UNION EUROPEENNE

SANCO

19. 07. 2007

Bruxelles, le
D(2007) prm D1/2007/D/411451)

Subject : **Meeting of the OIE Aquatic Animal Health Standards Commission – September 2007**

Dear Bernard,

Please find attached as an annex to this letter the Community written comments on the report of the Aquatic Animal Health Standards Commission of its March 2007 meeting.

I trust you will find this useful.

Thank you for your continued cooperation

Mr Carlos Agrela Pinheiro
CVO of Portugal

Md. Paola Testori
Directeur Général Adjoint

Annex: 1

Copy: All Directors/Chief Veterinary Officers of the Community and Bulgaria, Croatia, Iceland. Norway Romania, Switzerland and Turkey.

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 06.07.2007
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COMMISSION STAFF WORKING DOCUMENT

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

EXPLANATORY MEMORANDUM

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

The proposals for modifications were for possible adoption at the Annual General Session (AGS) in May 2007.

The Community sent its positions to the OIE before the AGS and stated them again during the AGS. Some of them were taken into account and some not.

The Community has now to comment on two kinds of texts: text being further considered and texts that were originally sent only for comments this year.

The Community comments needs to reach the OIE headquarters by August 2007 in order to be considered at their next meeting of the AAC in September 2007.

The Commission therefore proposes to the Council to authorise the Commission to present, as since 1995, the following written positions at Annex to the OIE before 6 August. This is to allow the OIE to take the Community comments into account during the next meeting of the AAC.

The cover letter to be sent with our response is attached (Doc prm D1/2007/D/411451)

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

ANNEX

CHAPTER 2.3.7.

CRAYFISH PLAGUE

Community comment

The Community cannot support the proposed chapter as no other alternative is given to obtain the freedom status than "the absence of susceptible species".
In addition, the Community would like that the AAC take into consideration the comments in submitted in each article.

Article 2.3.7.1.

For the purposes of the *Aquatic Code*, crayfish plague means *infection* with *Aphanomyces astaci* Schikora. This organism is a member of a group commonly known as the water moulds (the Oomycetida). Common synonyms are listed in Chapter 4.1.7. of the *Aquatic Manual*.

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

Article 2.3.7.2.

Scope

The recommendations in this Chapter apply to all species of crayfish in all three crayfish families (*Cambaridae*, *Astacidae*, and *Parastacidae*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Crayfish plague is most severe in European crayfish species including the noble crayfish (*Astacus astacus*), the white claw crayfish (*Austropotamobius pallipes*), stone crayfish (*Austropotamobius torrentium*), and the Turkish crayfish (*Astacus leptodactylus*). In general, the Parastacidae and the Astacidae (except N. American genera such as *Pacifastacus*) are highly susceptible, while the Cambaridae are resistant to *disease*, but are potential carriers.

There is some evidence of transfer by movement of fish (and their transport water) from waters containing infected crayfish.

Article 2.3.7.3.

Commodities

Community comment

In point 1 b), the Community would argue that, to require packaging for direct retail sale for commodities such as chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.) seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade".
An alternative solution would be to include those commodities in point 1.a).

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

   a) For the species referred to in Article 2.3.7.2. being used for any purpose:

i) *commodities* treated in a manner that inactivates the *disease agent* e.g. cooked (for >2 minutes at 60°), canned or pasteurised products and ready to eat meals; and crustacean oil and crustacean meal intended for use in animal feeds ~~commercially sterile canned products~~;

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

iii) chemically extracted chitin;

~~iv) crustacean meals or by-products made non-infectious by heating (>60°C for >5 minutes) or drying by-product (e.g. flame dried or sun dried);~~

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

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

vii) frozen products that have been subjected to -~~10~~20°C or lower temperatures for at least ~~24~~ 72 hours.

b) The following products destined for human consumption from species referred to in Article 2.3.7.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

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

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

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.7.2., other than those listed in point 1 of Article 2.3.7.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.7.7. to 2.3.7.11. relevant to the crayfish plague status of the *exporting country*, *zone* or *compartment*.
3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of crayfish plague of ~~any other~~ *commodity* of a species not covered in Article 2.3.7.2. but which could reasonably be expected to be a potential *A. astaci* ~~carrier~~ vector, the *Competent Authorities* should conduct a ~~*risk*~~ *analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of *A. astaci*, and the potential consequences, associated with the importation of the *commodity* prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.7.4.

Crayfish plague free country

Community comment

The Community cannot support the proposed article. Now the only alternative given for a disease free country is that there are no susceptible species present. If only this alternative is chosen then there is no reason to have crayfish plague on the list. Although there are weaknesses in diagnostic methods concerning surveillance the Community wish to remind that there still are crayfish plague free countries where crayfish plague is likely to cause acute and noticeable disease outbreak if this disease agent is imported. The Community position is that point 2, 3 and 4 should be restored.

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

If a country shares a *water catchment* or with one or more other countries, it can only make a *self-declaration of freedom* from crayfish plague if all the areas covered by the shared water are declared crayfish plague free countries or *zones* (see Article 2.3.7.5.).

1. A country where ~~none~~ neither of the *susceptible species* or potential carrier species referred to in Article 2.3.7.2. ~~is~~ are present may make a *self-declaration of freedom* from crayfish plague when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

~~OR~~

~~2. A country where the *susceptible species* referred to in Article 4.1.7.2. are present but there has never been any observed occurrence of the *disease* for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from crayfish plague when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.~~

~~OR~~

3. A country where the last observed occurrence of the *disease* was within the past 25 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from crayfish plague when:

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

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

~~OR~~

~~4. A country that has previously made a *self-declaration of freedom* from crayfish plague but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from crayfish plague again until the following conditions have been met:~~

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

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

   ~~c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 5 years without detection of *A. astaci*.~~

   ~~In the meantime, part of the non-affected area may be declared a free *zone* provided that they meet the conditions in point 3 of Article 4.1.7.5.~~

Article 2.3.7.5.

Crayfish plague free zone or free compartment

Community comment

The Community cannot support the proposed article. Now the only alternative given for a disease free zone and compartment is that there are no susceptible species present. If only this alternative is chosen then there is no reason to have crayfish plague on the list. Although there are weaknesses in diagnostic methods concerning surveillance the Community wish to remind

that there still are crayfish plague free countries, e.g. Australia and several islands, where crayfish plague is likely to cause acute and noticeable disease outbreak if this disease agent is imported. The Community position is that point 2, 3 and 4 should be restored.

In addition, the Community would argue that for certain compartments, disease free status could be regained if aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from crayfish plague but in which the disease is detected may not be declared free from crayfish plague until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

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

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

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

If a *zone* or *compartment* extends over more than one country, it can only be declared a crayfish plague free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where ~~none~~ neither of the *susceptible species* or potential carrier species referred to in Article 2.3.7.2. ~~is~~ are present may be declared free from crayfish plague when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

~~OR~~

~~2. A *zone* or *compartment* where the *susceptible species* referred to in Article 4.1.7.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from crayfish plague when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.~~

~~OR~~

~~3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from crayfish plague when:~~

Appendix XXI (contd)

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

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

~~OR~~

~~4. A *zone* previously declared free from crayfish plague but in which the *disease* is detected may not be declared free from crayfish plague again until the following conditions have been met:~~

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

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

~~c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *A. astaci*.~~

Article 2.3.7.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from crayfish plague following the provisions of points 1 or 2 of Articles 2.3.7.4. or 2.3.7.5. (as relevant) may maintain its status as crayfish plague free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from crayfish plague following the provisions of point 3 of Articles 2.3.7.4. or 2.3.7.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as crayfish plague free provided that conditions that are conducive to clinical expression of crayfish plague, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

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

Article 2.3.7.7.

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

When importing live *aquatic animals* of species referred to in Article 2.3.7.2. from a country, *zone* or *compartment* declared free from crayfish plague, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.7.4. or 2.3.7.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from crayfish plague.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.7.3.

Article 2.3.7.8.

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

Community comment

The Community maintains its concerns about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in that case, The ICES Code of Practice on the Introductions and Transfers of Marine Organism) because the lack of clarity of the validity of such external documents and any changes made to it. However, the Community welcomes the OIE initiative to establish more formal arrangements between the OIE and the ICES.

If the reference to the ICES Code of Practice is to be maintained, the Community would suggest some amendments to the current article:

A clear description (e.g. number of the document or date of publication) of which document we are referring to must be included.

Point 3 should include the whole Code of Practice or should be deleted to avoid inconsistencies between the summary and the current Code of Practice

If the summary in point 3 is to be maintained we would suggest the AAC the following structure in point 2 and 3:

2. If the intention of the introduction is the establishment of a new stock genetic lines, the following measures should be adopted
a) identify stock of interest (cultured or wild) in its current location;
b) evaluate stock health/*disease* history;
c) take and test samples for *A. astaci*, 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 *A. astaci* and perform general examinations for pests and general health/*disease* status;
g) if *A. astaci* 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 crayfish plague free or specific pathogen free (SPF) for *A. astaci*;
h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

3. In addition, consideration should be taken to international standards, such as the Guidelines Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES).

This Article does not apply to *commodities* listed in point 1 of Article 2.3.7.3.

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.7.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

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

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

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

2. If the intention of the introduction is the establishment of a new stock ~~genetic lines~~, international standards, such as the ~~Guidelines~~ Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

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

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

   b) evaluate stock health/*disease* history;

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

   g) if *A. astaci* 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 crayfish plague free or specific pathogen free (SPF) for *A. astaci*;

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.7.3.

Article 2.3.7.9.

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

When importing, for human consumption, live *aquatic animals* of species referred to in Article 2.3.7.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

Appendix XXI (contd)

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of *A. astaci.*

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.
This Article does not apply to *commodities* listed in point 1 of Article 2.3.7.3.

Article 2.3.7.9. bis.

Importation of live fish from a country, zone or compartment not declared free from crayfish plague

Community comment

This article seems to be reiterative as similar provisions can be found in Article 2.3.7.8. point 1 b) and Article 2.3.7.9. point 2.
We would suggest that the risks posed by the transport water of other non-crustacean animals would be better addressed in Chapter 1.5.1. of the Code (Recommendations for transport).

Because live fish and their transport water are potential vectors of crayfish plague, the *Competent Authority* of the *importing country* should require appropriate treatment of transport water as indicated in Chapter 1.5.1., when importing live fish from a country, *zone* or *compartment* not declared free from crayfish plague.

Article 2.3.7.10.

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

Community comment

It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming.
The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.3.7.2, the Competent Authority of the importing country should asses the risk and, if justified, apply risk mitigation measures.
The article does not apply to commodities referred to in point 1 of Article 2.3.7.3.

When importing *aquatic animal products* of species referred to in Article 2.3.7.2. from a country, *zone* or *compartment* declared free from crayfish plague, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.7.4. or 2.3.7.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from crayfish plague.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.
This Article does not apply to *commodities* listed in point 1 of Article 2.3.7.3.

Article 2.3.7.11.

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

When importing *aquatic animal products* of species referred to in Article 2.3.7.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.7.3.

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Appendix XXIII

CHAPTER 2.3.9.

INFECTIOUS MYONECROSIS

Community comment
The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 2.3.9.1.

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

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

Article 2.3.9.2.

Scope

The recommendations in this Chapter apply to: Pacific white shrimp (*Penaeus vannamei*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

For the purposes of this Chapter, the terms shrimp and prawn are used interchangeably.

Article 2.3.9.3.

Commodities

Community comment

In point 1 b), the Community would argue that, to require packaging for direct retail sale for commodities such as chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.) seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade".
An alternative solution would be to include those commodities in point 1.a).

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

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

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

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

      iii) chemically extracted chitin;

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

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

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

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

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

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

   For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.9.2., other than those listed in point 1 of Article 2.3.9.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.9.7. to 2.3.9.11. relevant to the IMN status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of IMN of ~~any other~~ *commodity* of a species not covered in Article 2.3.9.2. but which could

reasonably be expected to be a potential IMNV ~~carrier~~ vector, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of IMNV, and the potential consequences, associated with the importation of the commodity prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.9.4.

Infectious myonecrosis free country

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

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from IMN if all the areas covered by the shared water are declared IMN free countries or *zones* (see Article 2.3.9.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.9.2. is present may make a *self-declaration of freedom* from IMN when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.3.9.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from IMN when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~; for example~~ (e.g. because of the absence of conditions conducive to its clinical expression; as described in Chapter X.X.X. of the *Aquatic Manual*), may make a *self-declaration of freedom* from IMN when:

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

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

OR

4. A country that has previously made a *self-declaration of freedom* from IMN but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from IMN again ~~until~~ when the following conditions have been met:

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

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

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

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

In the meantime, part of the non-affected area may be declared a free *zone* provided that ~~they~~ such part meets the conditions in point 3 of Article 2.3.9.5.

Article 2.3.9.5.

Infectious myonecrosis free zone or free compartment

Community comment

The Community would argue that for certain compartments, disease free status could be regained if aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from IMNV but in which the disease is detected may not be declared free from IMNV until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

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

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

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

If a *zone* or *compartment* extends over more than one country, it can only be declared an IMN free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.3.9.2. is present may be declared free from IMN when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.3.9.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from IMN when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown; ~~for example~~ because of the absence of conditions conducive to its clinical expression; as described in Chapter X.X.X. of the *Aquatic Manual*), may be declared free from IMN when:

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

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

OR

4. A *zone* previously declared free from IMN but in which the *disease* is subsequently detected may ~~not~~ be declared free from IMN again ~~until~~ when the following conditions have been met:

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

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

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

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

Article 2.3.9.6.

Maintenance of free status

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

A country, *zone* or *compartment* that is declared free from IMN following the provisions of point 3 of Articles 2.3.9.4. or 2.3.9.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as IMN free provided that conditions that are conducive to clinical expression of IMN, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

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

Article 2.3.9.7.

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

When importing live *aquatic animals* of species referred to in Article 2.3.9.2. from a country, *zone* or *compartment* declared free from IMN, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.9.4. or 2.3.9.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from IMN.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.9.3.Appendix XXIII (contd)

Article 2.3.9.8.

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

Community comment

The Community maintains its concerns about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in that case, The ICES Code of Practice on the Introductions and Transfers of Marine Organism) because the lack of clarity of the validity of such external documents and any changes made to it. However, the Community welcomes the OIE initiative to establish more formal arrangements between the OIE and the ICES.

If the reference to the ICES Code of Practice is to be maintained, the Community would suggest some amendments to the current article:

A clear description (e.g. number of the document or date of publication) of which document we are referring to must be included.

Point 3 should include the whole Code of Practice or should be deleted to avoid inconsistencies between the summary and the current Code of Practice

If the summary in point 3 is to be maintained we would suggest the AAC the following structure in point 2 and 3:

2. If the intention of the introduction is the establishment of a new stock genetic lines, the following measures should b adopted
a) identify stock of interest (cultured or wild) in its current location;
b) evaluate stock health/*disease* history;
c) take and test samples for *IMNV*, pests and general health/*disease* status;
d) import and quarantine in a secure facility a founder (F-0) population;
e) produce F-1 generation from the F-0 stock in *quarantine*;
f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *IMNV* and perform general examinations for pests and general health/*disease* status;
g) if *IMNV* is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as IMNV free or specific pathogen free (SPF) for *IMNV*;
h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
3. In addition, consideration should be taken to international standards, such as the Guidelines Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES).

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

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

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

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

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

2. If the intention of the introduction is the establishment of a new stock ~~genetic lines~~, international standards, such as the ~~Guidelines~~ Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

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

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

   b) evaluate stock health/*disease* history;

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

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

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

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

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

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

Article 2.3.9.9.

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

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

Appendix XXIII (contd)

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of IMNV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.
This Article does not apply to *commodities* listed in point 1 of Article 2.3.9.3.

Article 2.3.9.10.

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

Community comment

It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.3.9.2, the Competent Authority of the importing country should asses the risk and, if justified, apply risk mitigation measures.
The article does not apply to commodities referred to in point 1 of Article 2.3.9.3.

When importing *aquatic animal products* of species referred to in Article 2.3.9.2. from a country, *zone* or *compartment* declared free from IMN, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.9.4. or 2.3.9.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from IMN.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.
This Article does not apply to *commodities* listed in point 1 of Article 2.3.9.3.

Article 2.3.9.11.

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

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

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

— text deleted

CHAPTER 2.3.10.

NECROTISING HEPATOPANCREATITIS

Community comment

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 2.3.10.1.

For the purposes of the *Aquatic Code*, necrotising hepatopancreatitis (NHP) means *infection* with necrotising hepatopancreatitis bacteria (NHP-B). This obligate intracellular bacterium is a member of the order α-Proteobacteria.

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

Article 2.3.10.2.

Scope

The recommendations in this Chapter apply to: Pacific white shrimp (*Penaeus vannamei*), blue shrimp (*P. stylirostris*), northern white shrimp (*P. setiferus*) and northern brown shrimp (*P. aztecus*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

For the purposes of this Chapter, the terms shrimp and prawn are used interchangeably.

Article 2.3.10.3.

Commodities

Community comment

In point 1 b), the Community would argue that, to require packaging for direct retail sale for commodities such as chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.) or de-headed and de-veined (intestine removed) shrimp tails seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade".
An alternative solution would be to include those commodities in point 1.a).

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any NHP related conditions, regardless of the NHP status of the *exporting country*, *zone* or *compartment.*
   a) For the species referred to in Article 2.3.10.2. being used for any purpose:

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

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

iii) chemically extracted chitin;

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

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

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

vii) frozen products.

b) The following products destined for human consumption from species referred to in Article 2.3.10.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

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

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

iii) de-headed and ~~de-veined~~ "de-veined" (intestine removed) shrimp tails.

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.10.2., other than those listed in point 1 of Article 2.3.10.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.10.7. to 2.3.10.11. relevant to the NHP status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of NHP of any ~~other~~ *commodity* of a species not covered in Article 2.3.10.2. but which could reasonably be expected to be a potential NHP-B ~~carrier~~ vector, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of NHP-B, and the potential consequences, associated with the importation of the *commodity* prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.10.4.

Necrotising hepatopancreatitis free country

A country may make a *self-declaration of freedom* from NHP 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 NHP if all the areas covered by the shared water are declared NHP free countries or zones (see Article 2.3.10.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.10.2. is present may make a *self-declaration of freedom* from NHP when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.3.10.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from NHP when *basic biosecurity conditions* have been continuously met in the

country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~; for example~~ (e.g. because of the absence of conditions conducive to its clinical expression; as described in Chapter X.X.X. of the *Aquatic Manual*), may make a *self-declaration of freedom* from NHP when:

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

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

OR

4. A country that has previously made a *self-declaration of freedom* from NHP but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from NHP again ~~until~~ when the following conditions have been met:

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

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

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

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

   In the meantime, part of the non-affected area may be declared a free *zone* provided that ~~they~~ such part meets the conditions in point 3 of Article 2.3.10.5.

