications in the manner used for *Codes* texts. Noting that this document is not intended for adoption as a *Terrestrial Code* text and in light of the technical challenge, the *ad hoc* Group decided to present the document as a clean text. The Trade Department undertook to keep a record of all text changes, to facilitate any review that may be needed in future.

Critical skills needed by senior level veterinarians in the Veterinary Authority

The *ad hoc* Group expanded the list of topics and included some additional detail to the document drafted at the December 2010 meeting.

3. Future work

The *ad hoc* Group had a discussion with Dr A. Thiermann, President of the Code Commission, on the appropriate modifications to be considered to the *Terrestrial Code* relative to the day 1 competencies. Options discussed included the drafting of a new chapter for the *Terrestrial Code* or the addition of text to *Terrestrial Code* Chapter 3.2. Dr Thiermann and the *ad hoc* Group felt that the day 1 competencies document should not be included in total in the *Terrestrial Code* but that it could be valuable to include new text capturing the key points of that document. The Group agreed to develop a short text capturing the key points and to provide that to the Code Commission but considered that the decision on placement of this text, and any appropriate modifications to other parts of Chapters 3.1. and 3.2., would be the purview of the Code Commission.

Annex XIX (contd)

Next steps will be to consider comments of the Aquatic Animals and Code Commissions (meetings in September and October, respectively), the OIE Animal Production Food Safety Working Group (meeting in November), and OIE Members' comments submitted to the OIE in the second semester of 2011.

4. Dates for next meeting

It was agreed that the next meeting would take place on 11–13 January 2012. Members agreed to inform the OIE International Trade Department of their availability.

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…/ Annexes

Annex XIX (contd)

Annex I

MEETING OF THE OIE *AD HOC* GROUP ON VETERINARY EDUCATION

Paris, 2–4 August 2011

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Annex XIX (contd)

Annex I (contd)

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Annex XIX (contd)

Annex II

MEETING OF THE OIE *AD HOC* GROUP ON VETERINARY EDUCATION

Paris, 2–4 August 2011

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Adopted agenda

Day 1 (2 August 2011) Morning

- Welcome, adoption of the agenda, and introductory remarks
- Discussion with the OIE Director General
- Revise AHG's work product: *Minimum Competencies Expected of Day 1 Veterinary Graduates to Assure Delivery of High-Quality National Veterinary Services*, taking into account comments from the OIE Code Commission, Members, and 79th General Session

Day 1 (2 August 2011) Afternoon

- Complete revisions to *Minimum Competencies* document
- Begin review and refinement of draft of critical skills needed by senior level veterinarians employed by the Veterinary Authority ("Senior Skills") developed during the December 2010 AHG meeting

Day 2 (3 August 2011) Morning

- Complete review and refinement of "Senior Skills" document
- Begin review, refinement, and potential combination of the two continuing education (CE) draft documents ("CE Delivery" and "NVS CE for Private Practitioners") developed during the December 2010 AHG meeting

Day 2 (3 August 2011) Afternoon

- Complete review and refinement of the CE documents
- Discuss and potentially develop recommendations to Code Commission regarding adoption of all AHG work products
  - Any changes to Code language needed?
  - Is a specific recommendation to OIE General Session delegates needed for adoption of *Minimum Competencies* document and other work products as guidance documents or as components of the PVS tools?

Day 3 (4 August 2011) Morning and Afternoon

- Review work completed during third meeting of the AHG and make any necessary final changes
- Finalize recommendations to the Code Commission
- Discussion of next steps
  - Code Commission to review in September 2011; sent thereafter to OIE Members as annex to the Code Commission Report; potential for Member comment to be considered by the Code Commission in January 2012
  - Need for a fourth meeting to review the Code Commission and OIE Member comments?
- Closing remarks

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Annex XIX (contd)

Annex III

MINIMUM COMPETENCIES EXPECTED OF DAY 1 VETERINARY GRADUATES TO ASSURE DELIVERY OF HIGH-QUALITY NATIONAL VETERINARY SERVICES

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 and veterinary public health. Many will frequently act 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 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.

Annex XIX (contd)

Annex III (contd)

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.

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.

Annex XIX (contd)

Annex III (contd)

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.

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 pathogens 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 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.

Annex XIX (contd)

Annex III (contd)

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;

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 unrecognized 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 or 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.

Annex XIX (contd)

Annex III (contd)

Specific learning objectives for this competency include the Day 1 veterinary graduate being able to:

1.2.5.1. describe established programmes 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 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.

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 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.

Annex XIX (contd)

Annex III (contd)

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;

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.

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.

Annex XIX (contd)

Annex III (contd)

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.

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.

Annex XIX (contd)

Annex III (contd)

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 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.

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.

Annex XIX (contd)

Annex III (contd)

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;
- dispose of infected carcasses in an appropriate manner;
- disinfect or destroy contaminated materials.

Annex XIX (contd)

Annex III (contd)

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 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 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;

Annex XIX (contd)

Annex III (contd)

- risk management: the process of identifying, selecting, and implementing measures that can be applied to reduce the level of risk;

- 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.

Annex XIX (contd)

Annex III (contd)

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.

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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