Article 2.3.10.5.

Necrotising hepatopancreatitis free zone or free compartment

Community comment

The Community would argue that for certain compartments, disease free status could be regained if aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from Necrotising hepatopancreatitis but in which the disease is detected may not be declared free from Necrotising hepatopancreatitis until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

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

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

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

If a *zone* or *compartment* extends over more than one country, it can only be declared a NHP free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.3.10.2. is present may be declared free from NHP when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.3.10.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from NHP when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~;~~ ~~for example~~ (e.g. because of the absence of conditions conducive to its clinical expression; as described in Chapter X.X.X. of the *Aquatic Manual*), may be declared free from NHP when:

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

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

OR

4. A *zone* previously declared free from NHP but in which the *disease* is subsequently detected may ~~not~~ be declared free from NHP again ~~until~~ when the following conditions have been met:

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

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

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

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

Article 2.3.10.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from NHP following the provisions of points 1 or 2 of Articles 2.3.10.4. or 2.3.10.5. (as relevant) may maintain its status as NHP free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from NHP following the provisions of point 3 of Articles 2.3.10.4. or 2.3.10.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as NHP free provided that conditions that are conducive to clinical expression of NHP, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

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

Article 2.3.10.7.

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

When importing live *aquatic animals* of species referred to in Article 2.3.10.2. from a country, *zone* or *compartment* declared free from NHP, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.10.4. or 2.3.10.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from NHP.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.10.3.

Article 2.3.10.8.

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

The Community maintains its concerns about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in that case, The ICES Code of Practice on the Introductions and Transfers of Marine Organism) because the lack of clarity of the validity of such external documents and any changes made to it. However, the Community welcomes the OIE initiative to establish more formal arrangements between the OIE and the ICES.

If the reference to the ICES Code of Practice is to be maintained, the Community would suggest some amendments to the current article:

A clear description (e.g. number of the document or date of publication) of which document we are referring to must be included.

Point 3 should include the whole Code of Practice or should be deleted to avoid inconsistencies between the summary and the current Code of Practice

If the summary in point 3 is to be maintained we would suggest the AAC the following structure in point 2 and 3:

2. If the intention of the introduction is the establishment of a new stock genetic lines, the following measures should be adopted
a) identify stock of interest (cultured or wild) in its current location;
b) evaluate stock health/*disease* history;
c) take and test samples for *NHP*, 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 *NHP* and perform general examinations for pests and general health/*disease* status;
g) if *NHP* 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 NHP free or specific pathogen free (SPF) for *NHP*;
h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
3. In addition, consideration should be taken to international standards, such as the Guidelines Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES).

This Article does not apply to *commodities* listed in point 1 of Article 2.3.10.3.

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.10.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

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

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

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

2. If the intention of the introduction is the establishment of a new stock ~~genetic lines~~, international standards, such as the ~~Guidelines~~ Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

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

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

   b) evaluate stock health/*disease* history;

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

   g) if NHP-B 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 NHP free or specific pathogen free (SPF) for NHP-B;

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.10.3.

Article 2.3.10.9.

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

When importing, for human consumption, live *aquatic animals* of species referred to in Article 2.3.10.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

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1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of NHP-B.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.
This Article does not apply to *commodities* listed in point 1 of Article 2.3.10.3.

Article 2.3.10.10.

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

Community comment

It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.3.10.2, the Competent Authority of the importing country should asses the risk and, if justified, apply risk mitigation measures.
The article does not apply to commodities referred to in point 1 of Article 2.3.10.3.

When importing *aquatic animal products* of species referred to in Article 2.3.10.2. from a country, *zone* or *compartment* declared free from NHP, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.10.4. or 2.3.10.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from NHP.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.
This Article does not apply to *commodities* listed in point 1 of Article 2.3.10.3.

Article 2.3.10.11.

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

When importing *aquatic animal products* of species referred to in Article 2.3.10.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.10.3.

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CHAPTER 2.3.11.

WHITE TAIL DISEASE

Community comment

The community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 2.3.11.1.

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

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

Article 2.3.11.2.

Scope

The recommendations in this Chapter apply to: the giant fresh water prawn (*Macrobrachium rosenbergii*). Other common names are listed in the *Aquatic Manual.* These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

For the purposes of this Chapter, the terms shrimp and prawn are used interchangeably.

Article 2.3.11.3.

Commodities

Community comment

In point 1 b), the Community would argue that, to require packaging for direct retail sale for commodities such as chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.) seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade".
An alternative solution would be to include those commodities in point 1.a).

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

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

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

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

      iii) chemically extracted chitin;

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

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

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

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

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

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

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.11.2., other than those listed in point 1 of Article 2.3.11.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.11.7. to 2.3.11.11. relevant to the WTD status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of WTD of ~~any other~~ *commodity* of a species not covered in Article 2.3.11.2. but which could reasonably be expected to be a potential MrNV ~~carrier~~ vector, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of MrNV, and the potential consequences, associated with the importation of the commodity prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.11.4.

White tail disease free country

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

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from WTD if all the areas covered by the shared water are declared WTD free countries or *zones* (see Article 2.3.11.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.11.2. is present may make a *self-declaration of freedom* from WTD when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.3.11.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from WTD when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown, ~~for example~~ because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*), may make a *self-declaration of freedom* from WTD when:

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

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

OR

4. A country that has previously made a *self-declaration of freedom* from WTD but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from WTD again ~~until~~ when the following conditions have been met:

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

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

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

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

   In the meantime, part of the non-affected area may be declared a free *zone* provided that ~~they~~ such part meets the conditions in point 3 of Article 2.3.11.5.

Article 2.3.11.5.

White tail disease free zone or free compartment

Community comment

The Community would argue that for certain compartments, disease free status could be regained if aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from White tail disease but in which the disease is detected may not be declared free from White tail disease until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

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

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

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

If a *zone* or *compartment* extends over more than one country, it can only be declared a WTD free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.3.11.2. is present may be declared free from WTD when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.3.11.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from WTD when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~;~~ ~~for example~~ (e.g. because of the absence of conditions conducive to its clinical expression~~;~~ as described in Chapter X.X.X. of the *Aquatic Manual*), may be declared free from WTD when:

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

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

OR

4. A *zone* previously declared free from WTD but in which the *disease* is subsequently detected may ~~not~~ be declared free from WTD again ~~until~~ when the following conditions have been met:

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

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

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

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

Article 2.3.11.6.

Maintenance of free status

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

A country, *zone* or *compartment* that is declared free from WTD following the provisions of point 3 of Articles 2.3.11.4. or 2.3.11.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as WTD free provided that conditions that are conducive to clinical expression of WTD, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

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

Article 2.3.11.7.

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

When importing live *aquatic animals* of species referred to in Article 2.3.11.2. from a country, *zone* or *compartment* declared free from WTD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.11.4. or 2.3.11.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from WTD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

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

Article 2.3.11.8.

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

Community comment

The Community maintains its concerns about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in that case, The ICES Code of Practice on the Introductions and Transfers of Marine Organism) because the lack of clarity of the validity of such external documents and any changes made to it. However, the Community welcomes the OIE initiative to establish more formal arrangements between the OIE and the ICES.

If the reference to the ICES Code of Practice is to be maintained, the Community would suggest some amendments to the current article:

A clear description (e.g. number of the document or date of publication) of which document we are referring to must be included.

Point 3 should include the whole Code of Practice or should be deleted to avoid inconsistencies between the summary and the current Code of Practice

If the summary in point 3 is to be maintained we would suggest the AAC the following structure in point 2 and 3:

2. If the intention of the introduction is the establishment of a new stock genetic lines, the following measures should be adopted
a) identify stock of interest (cultured or wild) in its current location;
b) evaluate stock health/*disease* history;

c) take and test samples for *MrNV*, pests and general health/*disease* status;
d) import and quarantine in a secure facility a founder (F-0) population;
e) produce F-1 generation from the F-0 stock in *quarantine*;
f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *MrNV* and perform general examinations for pests and general health/*disease* status;
g) if *MrNV* is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as MrNV free or specific pathogen free (SPF) for *MrNV*;
h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

3. In addition, consideration should be taken to international standards, such as the Guidelines Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES).

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

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

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

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

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

2. If the intention of the introduction is the establishment of a new stock ~~genetic lines~~, international standards, such as the ~~Guidelines~~ Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

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

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

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

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

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

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

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

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

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

Article 2.3.11.9.

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

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

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of MrNV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.
This Article does not apply to *commodities* listed in point 1 of Article 2.3.11.3.

Article 2.3.11.10.

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

Community comment

It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.3.11.2, the Competent Authority of the importing country should asses the risk and, if justified, apply risk mitigation measures.
The article does not apply to commodities referred to in point 1 of Article 2.3.11.3.

When importing *aquatic animal products* of species referred to in Article 2.3.11.2. from a country, *zone* or *compartment* declared free from WTD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.11.4. or 2.3.11.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from WTD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.
This Article does not apply to *commodities* listed in point 1 of Article 2.3.11.3.

Article 2.3.11.11.

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

When importing *aquatic animal products* of species referred to in Article 2.3.11.2. from a country, *zone* or *compartment* not declared free from WTD, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

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

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CHAPTER 2.3.12.

HEPATOPANCREATIC PARVOVIRUS DISEASE

Community comment

The Community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 2.3.12.1.

For the purposes of the *Aquatic Code*, hepatopancreatic parvovirus disease (HPVD) means *infection* with hepatopancreatic parvovirus (HPV). It is considered to be a member of the subfamily of the *Densovirinae* in the family *Parvoviridae.*

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

Article 2.3.12.2.

Scope

The recommendations in this Chapter apply to: Indian white shrimp (*Penaeus indicus*), black tiger shrimp (*Penaeus monodon*), Pacific white shrimp (*Penaeus vannamei*) and Pacific blue shrimp (*P. stylirostris*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.
For the purposes of this Chapter, the terms shrimp and prawn are used interchangeably.

Article 2.3.12.3.

Commodities

Community comment

In point 1 b), the Community would argue that, to require packaging for direct retail sale for commodities such as chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.) seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade".
An alternative solution would be to include those commodities in point 1.a).

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any HPVD related conditions, regardless of the HPVD status of the *exporting country*, *zone* or *compartment.*
   a) For the species referred to in Article 2.3.12.2. being used for any purpose:
      i) *commodities* treated in a manner that inactivates the *disease agent* e.g. boiled, canned or pasteurised products and ready to eat meals; and crustacean oil and crustacean meal intended for use in animal feeds ~~commercially sterile canned products~~;
      ~~ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);~~
      iii) chemically extracted chitin;
      ~~iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);~~

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

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

b) The following products destined for human consumption from species referred to in Article 2.3.12.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

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

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

ii~~i~~) de-headed and "de-veined" (intestine removed) shrimp tails.

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.12.2., other than those listed in point 1 of Article 2.3.12.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.12.7. to 2.3.12.11. relevant to the HPVD status of the *exporting country*, *zone* or *compartment*.
3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of HPVD of a~~ny other~~ *commodity* of a species not referred to in Article 2.3.12.2. but which could reasonably be expected to be a potential HPV ~~carrier~~ vector, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of HPV, and the potential consequences, associated with the importation of the commodity prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.12.4.

Hepatopancreatic parvovirus disease free country

A country may make a *self-declaration of freedom* from HPVD 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 HPVD if all the areas covered by the shared water are declared HPVD free countries or *zones* (see Article 2.3.12.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.12.2. is present may make a *self-declaration of freedom* from HPVD when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.3.12.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from HPVD when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

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

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

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

4. A country that has previously made a *self-declaration of freedom* from HPVD but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from HPVD again ~~until~~ when the following conditions have been met:

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

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

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

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

In the meantime, part of the non-affected area may be declared a free *zone* provided that ~~they~~ such part meets the conditions in point 3 of Article 2.3.12.5.

Article 2.3.12.5.

Hepatopancreatic parvovirus disease free zone or free compartment

Community comment

The Community would argue that for certain compartments, disease free status could be regained if aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from Hepatopancreatic parvovirus disease but in which the disease is detected may not be declared free from Hepatopancreatic parvovirus disease until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

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

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

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

If a *zone* or *compartment* extends over more than one country, it can only be declared a HPVD free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.3.12.2. is present may be declared free from HPVD when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.3.12.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from HPVD when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

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

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

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

OR

4. A *zone* previously declared free from HPVD but in which the *disease* is subsequently detected may ~~not~~ be declared free from HPVD again ~~until~~ when the following conditions have been met:

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

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

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

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

Article 2.3.12.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from HPVD following the provisions of points 1 or 2 of Articles 2.3.12.4. or 2.3.12.5. (as relevant) may maintain its status as HPVD free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from HPVD following the provisions of point 3 of Articles 2.3.12.4. or 2.3.12.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as HPVD free provided that conditions that are conducive to clinical expression of HPVD, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

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

Article 2.3.12.7.

Importation of live aquatic animals from a country, zone or compartment declared free from hepatopancreatic parvovirus disease

When importing live *aquatic animals* of species referred to in Article 2.3.12.2. from a country, *zone* or *compartment* declared free from HPVD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.12.4. or 2.3.12.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from HPVD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.12.3.

Article 2.3.12.8.

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

Community comment

The Community maintains its concerns about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in that case, The ICES Code of Practice on the Introductions and Transfers of Marine Organism) because the lack of clarity of the validity of such external documents and any changes made to it. However, the Community welcomes the OIE initiative to establish more formal arrangements between the OIE and the ICES.

If the reference to the ICES Code of Practice is to be maintained, the Community would suggest some amendments to the current article:

A clear description (e.g. number of the document or date of publication) of which document we are referring to must be included.

Point 3 should include the whole Code of Practice or should be deleted to avoid inconsistencies between the summary and the current Code of Practice

If the summary in point 3 is to be maintained we would suggest the AAC the following structure in point 2 and 3:

2. If the intention of the introduction is the establishment of a new stock genetic lines, the following measures should be adopted
a) identify stock of interest (cultured or wild) in its current location;
b) evaluate stock health/*disease* history;
c) take and test samples for *HPV*, 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

HPV and perform general examinations for pests and general health/_disease_ status;
g) if _HPV_ 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 HPV free or specific pathogen free (SPF) for _HPV_;
h) release SPF F-1 stock from _quarantine_ for _aquaculture_ or stocking purposes in the country, _zone_ or _compartment_.

3. In addition, consideration should be taken to international standards, such as the Guidelines Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES).

This Article does not apply to _commodities_ listed in point 1 of Article 2.3.12.3.

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.12.2. from a country, *zone* or *compartment* not declared free from HPVD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

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

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

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

2. If the intention of the introduction is the establishment of a new stock ~~genetic lines~~, international standards, such as the ~~Guidelines~~ Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

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

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

   b) evaluate stock health/*disease* history;

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

   g) if HPV 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 HPVD free or specific pathogen free (SPF) for HPV;

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.12.3.

Article 2.3.12.9.

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

When importing, for human consumption, live *aquatic animals* of species referred to in Article 2.3.12.2. from a country, *zone* or *compartment* not declared free from HPVD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

Appendix XXVI (contd)

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of HPV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.
This Article does not apply to *commodities* listed in point 1 of Article 2.3.12.3.

Article 2.3.12.10.

Importation of aquatic animal products from a country, zone or compartment declared free from hepatopancreatic parvovirus disease

Community comment.

It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.3.12.2, the Competent Authority of the importing country should asses the risk and, if justified, apply risk mitigation measures.
The article does not apply to commodities referred to in point 1 of Article 2.3.12.3.

When importing *aquatic animal products* of species referred to in Article 2.3.12.2. from a country, *zone* or *compartment* declared free from HPVD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.12.4. or 2.3.12.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from HPVD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.
This Article does not apply to *commodities* listed in point 1 of Article 2.3.12.3.

Article 2.3.12.11.

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

When importing *aquatic animal products* of species referred to in Article 2.3.12.2. from a country, *zone* or *compartment* not declared free from HPVD, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.12.3.

— text deleted

CHAPTER 2.3.13.

MOURILYAN VIRUS DISEASE

Community comment

The Community agrees with the proposed chapter, but would ask the OIE to consider the comments included under the specific Articles.

Article 2.3.13.1.

For the purposes of the *Aquatic Code*, Mourilyan virus disease (MoVD) means *infection* with Mourilyan virus (MoV). This virus is similar to members of the *Bunyaviridae*, but has yet to be formally classified.

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

Article 2.3.13.2.

Scope

The recommendations in this Chapter apply to: black tiger shrimp (*Penaeus monodon*) and kuruma shrimp (*Penaeus japonicus*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.
For the purposes of this Chapter, the terms shrimp and prawn are used interchangeably.

Article 2.3.13.3.

Commodities

Community comment

In point 1 b), the Community would argue that, to require packaging for direct retail sale for commodities such as chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.) seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade".
An alternative solution would be to include those commodities in point 1.a).

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

   a) For the species referred to in Article 2.3.13.2. being used for any purpose:

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

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

      ~~iii)~~ chemically extracted chitin;

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

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

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

b) The following products destined for human consumption from species referred to in Article 2.3.13.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

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

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

For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.13.2., other than those listed in point 1 of Article 2.3.13.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.13.7. to 2.3.13.11. relevant to the MoVD status of the *exporting country*, *zone* or *compartment*.
3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of MoVD of ~~any other~~ *commodity* of a species not covered in Article 2.3.13.2. but which could reasonably be expected to be a potential MoV ~~carrier~~ vector, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of MoV, and the potential consequences, associated with the importation of the *commodity* prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.13.4.

Mourilyan virus disease free country

A country may make a *self-declaration of freedom* from MoVD 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 MoVD if all the areas covered by the shared water are declared MoVD free countries or *zones* (see Article 2.3.13.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.13.2. is present may make a *self-declaration of freedom* from MoVD when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.3.13.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from MoVD when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years, or where the

infection status prior to *targeted surveillance* was unknown~~; for example~~ (e.g. because of the absence of conditions conducive to its clinical expression~~;~~ as described in Chapter X.X.X. of the *Aquatic Manual*), may make a *self-declaration of freedom* from MoVD when:

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

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

OR

4. A country that has previously made a *self-declaration of freedom* from MoVD but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from MoVD again ~~until~~ when the following conditions have been met:

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

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

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

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

In the meantime, part of the non-affected area may be declared a free *zone* provided that ~~they~~ such part meets the conditions in point 3 of Article 2.3.13.5.

Article 2.3.13.5.

Mourilyan virus disease free zone or free compartment

Community Comment

The Community would argue that for certain compartments, disease free status could be regained if aquatic animal population is removed and disposed off, the establishment is properly disinfected and where appropriate fallowed and restocked with aquatic animals from a certified free source. The Community asks the OIE AAC to include that option as an alternative as a possible point 5. A proposal for a possible point 5 would be:

A compartment previously declared free from Mourilyan virus disease but in which the disease is detected may not be declared free from Mourilyan virus disease until the followings conditions have been met:

a) the requirements in point 4, or

b) if the compartment is supplied by water from a spring, borehole or other safe supply independent of the surrounding waters and is equipped with a barrier preventing migration of aquatic animals of susceptible species into the compartments or its water supply;

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

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

population.

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

If a *zone* or *compartment* extends over more than one country, it can only be declared a MoVD free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.3.13.2. is present may be declared free from MoVD when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.3.13.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from MoVD when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown; ~~for example~~ (e.g. because of the absence of conditions conducive to its clinical expression; as described in Chapter X.X.X. of the *Aquatic Manual*), may be declared free from MoVD when:

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

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

OR

4. A *zone* previously declared free from MoVD but in which the *disease* is subsequently detected may ~~not~~ be declared free from MoVD again ~~until~~ when the following conditions have been met:

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

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

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

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

Article 2.3.13.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from MoVD following the provisions of points 1 or 2 of Articles 2.3.13.4. or 2.3.13.5. (as relevant) may maintain its status as MoVD free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from MoVD following the provisions of point 3 of Articles 2.3.13.4. or 2.3.13.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as MoVD free provided that conditions that are conducive to clinical expression of MoVD, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

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

Article 2.3.13.7.

Importation of live aquatic animals from a country, zone or compartment declared free from Mourilyan virus disease

When importing live *aquatic animals* of species referred to in Article 2.3.13.2. from a country, *zone* or *compartment* declared free from MoVD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.13.4. or 2.3.13.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from MoVD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.13.3.

Article 2.3.13.8.

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

Community comment

The Community maintains its concerns about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in that case, The ICES Code of Practice on the Introductions and Transfers of Marine Organism) because the lack of clarity of the validity of such external documents and any changes made to it. However, the Community welcomes the OIE initiative to establish more formal arrangements between the OIE and the ICES.

If the reference to the ICES Code of Practice is to be maintained, the Community would suggest some amendments to the current article:

A clear description (e.g. number of the document or date of publication) of which document we are referring to must be included.

Point 3 should include the whole Code of Practice or should be deleted to avoid inconsistencies between the summary and the current Code of Practice

If the summary in point 3 is to be maintained we would suggest the AAC the following structure in point 2 and 3:

2. If the intention of the introduction is the establishment of a new stock genetic lines, the following measures should be adopted
a) identify stock of interest (cultured or wild) in its current location;
b) evaluate stock health/*disease* history;
c) take and test samples for *MoV*, 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 *MoV* and perform general examinations for pests and general health/*disease* status;
g) if *MoV* 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 Mov free or specific pathogen free (SPF) for *MoV*;
h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
3. In addition, consideration should be taken to international standards, such as the Guidelines Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES).

This Article does not apply to *commodities* listed in point 1 of Article 2.3.13.3.

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.13.2. from a country, *zone* or *compartment* not declared free from MoVD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

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

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

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

... inactivation of MoV.

2. If the intention of the introduction is the establishment of a new stock ~~genetic lines~~, international standards, such as the ~~Guidelines~~ Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

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

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

   b) evaluate stock health/*disease* history;

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

   g) if MoV 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 MoVD free or specific pathogen free (SPF) for MoV;

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.13.3.

Article 2.3.13.9.

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

When importing, for human consumption, live *aquatic animals* of species referred to in Article 2.3.13.2. from a country, *zone* or *compartment* not declared free from MoVD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of MoV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.
This Article does not apply to *commodities* listed in point 1 of Article 2.3.13.3.

Article 2.3.13.10.

Importation of aquatic animal products from a country, zone or compartment declared free from Mourilyan virus disease

Community Comment

It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic

animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in article 2.3.13.2, the Competent Authority of the importing country should asses the risk and, if justified, apply risk mitigation measures.

The article does not apply to commodities referred to in point 1 of Article 2.3.13.3.

When importing *aquatic animal products* of species referred to in Article 2.3.13.2. from a country, *zone* or *compartment* declared free from MoVD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.13.4. or 2.3.13.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from MoVD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.
This Article does not apply to *commodities* listed in point 1 of Article 2.3.13.3.

Article 2.3.13.11.

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

When importing *aquatic animal products* of species referred to in Article 2.3.13.2. from a country, *zone* or *compartment* not declared free from MoVD, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.13.3.

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Appendix XXVIII

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

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

1. INTRODUCTION

One of the key objectives of the OIE *Aquatic Animal Health Code* (hereafter referred to as the *Aquatic Code*) is to help Member Countries trade safely in *aquatic animals* and their products by developing relevant aquatic animal health measures. These Guidelines address aquatic animal health *hazards* in aquatic animal *feeds*. It does not address food safety issues as this is not within the mandate of the OIE Aquatic Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission). These Guidelines should be read in conjunction with relevant recommendations of the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) (Appendix containing recommendations on animal *feed*). The Food and Agriculture Organization of the United Nations (FAO) has also published recommendations[1] relevant to terrestrial and aquatic animal *feed*.

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

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

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

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

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

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

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

[1] Technical guidelines for responsible fisheries – aquaculture development: 1. Good aquaculture feed manufacturing practice. FAO 2001.
Draft good practices for the animal feed industry – implementing the Codex Alimentarius' Code of practice on good animal feeding, IFIF/FAO (*In preparation*).

Appendix XXVIII (contd)

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

2. PURPOSE AND SCOPE

Community Comments
The Community raises a concern on the scope of these guidelines.
We would like further clarification of the future intention of the OIE AAC in relation to the certification of aquatic animal feeds. If the intention of the AAC is to draft new certificates for these commodities we think that, for example, articles 2.1.X.11 (Importation of products from a country, zone or compartment declared free) and 2.1.X.12 (Importation of products from a country, zone or compartment not declared free) in the case of fish diseases are enough to deal with this hazard.
The Community would like to highlight that some aquaculture species are fed with whole frozen fish caught in the wild. We would like that the OIE assesses the possible animal health risks linked with this type of farming.

In addition, a definition of what an aquarium species is needed.

To document risk mitigation measures, including traceability and certification, to deal with aquatic animal health risks through trade in aquatic animal *feeds* and *feed ingredients*. *Hazards* include *diseases* of interest i.e. *OIE-listed diseases* and any others considered to be important to aquatic animal health.

This guideline recommends the control of aquatic animal health *hazards* through adherence to recommended practices during the production (procurement, handling, storage, processing and distribution) and use of both commercial and on-farm produced *feed* (and *feed ingredients*) for *aquatic animals*. While *aquatic animals* grown for food are the main focus, the same principles apply to *feed* for aquarium species.

3. DEFINITIONS

The Community would like to have further clarification on the differences between "feed" and "feed ingredients"; in a few cases the text mentions only "feed", being unclear why in those cases "feed ingredients" are excluded (see points 4 a) 4g) or point 6)
In addition, in the definition of "feed ingredient" it is not clear what is meant by "feed ingredient of aquatic origin"; It is written "Ingredients may be of plant, animal or aquatic origin" which seems to be something that it is not a plant, an animal but is not water either.
Dry feed: Moisture content of 12 % is normally used when nutritional values or daily intake of dry feed is calculated. Thus, dry matter content of 88 % would be more feasible.
Feed additives: It is not clear from the definition what kind of substances fall into the categories of "attractants". We would like the OIE to clarify that definition.

Cross contamination

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

Dry feed

Means *feed* that has a dry matter content = or > than 90%.

Feed

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

Feed additives

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

Feed ingredient

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

Hazard

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

Intra/inter species feeding

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

Live feed

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

Medicated feed

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

Moist (or wet) feed

Means *feed* that has a dry matter content = or < than 30% (e.g. frozen adult Artemia, whole fish or fish *offal*, molluscs, crustaceans, polychaetes for feed purposes).

Semi-moist feed

Means *feed* that has a dry matter content between 30 and 90%.

Fish solubles

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

Undesirable substance

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

4. GENERAL PRINCIPLES

a) Roles and responsibilities

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

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

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

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

b) Regulatory standards for feed safety

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

c) Risk analysis

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

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

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

d) Good practices

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

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

e) Relationship between terrestrial animal disease agents and aquatic species

Community comment

The European Community has funded since several years research in order to find any evidence of the replication of TSE in fish. Currently one project relating to TSE in fish is ongoing. This project is carrying out a long term infection study in sea bream, bass and trout, to investigate the transfer of prions at the level of the gut and examines the molecular biology of fish prion protein homologues.

Although, based on previous research the risk of TSE in fish, either being fed directly or by amplification of infectivity is remote, the Community propose to await the conclusions of this research project expected end of 2007.

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

f) Bioaccumulation

Community comment

The Community would suggest to the OIE to add a reference to the dioxins.

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

g) Geographic and environmental considerations

Aquatic and terrestrial harvest areas for *feed ingredients* should not be located in proximity to sources of animal health or food safety *hazards*. Where this cannot be

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

avoided, preventive measures should be applied to control risk. The same recommendations apply for the processing of *feed ingredients*, the manufacture of *feed* and the location of *aquaculture* operations.
Aquatic animal health considerations include factors such as *disease* status, location of quarantined premises, existence of processing plants without proper biosecurity measures and the existence of *zones/compartments* of specified health status.
Public health considerations include factors such as industrial operations and waste treatment plants that generate pollutants and other hazardous products. The potential accumulation of pollutants in the food chain through *feed ingredients* needs to be considered.

h) Zoning and compartmentalisation

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

i) Sampling and analysis

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

j) Labelling

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

See Section 4.2. of Codex Code of practice on good animal feeding (CAC/RCP 54-2004).

k) Design and management of inspection programmes

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

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

l) Assurance and certification

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

m) Hazards associated with animal feed

Biological hazards

Biological hazards that may occur in *feed* and *feed ingredients* include agents such as bacteria, viruses, prions, fungi and parasites.

Chemical hazards

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

Physical hazards

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

n) Cross contamination

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

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

o) Antimicrobial resistance

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

p) Management of information

The *Competent Authority* should establish requirements for the provision of information by the private sector on regulatory requirements.

Records should be maintained in a readily accessible form on the production, distribution and use of *feed* and *feed ingredients*. These records are required to facilitate the prompt trace-back of *feed* and *feed ingredients* to the immediate previous source, and trace-forward to the next/subsequent recipients, to address animal health or public health concerns.

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

5. HAZARDS

Biological

This document addresses the following biological hazards:

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

b) prions.

Chemical

[under study]

Physical

[under study]

6. PATHOGENS IN FEED

a) Pathogens in *feed* can be introduced at two points:
   i) at source: via the harvest of infected *aquatic animals*;
   ii) during storage, processing and transport.
   Contamination may occur at the manufacturing facility via poor hygienic practices and/or the presence of pests.
   Feed and *feed ingredients* may be exposed to contamination during storage, manufacturing or transport, due to residues of previous batches of *feed* remaining in processing lines, containers or transport vehicles.

b) Exposure pathways include:
   i) Direct exposure
   The use of raw unprocessed *feed* or *feed ingredients* derived from *aquatic animals* to feed aquatic species presents a risk of exposure to *hazards* of infectious nature. There are risks associated with feeding whole *aquatic animals* and unprocessed products of *aquatic animals* to species that are susceptible to the same *diseases* as the 'fed animal' e.g. feeding salmonid *offal* to salmonids or feeding rotifers or Artemia species to crustaceans.
   ii) Indirect exposure
   Feed and *feed ingredients* containing pathogenic agents may be transmitted to *aquatic animals* in *aquaculture* and wild fish via contamination of the environment, including infection/contamination on non-target species.

7. RECOMMENDED APPROACHES TO RISK MITIGATION

The following measures are relevant to *exporting countries*:

a) Source of raw materials
   Raw materials/ingredients should not be sourced from areas/*populations* known to be infected with significant pathogens. It may be appropriate to adopt routine testing procedures to verify that pathogens are not present at unacceptable levels; or
   When using *feed* and *feed ingredients* originating from areas known to be affected by a significant pathogen:
   i) *feed* and *feed ingredients* should be delivered directly to feed manufacturing plants for processing under conditions approved by the *Competent Authority*; and
   ii) effluent and other wastes from the feed manufacturing plants should be treated under conditions approved by the *Competent Authority* before discharge into the aquatic environment; or
   iii) *feed* and *feed ingredients* known or suspected to be infected with significant pathogens should only be used and/or processed in a *zone* or *compartment* that does not contain species susceptible to the pathogen in question.

b) Feed production

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

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

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

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

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

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

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

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

c) The following measures are relevant to *importing countries*:

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

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

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

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

8. CERTIFICATION PROCEDURES FOR AQUATIC FEEDS

This section addresses risk assessment and risk management measures and certificates. The heading only refers to certification.

a) The following products represent a negligible risk because of the extensive processing used to produce them:
   i) fish oil;
   ii) crustacean oil;
   iii) *fish solubles*;
   iv) fish meal;
   v) crustacean meal;
   vi) squid meal and squid liver-meal;
   vii) bivalve meal;
   viii) finished *feed* (e.g. flake, pelleted and extruded *feeds*).
   For these products, *Competent Authorities* should not require conditions in relation to aquatic animal *diseases*, regardless of the aquatic health status of the *exporting country*, *zone* or *compartment*[4].

b) Other products
   The following risk mitigation measures should be considered:
   i) sourcing *feed* and *feed ingredients* from a *disease* free area; or
   ii) confirmation (e.g. by testing) that pathogens are not present in the product; or
   iii) treatment (e.g. by heat or acidification) of product to inactivate pathogens.

c) Importing country measures
   When importing *feed* and *feed ingredients* of aquatic origin, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* (or a *certifying official* approved by the *importing country*).
   This certificate should certify:
   i) that *feed* and *feed ingredients* of aquatic origin were imported from a country, *zone* or *compartment* that is free from relevant aquatic animal *diseases*[5]; or

[4] In relation to the risk associated with contamination after harvest/processing, point 4 (below) applies.
[5] Conditions agreed between the Competent Authorities of the importing and exporting countries in accordance with the recommendations of the OIE *Aquatic Animal Health Code*.

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

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

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

Some ingredients used in *aquaculture*, in particular of aquatic origin (e.g., krill, shrimp, fish, crab, Artemia) can be a source of pathogen contamination to cultured aquatic species. These ingredients can carry live pathogens (virus, bacteria, and parasites) and reach the aquaculture operation through different types of *feeds* (live, moist, semi-moist or dry feeds).

In aquaculture farms, there are two routes of pathogen contamination through aquatic animal feeding: transmission of pathogens and contamination. **Transmission of pathogens** can take place when the *feed* itself is already infected with a pathogen. This type of contamination is more common with *live feeds* and *moist feeds*. Ingredients that constitute their composition are either kept in a raw state in the final product (e.g., feeding tuna with wild caught fish) or at times require little treatment(s) prior to feeding aquatic organisms.

Harvest of aquatic ingredient sources from infected areas has a high *risk* of pathogen contamination, especially if these are transported to an *aquaculture* operation without any prior treatment. Processing of these ingredients places a moderate risk of contamination, and it should actually be taken as a possibility to reduce the risk of pathogen transmission (e.g., through heat, chemical treatments). Storage and transportation of these ingredients has a low risk of contamination, but should also be considered as a direct route of pathogen contamination. For example, when two or more batches of ingredients of different sanitary status are handled, stored and/or transported together without any biosecurity measure there is a risk of direct contamination to the farmed animal.

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

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

b) Feed manufacturing: during feed processing, ingredients are commonly subjected to heat treatment which can eliminate certain pathogens. However, use of

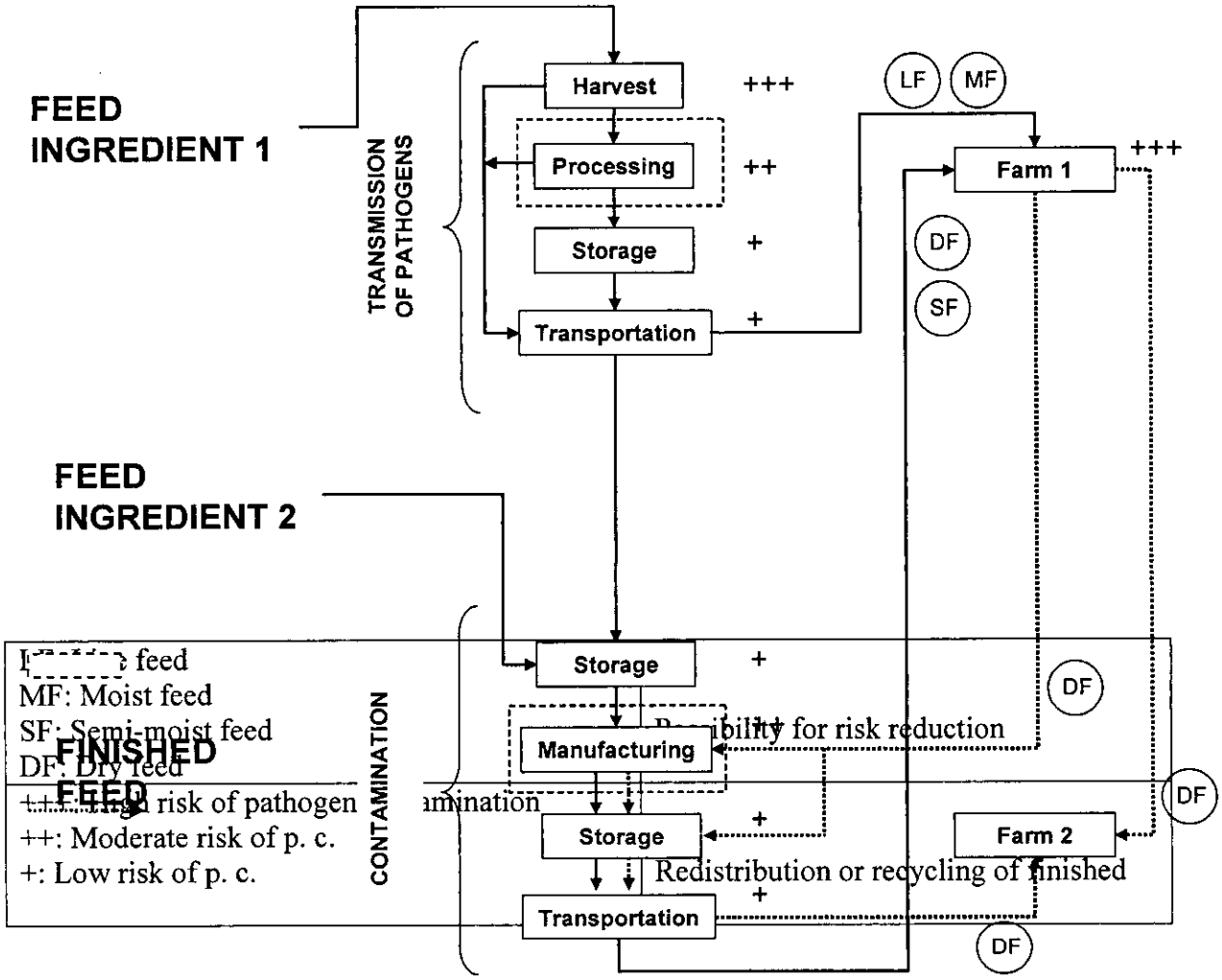
[6] Conditions agreed between the Competent Authorities of the importing and exporting countries in accordance with the recommendations of the OIE *Aquatic Animal Health Code*.

manufacturing lines with remains of contaminated ingredients from a previous batch of feed can result in cross contamination of feeds.

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

Appendix XXVIII (contd)

An aquaculture facility can also be a source of pathogen contamination in aquatic feeds. At this level, contamination can take place when a finished feed is delivered to a farm located in an infected area. Transmission of pathogens can occur when feed is withdrawn from the aquaculture and is returned to the manufacturing facility for reprocessing or transferred to another farm.



Appendix XXIX

APPENDIX X.X.X.

GENERAL GUIDELINES FOR AQUATIC ANIMAL HEALTH SURVEILLANCE

Community comment

The Community appreciates that these guidelines have been drafted, which can give valuable guidance for health surveillance. However, the texts in appendix XXIX is not so easy to read and application of the guidelines would benefit from simplification and clarification of the wording.

The Community has also a concern about the feasibility of the practical implementation of the guidelines.
Additionally, we cannot understand the benefit of making difference between disease and infection in connection with the surveillance. Surveillance for the OIE listed diseases must always be aimed to find infection.

Finally the Community encourages the OIE to draft specific guidelines for each listed disease as a priority in its working plan.

Article 3.8.1.1.

Introduction and objectives

1. Surveillance is aimed at:
   - demonstrating the absence of *disease* or *infection*,
   - identifying events requiring notification as listed in Article 1.2.1.3. of the *Aquatic Code*,
   - determining the occurrence or distribution of endemic *disease* or *infection*, including changes to their incidence or prevalence (or its contributing factors), in order to:
     - provide information for domestic *disease* control programmes,
     - provide relevant *disease* occurrence information to be used by trading partners for qualitative and quantitative risk assessment.

   The type of surveillance applied depends on the desired outputs needed to support decision-making. Surveillance data determine the quality of *disease* status reports and should satisfy information requirements for accurate risk analysis both for *international trade* as well as for national decision-making.
2. Essential prerequisites to enable a Member Country to provide information for the evaluation of its animal health status are:
   a) that the particular Member Country complies with the provisions of Chapter 1.4.3. of the *Aquatic Code* on the quality and evaluation of the *Competent Authorities*;
   b) that, where possible, surveillance data be complemented by other sources of information (e.g. scientific publications, research data, documented field observations and other non-survey data);
   c) that transparency in the planning and execution of surveillance activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.2.1. of the *Aquatic Code*.

The following guidelines may be applied to all *diseases*, their agents and susceptible species as listed in the *Aquatic Manual*, and are designed to assist with the development of surveillance methodologies. Where possible, the development of surveillance systems using these guidelines should be based on the relevant information in the individual *disease* chapters.

Article 3.8.1.2.

Definitions

Community comment

The Community would agree with the proposed definitions but would like to have the following comments taken into account:

"Early detection system": make a reference to zones and compartments as the OIE AAC is replacing the use of aquaculture establishment with the use of compartments.

"Outbreak": the definition given in this article (*substantial increase in the occurrence of disease above the expected level at a given time in a given population*) is different to that laid down in Chapter 1.1.1of the Code (*an occurrence of disease in an aquatic animal population*). Moreover, the proposed definition in this article corresponds to the concept of epidemics.

"Surveillance": the definition given in this article (*The systematic ongoing collection, collation, and analysis of data, and the timely dissemination of information to those who need to know so that action can be taken*) is different to that laid down in Chapter 1.1.1of the Code (*systematic series of investigation of a given population of aquatic animals to detect the occurrence of disease for control purposes, and which may involve testing samples of a population*). When revising the definitions in Chapter 1.1.1. of the Code, we would suggest to update the definition. As well, it is not clear if one of the objectives of the surveillance (identifying events requiring notification as listed in Article 1.2.1.3 of the Aquatic Code) is properly included in the proposed definition.

As well, we would suggest the OIE to refer to the definitions laid down in Chapter 1.1.1. of the Code or in the General Provisions of the Manual to avoid inconsistencies.

The following definitions apply for the purposes of this Appendix:

Bias: A tendency of an estimate to differ from the true value of a population parameter.
Case definition: A case definition is a set of criteria used to distinguish a case animal or *epidemiological unit* from a non-case.

Early detection system: an efficient system for ensuring the rapid recognition of signs that are suspicious of a *listed disease*, or an *emerging disease* situation, or unexplained mortality, in *aquatic animals* in an *aquaculture establishment* or in the wild, and the rapid communication of the event to the *Competent Authority*, with the aim of activating diagnostic investigation with minimal delay. Such a system will include the following characteristics:

a) broad awareness, e.g. among the personnel employed at *aquaculture establishments* or involved in *processing*, of the characteristic signs of the *listed diseases* and *emerging diseases*;

b) veterinarians or *aquatic animal* health specialists trained in recognising and reporting suspicious *disease* occurrence;

c) ability of the *Competent Authority* to undertake rapid and effective *disease* investigation;

d) access by the *Competent Authority* to laboratories with the facilities for diagnosing and differentiating *listed* and *emerging diseases*.

Outbreak: An outbreak is a substantial increase in the occurrence of *disease* above the expected level at a given time in a given population.

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

Sample: The group of elements (sampling units) drawn from a population, on which tests are performed or parameters measured to provide surveillance information.

Sampling unit: The unit that is sampled. This may be an individual animal or a group of animals (e.g. a pond). A list of all the sampling units comprises the sampling frame.

Sensitivity: The proportion of truly positive units that are correctly identified as positive by a test.

Specificity: The proportion of truly negative units that are correctly identified as negative by a test.

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

Surveillance: The systematic ongoing collection, collation, and analysis of data, and the timely dissemination of information to those who need to know so that action can be taken.

Survey: An investigation about a defined population in which information is systematically collected within a defined time period.

Target population: The population about which conclusions from analysing data are to be inferred.

Test: A procedure used to classify a unit as either positive, negative or suspect with respect to an *infection* or *disease.*

Article 3.8.1.3.

Community comment

2. Critical elements

A) Populations

The Community would suggest to include a reference to certain non-susceptible species for certain diseases but capable to spread that diseases into the susceptible population. In some situations this non-susceptible species may be included in the surveillance systems.

C) Clustering

The annual fluctuation of the pathogen has not been taken into account. We would propose the inclusion of that crucial factor in this heading.

F) Testing

The possibility of mixed infections should be handled. The situation of mixed infections by *Gyrodactylus* spp. is a practical example. There should be description of the procedure(s) to decide how many parasites must be determined to the species level in order to state freedom of infection of *Gyrodactylus salaris*. (How many parasites per sampled fish, of how many fish infected with *Gyrodactylus* spp. etc.). There probably are (and will be more in the future) other similar situations, where the problem of mixed infections complicates the surveillance.

F) Sentinel units

The susceptibility of the life-stages is an important factor of a surveillance programme. When implementing a programme supported by the use of sentinel farms or animals, the surveillance should be focused in the most susceptible life stages. Therefore, the Community would suggest to the AAC to make a reference to this important factor in that paragraph.

Principles of surveillance

1. Types of surveillance

a) Surveillance may be based on many different data sources and can be classified in a number of ways, including:

i) the means by which data are collected (targeted versus non-targeted);

ii) the *disease* focus (pathogen-specific versus general surveillance); and

iii) the way in which units for observation are selected (structured surveys versus non-random data sources).

b) Surveillance activities include:

i) structured population-based surveys, such as:

- systematic sampling at slaughter;
- random surveys;

ii) structured non-random surveillance activities, such as:

- *disease* reporting or notifications;
- control programmes/health schemes;
- targeted testing/screening;
- ante-mortem and post-mortem inspections;
- laboratory investigation records;
- biological specimen banks;
- sentinel units;
- field observations;
- farm production records.

c) In addition, surveillance data should be supported by related information, such as:

i) data on the epidemiology of the *infection*, including environmental, and host and wild reservoir population distributions;

ii) data on farmed and wild animal movements and trading patterns for aquatic animals and aquatic animal products, including potential for exposure to wild aquatic animal populations, water sources or other contacts;

iii) national animal health regulations, including information on compliance with them and their effectiveness;

iv) history of imports of potentially infected material; and

v) biosecurity measures in place.

d) The sources of evidence should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the

source(s) of the data, when the data were collected, and a consideration of any biases that may be inherent in the system.

2. Critical elements

In assessing the quality of a surveillance system, the following critical elements need to be addressed over and above quality of *Competent Authority* (Chapter 1.4.3.).

a) Populations

Ideally, surveillance should be carried out in such a way as to take into account all animal species susceptible to the *infection* in a country, *zone* or *compartment*. The surveillance activity may cover all individuals in the population or part of them. Estimates of total population at risk for each species are required. When surveillance is conducted only on a *subpopulation*, care should be taken regarding the inferences made from the results.
Definitions of appropriate populations should be based on the specific recommendations of the *disease* chapters of the *Aquatic Manual*.

b) Epidemiological unit

The relevant *epidemiological unit* for the surveillance system should be defined and documented to ensure that it is representative of the population or targeted *subpopulations* that would generate the most useful inferences about *disease* patterns. Therefore, it should be chosen taking into account factors such as carriers, reservoirs, vectors, immune status, genetic resistance and age, sex, and other host criteria.

c) Clustering

Infection in a country, *zone* or *compartment* usually clusters rather than being uniformly or randomly distributed through a population. Clustering may occur at a number of different levels (e.g. tank, pond, farm, or *compartment*). Clustering should be taken into account in the design of surveillance activities and the statistical analysis of surveillance data, at least at what is judged to be the most significant level of clustering for the particular animal population and *infection*.

d) Case and outbreak definitions

Clear and unambiguous case and outbreak definitions should be developed and documented for each *disease* under surveillance, using, where they exist, the standards in this Appendix and the *Aquatic Manual*.

e) Analytical methodologies

Surveillance data should be analysed using appropriate methodologies, and at the appropriate organisational levels to facilitate effective decision making, whether it be planning interventions or demonstrating status.

Methodologies for the analysis of surveillance data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be needed to accommodate the relevant pathogens, varying production and surveillance systems, and types and amounts of data and information available.

The methodology used should be based on the best available information that is in accord with current scientific thinking. The methodology should be in accordance with this Appendix and fully documented, and supported by reference to the scientific literature and other sources, including expert opinion. Sophisticated mathematical or statistical analyses should only be carried out when justified by the proper amount and quality of field data.

Consistency in the application of different methodologies should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

f) Testing

Surveillance involves the detection of *disease* or *infection* by the use of appropriate case definitions based on the results of one or more tests for evidence of *infection* status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its sensitivity and specificity and predictive values. Imperfect sensitivity and/or specificity will have an impact on the conclusions from surveillance. Therefore, these parameters should be taken into account in the design of surveillance systems and analysis of surveillance data as described in the *Aquatic Manual.*

Although not determined for many aquatic *diseases*, sensitivity and specificity should be estimated as best as possible for a specific testing situation. Alternatively, where values for sensitivity and/or specificity for a particular test and testing situation are estimated in the *Aquatic Manual*, these values may be used as a guide.

Samples from a number of animals or units may be pooled and subjected to a testing protocol. The results should be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pool size and testing procedure.

g) Quality assurance

Surveillance systems should incorporate the principles of quality assurance and be subjected to periodic auditing to ensure that all components of the system function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the design.

h) Validation

Results from animal health surveillance systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

Appendix XXIX (contd)

i) Data collection and management

The success of a surveillance system is dependent on a reliable process for data collection and management. The process may be based on paper records or computerised. Even where data are collected for non-survey purposes (e.g. during *disease* control interventions, inspections for movement control or during *disease* eradication schemes), the consistency and quality of data collection and event reporting in a format that facilitates analysis, is critical. Factors influencing the quality of collected data include:

- the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location;
- motivation of the people involved in the surveillance system;
- the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;
- maintenance of disaggregated data rather than the compilation of summary data;
- minimisation of transcription errors during data processing and communication.

Article 3.8.1.4.

Structured population-based surveys

In addition to the principles for surveillance discussed above, the following guidelines should be used when planning, implementing and analysing surveys.

1. Types of surveys

Surveys may be conducted on the entire target population (i.e. a census) or on a sample. Periodic or repeated surveys conducted in order to document *disease* freedom should be done using probability based sampling methods (simple random selection, cluster sampling, stratified sampling, systematic sampling) so that data from the study population can be extrapolated to the target population in a statistically valid manner. Non-probability based sampling methods (convenience, expert choice, quota) can also be used. Recognising the inherent impracticalities in sampling from some aquatic populations, non-probability based sampling could be used when biases are recognised and used to optimise detection.

The sources of information should be fully described and should include a detailed description of the sampling strategy used for the selection of units for testing. Also, consideration should be made of any biases that may be inherent in the survey design.

2. Survey design

The population of *epidemiological units* should first be clearly defined; hereafter sampling units appropriate for each stage, depending on the design of the survey, should be defined.

The design of the survey will depend on the size and structure of the population being studied, the epidemiology of the *infection* and the resources available.

3. Sampling

The objective of sampling from a population is to select a subset of units from the population that is representative of the population with respect to the object of the study such as the presence or absence of *infection*. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems. In order to detect the presence of an *infection* in a population of unknown *disease* status, targeted sampling methods that optimise the detection of *infection* can be used. In such cases, care should be taken regarding the inferences made from the results.

4. Sampling methods

When selecting *epidemiological units* from within a population the objectives of the surveillance system should be considered. In general, probability sampling (e.g. simple random selection) is preferable. When this is not possible, sampling should provide the best practical chance of generating optimal inferences about *disease* patterns in the target population.

In any case, the sampling method used at all stages should be fully documented and justified.

5. Sample size

In general, surveys are conducted either to demonstrate the presence or absence of a factor (e.g. *infection*) or to estimate a parameter (e.g. the prevalence of *infection*). The method used to calculate sample size for surveys depends on the purpose of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.

Article 3.8.1.5.

Structured non-random surveillance

Surveillance systems routinely use structured non-random data, either alone or in combination with surveys.

1. Common non-random surveillance data sources

A wide variety of non-random surveillance data sources may be available. These vary in their primary purpose and the type of surveillance information they are able to provide. Some surveillance systems are primarily established as *early detection systems*, but may also provide valuable information to demonstrate freedom from *infection*. Other systems provide cross-sectional information suitable for prevalence estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of incidence data (e.g. *disease* reporting systems, sentinel sites, testing schemes).

a) Disease reporting or notification systems

Data derived from *disease* reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for risk analysis, or for early detection. The first step of a *disease* reporting or notification system is often based on the observation of abnormalities (e.g. clinical signs, reduced growth, elevated mortality rates, behavioural changes, etc.), which can provide important information about the occurrence of endemic, exotic or new *diseases*. Effective laboratory support is, however, an important component of most reporting systems. Reporting systems relying on laboratory confirmation of suspect clinical cases should use tests that have a high specificity. Reports should be released by the laboratory in a timely manner, with the amount of time from *disease* detection to report generation minimised.

b) Control programmes/health schemes

Animal *disease* control programmes or health schemes, while focusing on the control or eradication of specific *diseases*, should be planned and structured in such a manner as to generate data that are scientifically verifiable and contribute to structured surveillance.

c) Targeted testing/screening

This may involve testing targeted to selected sections of the population (subpopulations), in which *disease* is more likely to be introduced or found. Examples include testing culled and dead animals, animals exhibiting clinical signs, animals located in a defined geographical area and specific age or commodity group.

d) Post-harvest inspections

Inspections of aquatic animal slaughter premises or processing plants may provide valuable surveillance data provided diseased aquatic animals survive to slaughter. Post-harvest inspections are likely to provide good coverage only for particular age groups and geographical areas. Post-harvest surveillance data are subject to obvious biases in relation to target and study populations (e.g. only animals of a particular class and age may be slaughtered for human consumption in significant numbers). Such biases need to be recognised when analysing surveillance data.

Both for traceback in the event of detection of *disease* and for analysis of spatial and population-level coverage, there should be, if possible, an effective identification system that relates each animal in the slaughter premises/processing plant to its locality of origin.

e) Laboratory investigation records

Analysis of laboratory investigation records may provide useful surveillance information. The coverage of the system will be increased if analysis is able to incorporate records from national, accredited, university and private sector laboratories. Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardised methods for interpretation and data recording. If available, the method listed in the *Aquatic Manual* in relation to the purpose of testing should be used. As with post-harvest inspections, there needs to be a mechanism to relate specimens to the farm of origin. It must be recognised that laboratory submissions may not accurately reflect the *infection* or *disease* situation on the farm.

f) Biological specimen banks

Specimen banks consist of stored specimens, gathered either through representative sampling or opportunistic collection or both. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from *infection*, and may allow certain studies to be conducted more quickly and at lower cost than alternative approaches.

g) Sentinel units

Sentinel units/sites involve the identification and regular testing of one or more of animals of known health/exposure status in a specified geographical location to detect the occurrence of *disease*. They are particularly useful for surveillance of *diseases* with a strong spatial component, such as vector-borne *diseases*. Sentinel units provide the opportunity to target surveillance depending on the likelihood of *infection* (related to vector habitats and host population distribution), cost and other practical constraints. Sentinel units may provide evidence of freedom from *infection*, or provide data on prevalence and incidence as well as the distribution of *disease*. Cohabitation with a susceptible population should be considered for testing *infection* or *disease* in populations of valuable animals, the lethal sampling of which may be unacceptable (e.g. ornamental fish).

h) Field observations

Clinical observations of epidemiological units in the field are an important source of surveillance data. The sensitivity and/or specificity of field observations may be relatively low, but these can be more easily determined and controlled if a clear, unambiguous and easy to apply standardised case definition is applied. Education of potential field observers in application of the case definition and reporting is an important component. Ideally, both the number of positive observations and the total number of observations should be recorded.

i) Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of *disease* at the population level. If production records are accurate and consistently maintained, the sensitivity of this approach may be quite high (depending on the *disease*), but the specificity is often quite low.

2. Critical elements for structured non-random surveillance

There is a number of critical factors that should be taken into account when using structured non-random surveillance data such as coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. Surveillance data from non-random data sources may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

3. Analytical methodologies

Different scientifically valid methodologies may be used for the analysis of non-random surveillance data. This most often requires information on parameters of importance to the surveillance system, such as sensitivity and specificity. Where no such data are available, estimates based on expert opinions, gathered and combined using a formal, documented and scientifically valid methodology may be used.

4. Combination of multiple sources of data

The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented including references to published material.
Surveillance information gathered from the same country, *zone* or *compartment* at different times (e.g. repeated annual surveys) may provide cumulative evidence of animal health status. Such evidence gathered over time may be combined to provide an overall level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources, may be able to achieve the same level of confidence in a shorter period of time.

Analysis of surveillance information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take into account the decreased value of older information. The sensitivity, specificity and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

Article 3.8.1.6.

Surveillance to demonstrate freedom from disease/infection

The Community would agree with the proposed definitions but would like to have the following comments taken into account:

<u>Requirements to declare a country, zone or compartment free from disease/infection without pathogen specific surveillance.</u>

Point 2 b). When following the "Historically free" path to obtain the freedom status, the 25 years period after the achievement of the eradication necessary to gain the freedom status seems disproportionate. We would argue that a 10 year period gives enough proof of the absence of the disease. Furthermore, the data collected during this 25 years period would be, in many cases, difficult to asses, as the epidemiological circumstances, the diagnostic tools, the surveillance schemes might have changed in this long period. Therefore, the Community would suggest to replace this timeframe with the same timeframe that the biosecurity measures must have been in place, i.e. 10 years.

Point 2 c). When following the "last occurrence within the previous 25 years" path, this 25 years period seems disproportionate. Please, replace it with a 10 years period as described above.

Concerning point 2 c) iii). It is written that specific surveillance in wild aquatic animals of susceptible species is necessary to obtain the freedom status in previously infected countries or zones. The Community would argue that surveillance in farmed animals would be enough to demonstrate the absence of the pathogen, provided that the number of farms in that zone or country is high enough to provide sufficient epidemiological data. Only when the number of farms is not enough to provide an acceptable level of confidence to the surveillance system, wild animals sampling should be compulsory.

<u>Guidelines for the discontinuation of pathogen-specific surveillance after recognition of freedom from infection</u>

Discontinuation of pathogen specific surveillance should only be possible provided that the conditions conducive to clinical expression of the disease in question exist.

<u>International recognition of disease/infection free status</u>

Prior to the introduction of such international recognition, Surveillance guidelines for each specific disease should be drafted by the AAC.

1. <u>Demonstration of freedom from infection</u>
   A surveillance system to demonstrate freedom from *infection* should meet the following requirements in addition to the general requirements for surveillance outlined in Article 3.8.1.3 of this Appendix. Freedom from *infection* implies the absence of the pathogenic agent in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of the absence of *infection*. Demonstrating freedom from *infection* involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Member Countries) that *infection* with a specified pathogen is not present in a population. In practice, it is not possible to prove (i.e. be 100% confident) that a population is free from *infection*. Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that *infection*, if present, is present in less than a specified proportion of the population.

However, apparent *infection* at any level in the target population automatically invalidates any freedom from *infection* claim unless the positive test results are accepted as false positives based on specificity values described in the relevant *disease* chapter.

2. Requirements to declare a country, zone or compartment free from *disease/infection* without pathogen specific surveillance

This Article provides general principles for declaring a country, *zone* or *compartment* free from *disease/infection* in relation to the time of last occurrence and in particular for the recognition of historical freedom.

The provisions of this Article are based on the principles described in Article 3.8.1.3. of this Appendix and the following premises:

- in the absence of *disease* and vaccination, the farmed and wild animal populations would become susceptible over a period of time;
- the *disease* agents to which these provisions apply are likely to produce identifiable clinical signs in observable susceptible animals;
- competent and effective *Competent Authority* will be able to investigate, diagnose and report *disease*, if present;
- the absence of *disease/infection* over a long period of time in a susceptible population can be substantiated by effective *disease* investigation and reporting by a Member Country.

a) Absence of susceptible species

Unless otherwise specified in the relevant *disease* chapter, a country, *zone* or *compartment* may be recognised as being free from *infection* without applying *targeted surveillance* if there are no susceptible species (as listed in the relevant chapter of this *Aquatic Manual*, or in the scientific literature) present in that country, *zone* or *compartment*.

b) Historically free

Unless otherwise specified in the relevant *disease* chapter, a country, *zone* or *compartment* may be recognised free from *infection* without formally applying a pathogen-specific surveillance programme when:

i) there has never been a substantiated occurrence of *disease* reported officially or in the scientific literature (peer reviewed), or

ii) eradication has been achieved or the *disease/infection* has ceased to occur for at least 25 years,

provided that for at least the past 10 years:

iii) the *basic biosecurity conditions* are in place and effectively enforced;

iv) no vaccination against the *disease* has been carried out unless otherwise allowed for in the *Aquatic Code*;

v) *infection* is not known to be established in wild aquatic animals within the country or *zone* intended to be declared free. (A country or *zone* cannot apply for historical freedom if there is any evidence of *infection* in wild aquatic animals. However, specific surveillance in wild aquatic animals is not necessary.)

A country, *zone* or *compartment* that was self-declared free on the basis of the absence of susceptible species, but subsequently introduces any of the susceptible species as listed in the *Aquatic Manual*, may be considered historically free from the *disease* provided that:

- the country, *zone* or *compartment* of origin was declared free of the *disease* at the time of introduction,
- *basic biosecurity conditions* were introduced prior to the introduction,
- no vaccination against the *disease* has been carried out unless otherwise allowed for in the *disease* specific chapter of this *Aquatic Code.*

c) Last occurrence within the previous 25 years

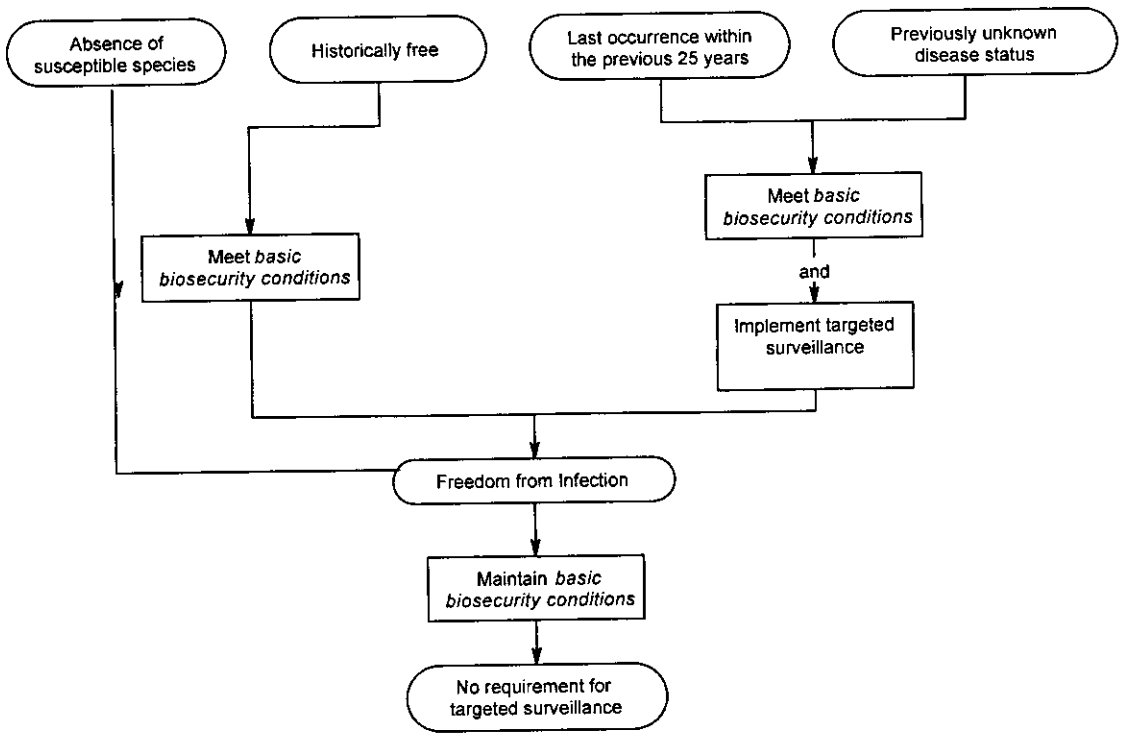
Countries, *zones* or *compartments* that have achieved eradication (or in which the *disease/infection* has ceased to occur) within the previous 25 years, should follow the pathogen-specific surveillance requirements in the *Aquatic Manual* if they exist. In the absence of *disease* specific information to aid the development of a surveillance system, declaration of *disease* freedom should follow at least 2 surveys per year (for at least 2 consecutive years) to be conducted 3 or more months apart, at the appropriate life stage and at times of the year when temperature and season offer the best opportunity to detect the pathogen. Surveys should be designed to provide an overall 95% confidence and with a design prevalence at the animal and higher (i.e. pond, farm, village, etc.) levels being 2% or lower (this value may be different for different *diseases* and may be provided in the specific *disease* chapter in the *Aquatic Manual*). Such surveys should not be based on voluntary submission and should be developed following the guidelines provided in the *Aquatic Manual.* Survey results will provide sufficient evidence of *disease* freedom provided that for at least the past 10 years these additional criteria are met:

i) the *basic biosecurity conditions* are in place and effectively enforced;

ii) no vaccination against the *disease* has been carried out unless otherwise provided in the *Aquatic Code*;

iii) *infection* is not known to be established in wild aquatic animals within the country or *zone* intended to be declared free. (A country or *zone* cannot apply for freedom if there is any evidence of *infection* in wild aquatic animals. Specific surveillance in wild aquatic animals of susceptible species is necessary to confirm absence.)

The different paths to recognition of freedom from *infection* are summarised in the diagram below.



2. Guidelines for the discontinuation of pathogen-specific surveillance after recognition of freedom from infection

A country or *zone* that has been recognised as free from *infection* following the provisions of the *Aquatic Code* may discontinue pathogen-specific surveillance while maintaining the *infection*-free status provided that:

a) the *basic biosecurity conditions* are in place and effectively enforced;
b) vaccination against the *disease* is not applied;
c) Surveillance has demonstrated that *infection* is not present in wild aquatic animal populations of susceptible species.

A special case can be made for a *compartment* located in a country or *zone* that is not proven to be free from *infection* if surveillance is maintained and exposure to potential sources of *infection* is prevented.

3. International recognition of disease/infection free status

For *diseases* for which procedures exist whereby the OIE can officially recognise the existence of a *disease/infection* free country, *zone* or *compartment*, a Member Country wishing to apply for recognition of this status shall, via its Permanent Delegate, send to the OIE all the relevant documentation relating to the country, *zone* or *compartment* concerned. Such documentation should be presented according to guidelines prescribed by the OIE for the appropriate animal *diseases*.

Article 3.8.1.7.

Surveillance for distribution and occurrence of infection

Surveillance to determine distribution and occurrence of *infection* or of other relevant health related events is widely used to assess the prevalence and incidence of selected *disease/infection* as an aid to decision making, for example implementation of control and eradication programmes. It also has relevance for the international movement of animals and products when movement occurs among infected countries.

In contrast to surveillance to demonstrate freedom from *infection*, surveillance for the distribution and occurrence of *infection* is usually designed to collect data about a number of variables of animal health relevance, for example:

a) prevalence or incidence of *infection* in wild or cultured animals;
b) morbidity and mortality rates;
c) frequency of *disease/infection* risk factors and their quantification;
d) frequency distribution of variables in *epidemiological units*;
e) frequency distribution of the number of days elapsing between suspicion of *infection* and laboratory confirmation of the diagnosis and/or to the adoption of control measures;
f) farm production records, etc.

Appendix XXX

CHAPTER 1.1.4.

GUIDELINES FOR AQUATIC ANIMAL HEALTH SURVEILLANCE [~~REQUIREMENTS FOR SURVEILLANCE FOR INTERNATIONAL RECOGNITION OF FREEDOM FROM INFECTION~~]

[~~PART 1~~

Community Comment

The Community appreciates that these guidelines have been drafted, which can give valuable guidance for health surveillance. However, the texts in appendix XXX is not so easy to read and application of the guidelines would benefit from simplification and clarification of the wording.

The Community has also a concern about the feasibility of the practical implementation of the guidelines.
In the particular case of achieving the freedom status, the proposed sample size is not feasible. Therefore, special attention should be given not only to the sampling size but also to factors as the specific epidemiological characteristics of the disease, the susceptibility of each specific life-stage to the disease or previous animal health inspections. In the Community experience, carefully planned sampling and clinical surveillance has been proven to be much more effective than the increase in the sampling size.

~~INTERNATIONAL RECOGNITION OF FREEDOM FROM INFECTION~~

~~1. General principles~~

~~General principles are provided below for declaring a country, zone or aquaculture establishment free from infection in relation to the time of last occurrence, and in particular for the recognition of historical freedom.~~

~~An essential prerequisite to provide the guarantees required for the recognition of freedom from infection is that the particular Member Country complies with the requirements of Chapter 1.4.3 of the *Aquatic Code* for the evaluation of the Competent Authorities.~~

~~The general principles are:~~

- ~~in the absence of infection or vaccination, the animal *population* would be susceptible to clinical disease, or infection, over a period of time;~~
- ~~the disease agents to which these provisions apply are likely to produce identifiable clinical or pathological signs in susceptible animals;~~
- ~~an animal *population* may be free from some specified pathogens but not from others~~
- ~~there are competent and effective personnel of the Competent Authority able to investigate, diagnose and report disease or infection, if present;~~
- ~~the absence of infection over a long period of time in susceptible *populations* can be substantiated by effective disease investigation and reporting by the Competent Authority of the Member Country.~~

~~2. Requirements to declare a country, zone or aquaculture establishment free from infection with a specified~~

pathogen

The requirements to declare a country, zone or aquaculture establishment free from infection differ depending on the previous infection status of the country, zone or aquaculture establishment, namely:

- Absence of susceptible species;
- Historically free;
- Last known occurrence within the previous 25 years;
- Previously unknown infection status.

2.1. Absence of susceptible species

Unless otherwise specified in the relevant disease chapter, a country, zone or aquaculture establishment may be recognised as being free from infection without applying *targeted surveillance* if there are no susceptible species (as listed in the relevant chapter of the *Aquatic Code*, or in the scientific literature) present in that country, zone or aquaculture establishment, provided that the *prescribed biosecurity conditions* have been in place continuously in the country, zone or aquaculture establishment for at least the previous 10 years.

2.2. Historically free

Unless otherwise specified in the relevant disease chapter, a country, zone or aquaculture establishment may be recognised as being free from infection without formally applying *targeted surveillance* when:

- there has never been any observed occurrence of disease;
- eradication has been achieved or the disease has ceased to occur for at least 25 years,

provided that the *prescribed biosecurity conditions* have been in place continuously in the country, zone or aquaculture establishment for at least the previous 10 years.

2.3. Last known occurrence within the previous 25 years

For countries or zones that have achieved eradication (or in which the disease has ceased to occur) within the previous 25 years, in addition to the *prescribed biosecurity conditions*, appropriate *targeted surveillance* must have been applied to demonstrate the absence of the infection, consistent with the provisions of Section B of this chapter.

2.4. Previously unknown infection status

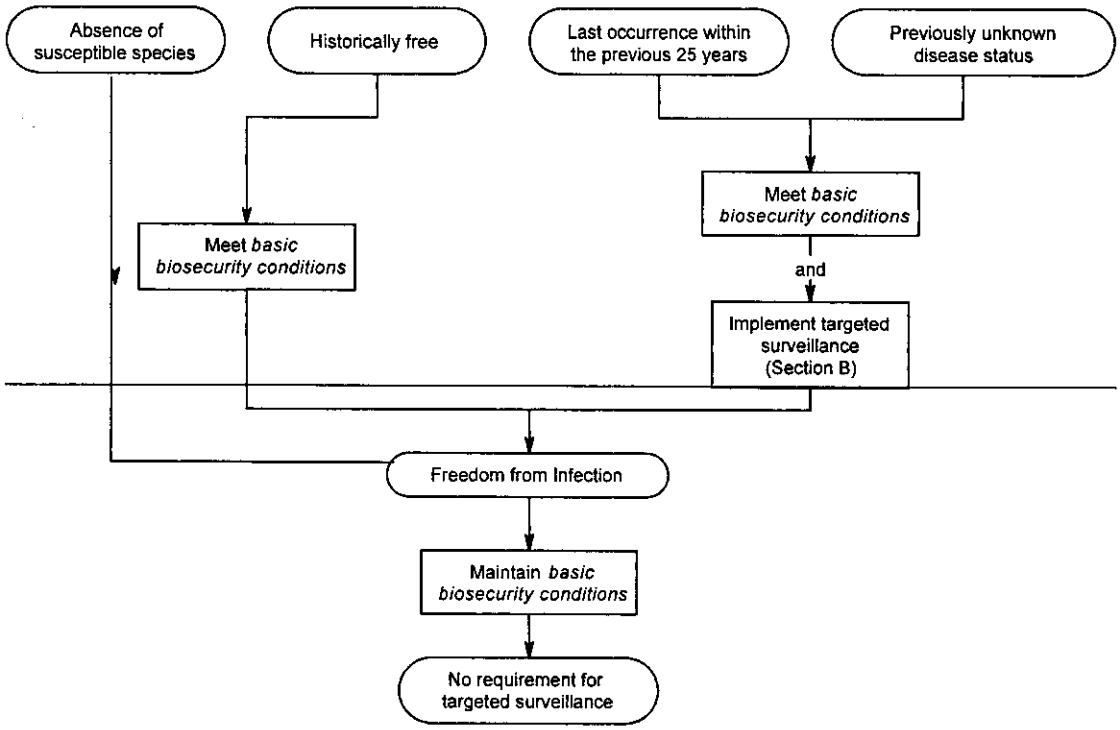
For countries or zones with previously unknown infection status, or which have not previously met the requirements of the Sections A.2.1, A.2.2 or A.2.3 above, the *prescribed biosecurity conditions* must be introduced in addition to *targeted surveillance* consistent with the provisions of Section B of this chapter.

3. Guidelines for the maintenance of continued recognition of freedom from infection

A country, zone or aquaculture establishment that has been recognised free from infection following the provisions of Sections A.2.1 or A.2.2, may maintain its official status as infection free provided that the *prescribed biosecurity conditions* are continuously maintained.

A country, zone or aquaculture establishment that has been recognised free from infection following the provisions of Sections A.2.3 or A.2.4, may discontinue *targeted surveillance* and maintain its official status as infection free provided that the *prescribed biosecurity conditions* are continuously maintained.

The different paths to recognition of freedom from infection are summarised in the diagram below.]


Absence of susceptible species
Historically free
Last occurrence within the previous 25 years
Previously unknown disease status
Meet basic biosecurity conditions
Meet basic biosecurity conditions
and
Implement targeted surveillance (Section B)
Freedom from Infection
Maintain basic biosecurity conditions
No requirement for targeted surveillance

Appendix XXX (contd)

~~B. GUIDELINES FOR AQUATIC ANIMAL HEALTH SURVEILLANCE~~

1. Introduction

1. [~~This section provides standards to be applied when demonstrating country, zone or aquaculture establishment freedom from infection, in accordance with the principles of Section A. Standards described in this section~~] Surveillance is aimed at:

   - demonstrating the absence of *disease* or *infection*,
   - identifying events requiring notification as listed in Article 1.2.1.3 of the *Aquatic Code*,
   - determining the occurrence or distribution of endemic *disease* or *infection*, including changes to their incidence or prevalence (or its contributing factors), in order to:
     - provide information for domestic disease control programmes,
     - provide relevant disease occurrence information to be used by trading partners for qualitative and quantitative risk assessment.

   The type of surveillance applied depends on the desired outputs needed to support decision-making. Surveillance data determine the quality of disease status reports and should satisfy information requirements for accurate risk analysis both for *international trade* as well as for national decision-making.
   The following guidelines may be applied to all *diseases*, their agents and susceptible species as listed in the *Aquatic Manual*, and are designed to assist with the development of surveillance methodologies. Where possible, the development of surveillance systems using these guidelines should be based on the relevant information in the individual disease chapters.
   There is sometimes a perception that surveillance can only be conducted using sophisticated methodologies. However, an effective surveillance system can also be developed by making use of gross observations and already available resources.
   Surveillance of endemic diseases provides valuable information for day-to-day health management and can act as the foundation for detecting outbreaks of exotic disease and demonstrating specific disease freedom.
   Surveillance may address both infectious and non-infectious diseases of concern to the country.
   Section B provides standards to be applied when: (a) demonstrating country, zone or compartment freedom from infection, in accordance with the principles of Section A and (b) assessing the occurrence and distribution of a specific *infection/ disease* or syndrome
   Standards described in this section may be applied to all *diseases*, their agents and susceptible species as listed in the *Aquatic Code*, and are designed to assist with the development of surveillance methodologies. Nevertheless surveillance may include also non listed diseases
   It would be impractical to try to develop a surveillance system for all the known aquatic animal diseases for which a country has susceptible species. Therefore prioritising the diseases to be included in a surveillance system should be conducted considering:

Appendix XXX (contd)

- the needs to provide assurance of disease status for trade purposes
- the resources of the country
- the financial impact or threat posed by the different diseases
- the importance of an industry-wide disease control programme within a country or region

The concept of risk encompasses both the probability of the disease occurring and the severity of its consequences

More detailed information in each disease chapter (where it exists) of this *Aquatic Manual* may be used to further refine the general approaches described in this chapter. Where detailed *disease/infection*-specific information is not available, surveillance can also be conducted following the guidelines in this chapter. Access to epidemiological expertise would be invaluable for the design, implementation of the system and interpretation of results derived from a surveillance system.

2. General principles

[~~Demonstrating freedom from infection involves providing sufficient evidence to demonstrate that infection with a specified agent is not present in a specified *population*. In practice, it is not possible to definitively prove that a *population* is free from infection (unless every member of the *population* is examined simultaneously with a perfect *test* with both *sensitivity* and *specificity* equal to 100%). Instead, the aim is to provide adequate evidence (to an acceptable level of *confidence*), that infection, if present, is present in less than a specified proportion of the *population*.~~

~~Methodologies to demonstrate freedom from infection should be~~] Surveillance methodologies should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Methodologies must be able to accommodate the variety of aquatic animal species, the multiple diseases of relevance, varying production [~~and surveillance~~] systems, and types and amounts of data and information available.

The methodology used should be based on the best available information that is in accord with current scientific thinking. The methodology should be well documented and supported with references to the scientific literature and other sources, including expert opinion. Efforts should be made to address the information gaps wherever possible.

[~~Consistency in methodologies should be encouraged and transparency is~~] Methodologies that are consistent and transparent are essential to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties. [~~Applications for~~] The presentation of the results generated through surveillance (e.g. recognition of infection-free status or measures of disease frequency) should document the uncertainties, the assumptions made, and the potential effect of these on the final estimate.

3. Surveillance ~~General requirements~~ for demonstration of freedom from disease [~~infection~~]

This section describes surveillance to demonstrate freedom from disease.

3.1. Objectives [~~Population~~]

[~~The *target population* to which the demonstration of freedom from infection applies is all individuals of all species susceptible to the infection in a country, zone or aquaculture establishment.~~

~~The *study population* may be the same as the *target population* or a subset of it. The *study population* should be (in order of preference):~~

- ~~The appropriate *study population* as defined in the relevant disease chapter of the *Aquatic Code* (if such a definition exists),~~
- ~~A subset of the *target population* that defines a group of animals which, if infection were present, would be most likely to have a higher prevalence of infection than the *target population*. This subset should be defined in terms of:~~
  - ~~species;~~
  - ~~time (e.g. season or month of year);~~
  - ~~stage of life-cycle or growth period;~~
  - ~~production system and/or management characteristics;~~
  - ~~location;~~
  - ~~readily identifiable physical or behavioural characteristics.~~
- ~~The same as the *target population*,~~
- ~~A subset of the *target population* with the same or lower probability of infection. The nature and impact of any biases on the results of the analysis must be considered, documented and taken into account in the analysis.~~]

The objective of this kind of surveillance system is to contribute on an on-going basis evidence to demonstrate freedom from disease in a particular country, *zone* or *compartment* with a known confidence and reference to a predetermined design prevalence and diagnostic test characteristics. The level of confidence and the design prevalence will depend on the testing situation, disease and host population characteristics and on the resources available.

A single such survey can contribute evidence adding to an on-going collection of health data (see also Section 5. Specific requirements for complex non-survey data sources). However, single surveys in isolation rarely, if ever, provide sufficient evidence that an aquatic animal disease is absent and must be augmented with on-going targeted evidence collection (e.g. ongoing disease sampling or passive detection capabilities) to substantiate claims of freedom from disease.

3.2. Population

The *population* of *epidemiological units* must be clearly defined. The *target population* consists of all individuals of all species susceptible to the disease or infection in a country, zone or compartment to which the surveillance results apply. Sometimes components of the target population are at higher risk of being the point of introduction for an exotic disease. In these cases, it is advisable to focus surveillance efforts on this part of the population, such as farms on a geographical border.

The design of the survey will depend on the size and structure of the *population* being studied. If the *population* is relatively small and can be considered to be homogenous with regards to risk of infection, a single-stage survey can be used.

In larger *populations* where a sampling frame is not available, or when there is a likelihood of clustering of disease, multi-stage sampling is required. In two-stage sampling, at the first stage of sampling, groups of animals (e.g. ponds, farms or villages) are selected. At the second stage, animals are selected for testing from each of the selected groups.

In the case of a complex (e.g. multi-level) population structure, multi-level sampling (ref) may be used and the data analysed accordingly ~~in survey design~~.

Appendix XXX (contd)

3.3. Sources of evidence

Surveillance data may originate [~~Evidence of freedom from infection may be based on a~~] from a number of different sources, including:

- structured, population-based surveys using one or more *tests* to detect [~~for the presence of~~] the agent;
- other [~~surveillance, including~~] structured non-random [~~surveillance~~]sources, such as:
  - sentinel sites;
  - disease notifications and laboratory investigation records;
  - academic and other scientific studies;
- a knowledge of the biology of the agent, including environmental, host *population* distribution, known geographical distribution, vector distribution and climatic information;
- history of imports of potentially infected material;
- biosecurity measures in place;
- [~~evaluation of the official services; or~~]
- any other sources of information that provide contributory evidence regarding disease or [~~that~~] infection [~~is not present~~] in the country, zone or compartment [~~aquaculture establishment~~].

The sources of evidence [~~used to demonstrate freedom from infection~~] must be fully described. In the case of a structured survey, this must include a description of the sampling strategy used for the selection of *units* for testing. For complex *surveillance systems*, a full description of the system is required including consideration of any biases that may be inherent in the system. Evidence to support claims of freedom of disease can use structured non-random sources of information provided any potential error is to detect rather than miss positive cases (i.e. it should be biased towards detection).

3.4. Statistical methodology

Analysis of *test* results from a survey shall be in accordance with the provisions of this chapter and consider the following factors:

- The survey design;
- The sensitivity and specificity of the *test*, or *test system;*
- The design prevalence (or prevalences where a multi-stage design is used);
- The results of the survey.

Analysis of data for evidence of freedom from infection involves estimating the probability (α) that the evidence observed (the results of surveillance) could have been produced under the null hypothesis that infection is present in the *population* at a specified prevalence(s) (the design prevalence[s]). The *confidence* in (or, equivalently, the sensitivity of) the *surveillance system* that produced the evidence is equal to $1-\alpha$. If the *confidence* level exceeds a pre-set threshold, the evidence is deemed adequate to demonstrate freedom from infection.

The required level of *confidence* in the *surveillance system* (probability that the system would detect infection if infection were present at the specified level) must be greater than or equal to 95%.

The power (probability that the system would report that no infection is present if infection is truly not present) may be set to any value. By convention, this is often set to 80%, but may be adjusted according to the country's or zone's requirements.

Different statistical methodologies for the calculation of the probability α, including both quantitative and qualitative approaches, are acceptable as long as they are based on accepted scientific principles.

The methodology used to calculate the *confidence* in the *surveillance system* must be scientifically based and clearly documented, including references to published work describing the methodology.

~~[3.4. Clustering of infection~~

~~Infection in a country, zone or aquaculture establishment usually clusters rather than being uniformly distributed through a *population*. Clustering may occur at a number of different levels (e.g. a cluster of moribund fish in a pond, a cluster of ponds in a farm, or a cluster of farms in a zone). Except when dealing with demonstrably homogenous *populations*, approaches to demonstrating freedom must take this clustering into account in the design and the statistical analysis of the data, at least at what is judged to be the most significant level of clustering for the particular animal *population* and infection.~~

~~3.5. Design prevalence]~~

Statistical analysis of surveillance data often requires assumptions about population parameters or test characteristics. These are usually based on expert opinion, previous studies on the same or different populations, expected biology of the agent, and so on. The uncertainty around these assumptions must be quantified and considered in the analysis (e.g. in the form of prior probability distributions in a Bayesian setting).

For surveillance systems used to demonstrate freedom from specific diseases, calculation of the *confidence* of a *surveillance system* is based on the null hypothesis that infection is present in the *population*. The level of infection is specified by the design prevalence. In the simplest case, this is the prevalence of infection in a homogenous *population*. More commonly, in the presence of a complex (e.g. multi-level) population structure ~~disease clustering, two~~ more than one design prevalence value is required, for instance, the animal-level prevalence (proportion of ~~[fish]~~ infected animals in an infected farm) and the group-level prevalence (proportion of infected farms in the country, zone or compartment ~~[aquaculture establishment]~~). Further levels of clustering may be considered, requiring further design prevalence values.

The values for design prevalence used in calculations must be those specified in the relevant disease chapter (if present) of this *Aquatic Manual*. If not specified for the particular disease, justification for the selection of design prevalence values must be provided, and should be based on the following guidelines:

- At the individual animal level, the design prevalence is based on the biology of the infection in the *population*. It is equal to the minimum expected prevalence of infection in the *study population*, if the infection had become established in that *population*. It is dependent on the dynamics of infection in the *population* and the definition of the *study population* (which may be defined to maximise the expected prevalence in the presence of infection).

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- A suitable design prevalence value at the animal level (e.g. prevalence of infected animals in a cage) may be:
  - between 1% and 5% for infections that are present in a small part of the population e.g. are transmitted slowly or are at the early stages of an outbreak, etc.; [and]
  - over 5% for highly transmissible infections [more contagious infections].

  If reliable information on the expected prevalence in an infected population is not available, a value of 2% should be used for the design prevalence.

- At higher levels (e.g. cage, pond, farm, village, etc.) the design prevalence usually reflects the prevalence of infection that is practically and reasonably able to be detected by a *surveillance system*. Detection of infection at the lowest limit (a single infected *unit* in the *population*) is rarely feasible in large *populations*. The expected behaviour of the infection may also play a role. Infections that have the ability to spread rapidly between farms may have a higher farm-level design prevalence than slow-moving infections.

  A suitable design prevalence value for the first level of clustering, (e.g. proportion of infected farms in a zone) may be up to 2%.

When surveillance data are used to estimate incidence and prevalence measures for the purpose of describing disease occurrence in terms of animal unit, time and place. These measures can be calculated for an entire population and specific time period, or for subsets defined by host characteristics (e.g. age-specific incidence). Incidence estimation requires on-going surveillance to detect new cases while prevalence is the estimated proportion of infected individuals in a population at a given time point. The estimation process must consider test sensitivity and specificity.

3.5. Clustering of infection

Infection in a country, zone or compartment [aquaculture establishment] usually clusters rather than being uniformly distributed through a *population*. Clustering may occur at a number of different levels (e.g. a cluster of moribund fish in a pond, a cluster of ponds in a farm, or a cluster of farms in a zone). Except when dealing with demonstrably homogenous *populations*, surveillance must take this clustering into account in the design and the statistical analysis of the data, at least at what is judged to be the most significant level of clustering for the particular animal *population* and infection.

[3.5. Expected prevalence]

3.6. Test characteristics

All surveillance involves performing one or more *tests* for evidence of the presence of current or past infection, ranging from detailed laboratory examinations to farmer observations. The performance level of a *test* at the *population* level is described in terms of its *sensitivity* and *specificity*. Imperfect sensitivity and/or specificity impact on the interpretation of surveillance results and must be taken into account in the analysis of surveillance data. For example, in the case of a test with imperfect specificity, if the population is free of disease or has a very low prevalence of infection, all or a large proportion of positive tests will be false. Subsequently, samples that test positive can be confirmed or refuted using a highly specific test. Where more than one test is used in a *surveillance system* (sometimes called using tests in series or parallel), the *sensitivity* and *specificity* of the test combination must be calculated [using a scientifically valid method].

All calculations must take the performance level (sensitivity and specificity) of any *tests* used into account. The values of sensitivity and specificity used for calculations must be specified, and the method used to determine or estimate these values must be documented. [~~Where~~] Test sensitivity and specificity can be different when applied to different populations and testing scenarios. For example, test sensitivity may be lower when testing carrier animals with low level infections compared to moribund animals with clinical disease. Alternatively, specificity depends on the presence of cross-reacting agents, the distribution of which may be different under different conditions or regions. Ideally, test performance should be assessed under the conditions of use otherwise increased uncertainty exists regarding their performance. In the absence of local assessment of tests, values for sensitivity and/or specificity for a particular *test* that are specified in this *Aquatic Manual* may be used but the increased uncertainty associated with these estimates should be incorporated into the analysis of results [~~these values may be used without justification~~].

Pooled testing involves the pooling of specimens from multiple individuals and performing a single *test* on the pool. Pooled testing is an acceptable approach in many situations. Where pooled testing is used, the results of testing must be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pooled testing procedure and for the applicable pool sizes being used. Analysis of the results of pooled testing must, where possible, be performed using accepted, statistically based methodologies, which must be fully documented, including published references.

3.7. Multiple sources of information [~~evidence~~]

Where multiple different data sources providing evidence of freedom from infection exist [~~or are generated~~], each of these data sources may be analysed accordingly [~~to the provisions of Sections B.3, B.4 (for structured surveys) and B.5 (for complex data sources)~~]. The resulting estimates of the *confidence* in each data source may be combined to provide an overall level of *confidence* for the combined data sources.

The methodology used to combine the estimates from multiple data sources:

- must be scientifically valid, and fully documented, including references to published material; and
- should, where possible, take into account any lack of statistical independence between different data sources.

Surveillance information gathered from the same country, *zone* or *compartment* at different times (e.g. repeated annual surveys) may provide cumulative evidence of animal health status. Such evidence gathered over time may be combined to provide an overall level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources, may be able to achieve the same level of confidence in a shorter period of time.

[~~Surveillance information gathered from the same country, zone or aquaculture establishment at different times may provide cumulative evidence of freedom from infection. Such evidence gathered over time may be combined into an overall level of *confidence*. For instance, repeated annual surveys may be analysed to provide a cumulative level of *confidence*. However, a single (larger) survey may be able to achieve the same level of *confidence* in just 1 year.~~]

Analysis of surveillance information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take into account the decreased value of older information. The sensitivity, specificity and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

[~~3.8. Survey design~~

~~The most important *unit* of diagnosis is the *epidemiological unit*.~~]

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3.8. Sampling

The objective of sampling from a *population* is to select a subset of *units* from the *population* that is representative of the *population* with respect to the characteristic of interest (in this case, the presence or absence of infection). The survey design may involve sampling at several levels. For sampling at the level of the *epidemiological units* or higher *units*, a formal *probability sampling* (e.g. simple random sampling) method must be used. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the *population*, within the practical constraints imposed by different environments and production systems.

~~**[3.9. Sampling methods]**~~

When sampling below the level of the *epidemiological unit* (e.g. individual animal), the sampling method used should provide the best practical chance of generating a sample that is representative of the *population* of the chosen *epidemiological unit*. Collecting a truly representative sample of individual animals (whether from a pond, cage or fishery) is often very difficult. To maximise the chance of finding infection, the aim should be to bias the sampling towards infected animals, e.g. selecting moribund animals, life stages with a greater chance of active infection, etc.

Biased or targeted sampling in this context involves sampling from a defined *study population* that has a different probability of infection than the *target population* of which it is a subpopulation. Once the *study population* has been identified, the objective is still to select a representative sample from this subpopulation.

The sampling method used at all levels must be fully documented and justified.

3.9. Sample size

The number of *units* to be sampled from a *population* should be calculated using a statistically valid technique that takes at least the following factors into account:

- The sensitivity and specificity of the *diagnostic test*, or *test system;*
- The design prevalence (or prevalences where a multi-stage design is used);
- The level of *confidence* that is desired of the survey results.

Additionally, other factors may be considered in sample size calculations, including (but not limited to):

- The size of the *population* (but it is acceptable to assume that the *population* is infinitely large);
- The desired power of the survey;
- Uncertainty about ~~[or variability in estimates of]~~ sensitivity and specificity.

The specific sampling requirements will need to be tailor-made for each individual disease, taking into account its characteristics and the specificity and sensitivity of the accepted testing methods for detecting the disease agent in host populations.

Appendix XXX (contd)

FreeCalc[7] is a suitable software for the calculation of sample sizes at varying parameter values. The table below provides examples of sample sizes generated by the software for a type I and type II error of 5% (i.e. 95% confidence and 95% statistical power). However, this does not mean that a type 1 and type 2 error of 0.05 should always be used. For example, using a test with sensitivity and specificity of 99%, 528 units should be sampled. If 9 or less of those units test positive, the population can still be considered free of the disease at a design prevalence of 2% provided that all effort is made to ensure that all presumed false positives are indeed false. This means that there is a 95% confidence that the prevalence is 2% or lower.

In the case in which the values of Se and Sp are not known (e.g. no information is available in the specific disease chapter in the *Aquatic Manual*), they should not automatically be assumed to be 100%. All positive results should be included and discussed in any report regarding that particular survey and all efforts should be made to ensure that all presumed false positives are indeed false.

[7] FreeCalc – Cameron, AR. Software for the calculation of sample size and analysis of surveys to demonstrate freedom from disease. Available for free download from http://www.ausvet.com.au.

Appendix XXX (contd)

Design prevalence	Sensitivity (%)	Specificity (%)	Sample size	Maximum number of false +ve if the population is free
2	100	100	149	0
2	100	99	524	9
2	100	95	1671	98
2	99	100	150	0
2	99	99	528	9
2	99	95	1707	100
2	95	100	157	0
2	95	99	542	9
2	95	95	1854	108
2	90	100	165	0
2	90	99	607	10
2	90	95	2059	119
2	80	100	186	0
2	80	99	750	12
2	80	95	2599	148
5	100	100	59	0
5	100	99	128	3
5	100	95	330	23
5	99	100	59	0
5	99	99	129	3
5	99	95	331	23
5	95	100	62	0
5	95	99	134	3
5	95	95	351	24
5	90	100	66	0
5	90	99	166	4
5	90	95	398	27
5	80	100	74	0
5	80	99	183	4
5	80	95	486	32
10	100	100	29	0
10	100	99	56	2
10	100	95	105	9
10	99	100	29	0
10	99	99	57	2
10	99	95	106	9
10	95	100	30	0
10	95	99	59	2
10	95	95	109	9
10	90	100	32	0
10	90	99	62	2
10	90	95	123	10
10	80	100	36	0

10	80	99	69	2
10	80	95	152	12

[~~Detailed guidelines are to be provided in the next (fifth) edition of the *Aquatic Manual*. In the meantime, the sampling procedures given in Chapters I.1, I.2 and I.3 may be applied~~.]

3.10. Quality assurance

Surveys should include a documented quality assurance system, to ensure that field and other procedures conform to the specified survey design. Acceptable systems may be quite simple, as long as they provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the survey design.

4. Specific requirements for complex non-survey data sources for freedom from disease

Data sources that provide evidence of freedom from infection, but are not based on structured population-based surveys may also be used to demonstrate freedom, either alone or in combination with other data sources. Different methodologies may be used for the analysis of such data sources, but the methodology must comply with the provisions of Section B.3. The approach used should, where possible, also take into account any lack of statistical independence between observations. Analytical methodologies based on the use of step-wise probability estimates to describe the *surveillance system* may determine the probability of each step either by:

- the analysis of available data, using a scientifically valid methodology; or where no data are available,
- the use of estimates based on expert opinion, gathered and combined using a formal, documented and scientifically valid methodology.

Where there is significant uncertainty and/or variability in estimates used in the analysis, stochastic modelling or other equivalent techniques should be used to assess the impact of this uncertainty and/or variability on the final estimate of confidence.

5. Specific requirements for structured survey design and analysis to assess disease occurrence

This section describes surveillance to estimate parameters of disease occurrence.

5.1. Objectives

The objective of this kind of surveillance system is to contribute on an on-going basis evidence to assess the occurrence and distribution of disease or infection in a particular country, *zone* or *compartment*. This will provide information for domestic disease control programmes and relevant disease occurrence information to be used by trading partners for qualitative and quantitative risk assessment.

A single such survey can contribute evidence adding to an on-going collection of health data (see also Section 5. Specific requirements for complex non-survey data sources).

5.2. Population

The *population* of *epidemiological units* must be clearly defined. The *target population* consists of all individuals of all species susceptible to the disease or infection in a country, zone or compartment to which the surveillance results apply. Some local areas within a region may be known to be free of the disease of concern, allowing resources to be concentrated on known positive areas for greater precision of prevalence estimates and only verification of expected 0 prevalence areas.

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The design of the survey will depend on the size and structure of the *population* being studied. If the *population* is relatively small and can be considered to be homogenous with regards to risk of infection, a single-stage survey can be used.

In larger *populations* where a sampling frame is not available, or when there is a likelihood of clustering of disease, multi-stage sampling is required. In two-stage sampling, at the first stage of sampling, groups of animals (e.g. ponds, farms or villages) are selected. At the second stage, animals are selected for testing from each of the selected groups.

In the case of a complex (e.g. multi-level) population structure, multi-level sampling (ref) may be used and the data analysed accordingly.

5.3. Sources of evidence

Surveillance data may originate from a number of different sources, including:

- structured, population-based surveys using one or more *tests* to detect the agent;
- other structured non-random sources, such as:
  - sentinel sites;
  - disease notifications and laboratory investigation records;
  - academic and other scientific studies;
- a knowledge of the biology of the agent, including environmental, host *population* distribution, known geographical distribution, vector distribution and climatic information;
- history of imports of potentially infected material;
- biosecurity measures in place;
- any other sources of information that provide contributory evidence regarding disease or infection in the country, zone or compartment.

The sources of evidence must be fully described. In the case of a structured survey, this must include a description of the sampling strategy used for the selection of *units* for testing. For complex *surveillance systems*, a full description of the system is required including consideration of any biases that may be inherent in the system. Evidence to support changes in prevalence/incidence of endemic disease must be based on valid, reliable methods to generate precise estimates with known error.

5.4. Statistical methodology

Analysis of survey data should be in accordance with the provisions of this chapter and should consider the following factors:

- The survey design;
- The sensitivity and specificity of the *test*, or *test system;*
- The results of the survey.

For surveillance systems used to describe disease patterns, the purpose is to estimate prevalence or incidence with confidence intervals or probability intervals. The magnitude of these intervals expresses the precision of the estimates and is related to sample size. Narrow intervals are desirable but will require larger sample sizes and more dedication of resources. The precision of the estimates and the power to detect differences in prevalence between populations or between time points depends not only on sample size, but also on the actual value of the prevalence in the population or the actual difference. For this reason, when designing the surveillance system, a prior estimate/assumption of expected prevalence or expected difference in prevalence must be made.

For the purpose of describing disease occurrence, measures of animal unit, time and place can be calculated for an entire population and specific time period, or for subsets defined by host characteristics (e.g. age-specific incidence). Incidence estimation requires on-going surveillance to detect new cases in a specified time period while prevalence is the estimated proportion of infected individuals in a population at a given time point. The estimation process must consider test sensitivity and specificity.

Statistical analysis of surveillance data often requires assumptions about population parameters or test characteristics. These are usually based on expert opinion, previous studies on the same or different populations, expected biology of the agent, information contained in the specific disease chapter of the *Aquatic Manual*, and so on. The uncertainty around these assumptions must be quantified and considered in the analysis (e.g. in the form of prior probability distributions in a Bayesian setting).

When surveillance objectives are to estimate prevalence/incidence or changes in disease patterns, statistical analysis must account for sampling error. Analytic methods should be thoroughly considered and consultation with biostatistician/quantitative epidemiologist consulted beginning in the planning stages and continued throughout the programme.

5.5. Clustering of infection

Infection in a country, zone or compartment usually clusters rather than being uniformly distributed through a *population*. Clustering may occur at a number of different levels (e.g. a cluster of moribund fish in a pond, a cluster of ponds in a farm, or a cluster of farms in a zone). Except when dealing with demonstrably homogenous *populations*, surveillance must take this clustering into account in the design and the statistical analysis of the data, at least at what is judged to be the most significant level of clustering for the particular animal *population* and infection. For endemic diseases, it is important to identify characteristics of the population which contribute to clustering and thus provide efficiency in disease investigation and control.

5.6. Test characteristics

All surveillance involves performing one or more *tests* for evidence of the presence of current or past infection, ranging from detailed laboratory examinations to farmer observations. The performance level of a *test* at the *population* level is described in terms of its *sensitivity* and *specificity*. Imperfect sensitivity and/or specificity impact on the interpretation of surveillance results and must be taken into account in the analysis of surveillance data. For example, in populations with low prevalence of infection, a large proportion of positive tests may be false unless the tests used have perfect specificity. To ensure detection in such instances, a highly sensitive test is frequently used for initial screening and then confirmed with highly specific tests.

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All calculations must take the performance level (sensitivity and specificity) of any *tests* used into account. The values of sensitivity and specificity used for calculations must be specified, and the method used to determine or estimate these values must be documented. Test sensitivity and specificity can be different when applied to different populations and testing scenarios. For example, test sensitivity may be lower when testing carrier animals with low level infections compared to moribund animals with clinical disease. Alternatively, specificity depends on the presence of cross-reacting agents, the distribution of which may be different under different conditions or regions. Ideally, test performance should be assessed under the conditions of use otherwise increased uncertainty exists regarding their performance. In the absence of local assessment of tests, values for sensitivity and/or specificity for a particular *test* that are specified in this *Aquatic Manual* may be used but the increased uncertainty associated with these estimates should be incorporated into the analysis of results.

Pooled testing involves the pooling of specimens from multiple individuals and performing a single *test* on the pool. Pooled testing is an acceptable approach in many situations. Where pooled testing is used, the results of testing must be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pooled testing procedure and for the applicable pool sizes being used. Analysis of the results of pooled testing must, where possible, be performed using accepted, statistically based methodologies, which must be fully documented, including published references.

Test results from surveillance for endemic disease will provide estimates of apparent prevalence (AP). Using diagnostic sensitivity (DSe) and diagnostic specificity (DSp) as described in chapter 1.1.2 of this *Aquatic Manual*, true prevalence (TP) should be calculated with the following formula:

$$TP = (AP + DSp - 1)/(DSe + DSp - 1)$$

In addition, it should be remembered that different laboratories may obtain conflicting results for various test, host, or procedure-related reasons. Therefore, sensitivity and specificity parameters should be validated for the particular laboratory and process.

5.7. Multiple sources of information

Where multiple different data sources providing information on infection or disease are generated, each of these data sources may be analysed and presented separately.

Surveillance information gathered from the same country, *zone* or *compartment* at different times and similar methodology (e.g. repeated annual surveys) may provide cumulative evidence of animal health status and changes. Such evidence gathered over time may be combined (e.g. using Bayesian methodology) to provide more precise estimates and details of disease distribution within a population.

Apparent changes in disease occurrence of endemic diseases may be real or due to other factors influencing detection proficiency.

5.8. Sampling

The objective of sampling from a *population* is to select a subset of *units* from the *population* that is representative of the *population* with respect to the characteristic of interest (in this case, the presence or absence of infection). The survey design may involve sampling at several levels. For sampling at the level of the *epidemiological units* or higher *units*, a formal *probability sampling* (e.g. simple random sampling) method must be used. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the *population*, within the practical constraints imposed by different environments and production systems.

When sampling below the level of the *epidemiological unit* (e.g. individual animal), the method used should be probability-based sampling. Collecting a true probability-based sample is often very difficult and care should therefore be taken in the analysis and interpretation of results obtained using any other method, the danger being that inferences could not be made about the sampled *population*.

The sampling method used at all levels must be fully documented and justified.

5.9. Sample size

The number of *units* to be sampled from a *population* should be calculated using a statistically valid technique that takes at least the following factors into account:

- The sensitivity and specificity of the *diagnostic test* (single or in combination);
- Expected prevalence or incidence in the *population* (or prevalences/incidences where a multi-stage design is used);
- The level of *confidence* that is desired of the survey results.
- The *precision* desired (i.e. the width of the *confidence* or *probability intervals*).

Additionally, other factors may be considered in sample size calculations, including (but not limited to):

- The size of the *population* (but it is acceptable to assume that the *population* is infinitely large);
- Uncertainty about sensitivity and specificity.

The specific sampling requirements will need to be tailor-made for each individual disease, taking into account its characteristics and the specificity and sensitivity of the accepted testing methods for detecting the disease agent in host populations.

A number of software packages, e.g. Survey Tool Box, WinPEPI (add links and refs) can be used for the calculation of sample sizes.

In the case in which the values of Se and Sp are not known (e.g. no information is available in the specific disease chapter in the *Aquatic Manual*), they should not automatically be assumed to be 100%. Assumed values should be produced in consultation with subject-matter experts.

5.10. Quality assurance

Surveys should include a documented quality assurance system, to ensure that field and other procedures conform to the specified survey design. Acceptable systems may be quite simple, as long as they provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the survey design.

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~~PART 2~~

6. EXAMPLE SURVEILLANCE SYSTEMS FOR FREEDOM FROM DISEASE

The following examples describe surveillance systems and approaches to the analysis of evidence for demonstrating freedom from *disease* [~~that are able to meet the requirements of this chapter~~]. The purpose of these examples is:

- to illustrate the range of approaches that may be acceptable;
- to provide practical guidance and models that may be used for the design of specific surveillance systems; and
- to provide references to available resources that are useful in the development and analysis of surveillance systems.

While these examples demonstrate ways in which freedom from infection may be successfully demonstrated, they are not intended to be prescriptive. Countries are free to use different approaches, as long as they meet the requirements of this chapter.

The examples deal with the use of structured surveys and are designed to illustrate different survey designs, sampling schemes, the calculation of sample size, and analysis of results. It is important to note that alternative approaches to demonstrating freedom using complex non-survey-based data sources are also currently being developed and may soon be published[8].

Example 1 – one-stage structured survey (farm certification [~~accreditation~~])

Context

A freshwater aquaculture industry raising fish in tanks has established a farm certification [~~accreditation~~] scheme. This involves demonstrating farm-level freedom from a particular (hypothetical) disease (Disease X). The disease does not spread very quickly, and is most common during the winter months, with adult fish at the end of the production cycle being most severely affected. Farms consist of a number of grow-out tanks, ranging from 2 to 20, and each tank holds between 1000 and 5000 fish.

Objective

The objective is to implement surveillance that is capable of providing evidence that an individual farm is free from Disease X. (The issue of national or zone freedom, as opposed to farm freedom, is considered in the next example.)

[8] International EpiLab, Denmark, Research Theme 1: Freedom from disease. http://www.vetinst.dk/high_uk.asp?page_id=196

Approach

The accreditation scheme establishes a set of standard operating procedures and requirements for recognition of freedom, based on the guidelines given in this chapter. These require farms to undertake a structured survey capable of producing 95% confidence that the disease would be detected if it were present. Once farms have been surveyed without detecting disease, they are recognised as free, as long as they maintain a set of minimum biosecurity standards. These standards are designed to prevent the introduction of Disease X into the farm (through the implementation of controls specific to the method of spread of that disease) and to ensure that the disease would be detected rapidly if it were to enter the farm (based on evidence of adequate health record keeping and the prompt investigation of unusual disease events). The effective implementation of these biosecurity measures is evaluated with annual on-farm audits conducted by independent auditors.

Survey standards

Based on the guidelines given in this chapter, a set of standards are established for the conduct of surveys to demonstrate freedom from infection with causative agent of Disease X. These standards include:

- The level of confidence required of the survey is 95% (i.e. Type I error = 5%).

- The power of the survey is arbitrarily set at 95% (i.e. Type II error = 5%, which means that there is a 5% chance of concluding that a non-diseased farm is infected).

- The target population is all the fish on the farm. Due to the patterns of disease in this production system, in which only fish in the final stages of grow-out, and only in winter are affected, the study population is defined as grow-out fish during the winter months.

- The issue of clustering is considered. As fish are grouped into tanks, this is the logical level at which to consider clustering. However, when a farm is infected, the disease often occurs in multiple tanks, so there is little evidence of strong clustering. Also, the small number of tanks on a single farm means that it is difficult to define a design prevalence at the tank level (i.e. the proportion of infected tanks that the survey should be able to detect on the farm). For these reasons, it is decided to treat the entire grow-out population of each farm as a single homogenous population.

- Stratification is also considered. In order to ensure full representation, it is decided to stratify the sample size by tank, proportional to the population of each tank.

- The design prevalence at the animal level is determined based on the epidemiology of the disease. The disease does not spread quickly, however, in the defined target population, it has been reported to affect at least 10% of fish, if the population is infected. In order to take the most conservative approach, an arbitrarily low design prevalence of 2% is used. A prevalence of 10% may have been used (and would result in a much smaller sample size), but the authorities were not convinced by the thought that the population could still be infected at a level of say 5%, and disease still not be detected.

- The test used involves destructive sampling of the fish, and is based on an antigen-detection enzyme-linked immunosorbent assay (ELISA). Disease X is present in some parts of the country (hence the need for a farm-level accreditation programme). This has provided the opportunity for the sensitivity and the specificity of the ELISA to be evaluated in similar populations to those on farms. A recent study (using a combination of histology and culture as a gold standard) estimated the sensitivity of the ELISA to be 98% (95% confidence interval 96.7–99.2%), and the specificity to be 99.4% (99.2–99.6%). Due to the relatively narrow confidence intervals, it was decided to use the point estimates of the sensitivity and specificity rather than complicate calculations by taking the uncertainty in those estimates into account.

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Sample size

The sample size required to meet the objectives of the survey is calculated to take the population size, the test performance, the confidence required and the design prevalence into account. As the population of each farm is relatively large, differences in the total population of each farm have little effect on the calculated sample size. The other parameters for sample size calculation are fixed across all farms. Therefore, a standard sample size (based on the use of this particular ELISA, in this population) is calculated. The sample size calculations are performed using the *FreeCalc* software[9]. Based on the parameters listed above, the sample size required is calculated to be 410 fish per farm. In addition, the program calculates that, given the imperfect specificity, it is still possible for the test to produce up to five false-positive reactors from an uninfected population using this sample size. The authorities are not comfortable with dealing with false-positive reactors, so it is decided to change the test system to include a confirmatory test for any positive reactors. Culture is selected as the most appropriate test, as it has a specificity that is considered to be 100%. However, its sensitivity is only 90% due to the difficulty of growing the organism.

As two tests are now being used, the performance of the test system must be calculated, and the sample size recalculated based on the test system performance.

Using this combination of tests (in which a sample is considered positive only if it tests positive to both tests), the specificity of the combined two tests can be calculated by the formula:

$$Sp_{Combined} = Sp_1 + Sp_2 - (Sp_1 \times Sp_2)$$

which produces a combined specificity of $1 + 0.994 - (1 \times 0.994) = 100\%$

The sensitivity may be calculated by the formula:

$$Se_{Combined} = Se_1 \times Se$$

which produces a combined sensitivity of $0.9 \times 0.98 = 88.2\%$

These new values are used to calculate the survey sample size yielding a result of 169 fish. It is worth noting that attempts to improve the performance of a test (in this case increase specificity) generally result in a decrease in the performance of the other aspect of the test performance (sensitivity in this example). However, in this case, the loss of sensitivity is more than compensated for by the decreased sample size due to the improved specificity.

It is also worth noting that, when using a test system with 100% specificity, the effective power of the survey will always be 100%, regardless of the figure used in the design. This is because it is not possible to make a Type II error, and conclude that the farm is infected when it is not.

A check of the impact of population size on the calculated sample size is worthwhile. The calculated sample size is based on an infinitely large population. If the population size is smaller, the impact on sample size is shown in the following table:

[9] FreeCalc – Cameron, AR. Software for the calculation of sample size and analysis of surveys to demonstrate freedom from disease. Available for free download from http://www.ausvet.com.au.

Population size	Sample size
1000	157
2000	163
5000	166
10,000	169

Based on these calculations, it is clear that, for the population sizes under consideration, there is little effect on the sample size. For the sake of simplicity, a standard sample size of 169 is used, regardless of the number of grow-out fish on the farm.

Sampling

The selection of individual fish to include in the sample should be done in such a manner as to give the best chance of the sample being representative of the study population. A fuller description of how this may be achieved under different circumstances is provided in *Survey Toolbox*[10]. An example of a single farm will be used to illustrate some of the issues.

One farm has a total of eight tanks, four of which are used for grow-out. At the time of the survey (during winter), the four grow-out tanks have 1850, 4250, 4270 and 4880 fish, respectively, giving a total population of 15,250 grow-out fish.

Simple random sampling from this entire population is likely to produce sample sizes from each tank roughly in proportion to the number of fish in each tank. However, proportional stratified sampling will guarantee that each tank is represented in proportion. This simply involves dividing the sample size between tanks in proportion to their population. The first tank has 1850 fish out of a total of 15,250, representing 12.13%. Therefore 12.13% of the sample (21 fish) should be taken from the first tank. Using a similar approach the sample size for the other three tanks is 47, 47 and 54 fish, respectively.

Once the sample for each tank is determined, the problem remains as to how to select 21 fish from a tank of 1850 so that they are representative of the population. Several options exist.

- If the fish can be handled individually, random systematic sampling may be used. This is likely to be the case if, for example:
  - fish are harvested during winter and samples can be collected at harvest; or
  - routine management activities involving handling the fish (such as grading or vaccination) are conducted during the winter.

  If fish are handled, systematic sampling simply involves selecting a fish at regular intervals. For instance, to select 21 from 1850, the sampling interval should be 1850/21 = 88. This means that every 88th fish from the tank should be sampled. To ensure randomness, it is good practice to use a random number between 1 and 88 (in this case) to select the *first* fish (e.g. using a random number table), and then select every 88th fish after that.

[10] Survey Toolbox for Aquatic Animal Diseases – A Practical Manual and Software Package. Cameron A.R. (2002). Australian Centre for International Agricultural Research (ACIAR), Monograph No. 94, 375 pp. ISBN 1 86320 350 8. Printed version available from ACIAR (http://www.aciar.gov.au) Electronic version available for free download from http://www.ausvet.com.au.

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- If fish cannot be handled individually (by far the most common, and more difficult, circumstance) then the fish to be sampled must be captured from the tanks. Fish should be captured in the most efficient and practical way possible, however every effort should be made to try to ensure that the sample is representative. In this example, a dip net is the normal method used for capturing fish. Using a dip net, convenience sampling would involve capturing 21 fish by repeatedly dipping at one spot and capturing the easiest fish (perhaps the smaller ones). This approach is strongly discouraged. One method of increasing the representativeness is to sample at different locations in the tank – some at one end, some at either side, some at the other end, some in the middle, some close to the edge. Additionally, if there are differences among the fish, an attempt should be made to capture fish in such a way as to give different groups of fish a chance of being caught (i.e. do not just try to catch the small ones, but include big ones as well).

  This method of collecting a sample is far from the ideal of random sampling, but due to the practical difficulties of implementing random sampling of individual fish, this approach is acceptable, as long as the efforts made to increase the representativeness of the sample are both genuine and fully documented.

Testing

Specimens are collected, processed and tested according to standardised procedures developed under the certification ~~[accreditation]~~ programme and designed to meet the requirements of this *Aquatic Manual*. The testing protocol dictates that any specimens that test positive to ELISA be submitted for culture, and that any positive culture results indicate a true positive specimen (i.e. that the farm is not free from disease). It is important that this protocol be adhered to exactly. If a positive culture is found, then it is not acceptable to retest it, unless further testing is specified in the original testing protocol, and the impact of such testing accounted for in the test system sensitivity and specificity estimates (and therefore the sample size).

Analysis

If the calculated sample size of 169 is used, and no positive reactors are found, then the survey will have a confidence of 95%. This can be confirmed by analysing the results using the *FreeCalc* software mentioned above (which reports a confidence level of 95.06%).

It may happen in some cases that the survey is not conducted exactly as planned, and the actual sample size is less than the target sample size. However, the size of the farm may also be smaller. In these cases, it is advisable to analyse the farm data on a farm-by-farm basis. For example, if only 165 specimens were collected from a farm with only 2520 fish, the resulting confidence would still be 95%. If only 160 fish were collected, the confidence is only 94.5%. If a rigid target of 95% confidence is used, then this survey would fail to meet that target and more evidence would be required.

Example 2 – two-stage structured survey (national freedom)

Context

A country aims to declare freedom from Disease Y of crustaceans. The industry in this country is based largely on small-holder ponds, grouped closely together in and around villages. The disease is reasonably highly contagious, and causes mass mortality mid to late in the production cycle, with affected animals becoming moribund and dying in a matter of days. Affected animals show few characteristic signs, but an infected pond will almost invariably break down with mass mortality unless harvested beforehand. It is more common in late summer, but can occur at any time of year. It also occurs occasionally early in the production cycle. In this country, there are some limitations to the availability of laboratory facilities and the transport infrastructure. However, there is a relatively large government structure, and a comprehensive network of fisheries officers.

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Objective

The objective is to establish national freedom from Disease Y. The surveillance system must meet the requirements of ~~[Part 1 of]~~ this chapter, but must also be able to be practically implemented in this small-holder production system.

Approach

The aquaculture authorities decide to use a survey to gather evidence of freedom, using a two-stage survey design (sampling villages at the first level, and ponds at the second). Laboratory testing of specimens from a large number of farms is not considered feasible, so a combined test system is developed to minimise the need for expensive laboratory tests.

The unit of observation and analysis is, in this case, the pond, rather than the individual animal. This means that the diagnosis is being made at the pond level (an infected pond or a non-infected pond) rather than at the animal level.

The survey is therefore a survey to demonstrate that no villages are infected (using a random sample of villages and making a village-level diagnosis). The test used to make a village-level diagnosis is, in fact, another survey, this time to demonstrate that no ponds in the village are affected. A test is then performed at the pond level (farmer observation followed, if necessary, by further laboratory testing).

Survey standards

- The confidence to be achieved by the survey is 95%. The power is set at 95% (but is likely to be virtually 100% if the test system used achieves nearly 100% specificity, as demonstrated in the previous example).
- The target population is all ponds stocked with shrimp in the country during the study period. The study population is the same, except that those remote areas to which access is not possible are excluded. As outbreaks can occur at any time of year, and at any stage of the production cycle, it is decided not to further refine the definition of the population to target a particular time or age.
- Three tests are used. The first is farmer observation, to determine if mass mortality is occurring in a particular pond. If a pond is positive to the first test (i.e. mass mortality is detected), a second test is applied. The second test used is polymerase chain reaction (PCR). Cases positive to PCR are further tested using transmission experiments.
    - Farmer observation can be treated as a test just like any other. In this case, the observation of mass mortality is being used as a test for the presence of Disease Y. As there are a variety of other diseases that are capable of causing mass mortality, the test is not very specific. On the other hand, it is quite unusual for Disease Y to be present, and not result in mass mortality, so the test is quite sensitive. A standard case definition is established for 'mass mortality' (for instance, greater than 20% of the pond's population of shrimp observed dead in the space of less than 1 week). Based on this definition, farmers are able to 'diagnose' each pond as having mass mortality. Some farmers may be over-sensitive and decide that mass mortality is occurring when only a small proportion of shrimp are found dead (false positives, leading to a decrease in specificity) while a small number of others fail to recognise the mortalities, decreasing sensitivity.

      In order to quantify the sensitivity and specificity of farmer observation of mass mortalities, as a test for Disease Y, a separate study is carried out. This involves both a retrospective study of the number of mass mortality events in a population that is thought to be free from disease, as well as a study of farmers presented with a series of mortality scenarios, to assess their ability to accurately identify a pond with mass mortality. By combining these results, it is estimated that the sensitivity of farmer-reported mass mortalities as a test for Disease Y is 87% while the specificity is 68%.

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- When a farmer detects a pond with mass mortality, specimens are collected from moribund shrimp following a prescribed protocol. Tissue samples from 20 shrimp are collected, and pooled for PCR testing. In the laboratory, the ability of pooled PCR to identify a single infected animal in a pool of 20 has been studied, and the sensitivity of the procedure is 98.6%. A similar study of negative specimens has shown that positive results have occasionally occurred, probably due to laboratory contamination, but maybe also because of the presence of non-viable genetic material from another source (shrimp-based feed stuffs are suspected). The specificity is therefore estimated at 99%.
- Published studies in other countries have shown that the sensitivity of transmission tests, the third type of test to be used, is 95%, partly due to variability in the load of the agent in inoculated material. The specificity is agreed to be 100%.
- Based on these figures, the combined test system sensitivity and specificity are calculated using the formulae presented in Example 1, first with the first two tests, and then with the combined effect of the first two tests and the third test. The result is a sensitivity of 81.5% and a specificity of 100%.

- The design prevalence must be calculated at two levels. First, the pond-level design prevalence (the proportion of ponds in a village that would be infected if disease were present) is determined. In neighbouring infected countries, experience has shown that ponds in close contact with each other are quickly infected. It is unusual to observe an infected village with fewer than 20% of ponds infected. Conservatively, a design prevalence of 5% is used. The second value for design prevalence applies at the village level, or the proportion of infected villages that could be identified by the survey. As it is conceivable that the infection may persist in a local area without rapid spread to other parts of the country, a value of 1% is used. This is considered to be the lowest design prevalence value for which a survey can be practically designed.
- The population of villages in the country is 65,302, according to official government records. Those with shrimp ponds number 12,890, based on records maintained by the aquaculture authorities. These are generated through a five-yearly agricultural census, and updated annually based on reports of fisheries officers. There are no records available of the number of ponds in each of these villages.

Sample size

Sample size is calculated for the two levels of sampling, first the number of villages to be sampled and then the number of ponds to be sampled. The number of villages to be sampled depends on the sensitivity and the specificity of the test used to classify villages as infected or not infected. As the 'test' used in each village is really just another survey, the sensitivity is equal to the confidence and the specificity is equal to the power of the village-level survey. It is possible to adjust both confidence and power by changing the sample size in the village survey (number of ponds examined), which means that we can determine, within certain limits, what sensitivity and specificity we achieve.

This allows a flexible approach to sample size calculation. If a smaller first-stage sample size is desired (a small number of villages), a high sensitivity and specificity are needed, which means that the number of ponds in each village that need to be examined is larger. A smaller number of ponds will result in lower sensitivity and specificity, requiring a larger number of villages. The approach to determining the optimal (least cost) combination of first- and second-stage sample sizes is described in *Survey Toolbox*.

A further complication is presented by the fact that each village has a different number of ponds. In order to achieve the same (or similar) confidence and power (sensitivity and specificity) for each village, a different sample size may be required. The authorities choose to produce a table of sample sizes for the number of ponds to sample in each village, based on the total ponds in each village.

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An example of one possible approach to determining the sample size follows:

The target sensitivity (confidence) achieved by each village-level survey is 95%. The target specificity is 100%. Using the *FreeCalc* software, with a design prevalence of 1% (the survey is able to detect disease if 1% or more villages are infected), the first-stage sample size is calculated as 314 villages. Within each village, the test used is the combined test system described above with a sensitivity of 81.5% and a specificity of 100%. Based on these figures the following table is developed, listing the number of ponds that need to be sampled in order to achieve 95% sensitivity.

Population	Sample size
30	29
40	39
60	47
80	52
100	55
120	57
140	59
160	61
180	62
200	63
220	64
240	64
260	65
280	65
300	66
320	66
340	67
360	67
380	67
400	67
420	68
440	68
460	68
480	68
500	68
1000	70

Appendix XXX (contd)

Sampling

First-stage sampling (selection of villages) is done using random numbers and a sampling frame based on the fisheries authorities list of villages with shrimp ponds. The villages are listed on a spreadsheet with each village numbered from 1 to 12,890. A random number table (such as that included in *Survey Toolbox*) or software designed for the generation of random numbers (such as EpiCalc[11]) is used.

The second stage of sampling involves random selection of ponds within each village. This requires a sampling frame, or list of each pond in the village. The fisheries authorities use trained local fisheries officers to coordinate the survey. For each selected village, the officer visits the village and convenes a meeting of all shrimp farmers. At the meeting, they are asked how many ponds they have and a list of farmers' names and the number of ponds is compiled. A simple random sample of the appropriate number of ponds (between 29 and 70, from the table above, depending on the number of ponds in the village) is selected from this list. This is done either using software (such as Survey Toolbox's *RandomAnimal* program), or manually with a random number table or decimal dice for random number selection. Details of this process are described in *Survey Toolbox*. This selection process identifies a particular pond in terms of the name of the owner, and the sequence number amongst the ponds owned (e.g. Mr Smith's 3rd pond). Identification of the actual pond is based on the owners own numbering system for the ponds.

Testing

Once ponds have been identified, the actual survey consists of 'testing those ponds'. In practice, this involves the farmers observing the ponds during one complete production cycle. The local fisheries officer makes weekly visits to each farmer to check if any of the selected ponds have suffered mass mortality. If any are observed (i.e. the first test is positive), 20 moribund shrimp are collected for laboratory examination (first PCR, and then, if positive, transmission experiments).

Analysis

Analysis is performed in two stages. First, the results from each village are analysed to ensure that they meet the required level of confidence. If the target sample size is achieved (and only negative results obtained), the confidence should be 95% or greater in each village. At the second stage, the results from each village are analysed to provide a country level of confidence. Again, if the target sample size (number of villages) is achieved, this should exceed 95%.

Example 3 – spatial sampling and the use of tests with imperfect specificity

Context

A country has an oyster culture industry, based primarily on rack culture of oysters in 23 estuaries distributed along the coastline. In similar regions in other countries, Disease Z causes mortalities in late summer/early autumn. During an outbreak a high proportion of oysters are affected, however, it is suspected that the agent may be present at relatively low prevalence in the absence of disease outbreaks.

Objective

The national authorities wish to demonstrate national freedom from Disease Z. If the disease should be detected, a secondary objective of the survey is to collect adequate evidence to support zoning at the estuary level.Appendix XXX (contd)

[11] http://www.myatt.demon.co.uk/epicalc.htm

Approach

The authorities conclude that clinical surveillance for disease outbreaks is inadequate because of the possibility of low level subclinical infections. It is therefore decided to base surveillance on a structured two-stage survey, in which sampled oysters are subjected to laboratory testing. The first stage of the survey is the selection of estuaries. However, due to the objective of providing evidence for zoning (should disease be found in any of the estuaries), it is decided to use a census approach and sample every estuary. In essence this means that there will be 23 separate surveys, one for each estuary. A range of options for sampling oysters are considered, including sampling at harvest or marketing, or using farms (oyster leases) as a level of sampling or stratification. However the peak time of activity of the agent does not correspond to the harvest period, and the use of farms would exclude the significant numbers of wild oysters present in the estuaries. It is therefore decided to attempt to simulate simple random sampling from the entire oyster population in the estuary, using a spatial sampling approach.

Survey standards

- The target population is all of the oysters in each of the estuaries. The study population is the oysters present during the peak disease-risk period in late summer early autumn. Wild and cultured oysters are both susceptible to disease, and may have associated with them different (but unknown) risks of infection. They are therefore both included in the study population. As will be described below, sampling is based on mapping. Therefore the study population can more accurately be described as that population falling within those mapped areas identified as oyster habitats.

- A design prevalence value is only required at the oyster level (as a census is being used at the estuary level). While the disease is often recognised with very high prevalence during outbreaks, a low value is used to account for the possibility of persistence of the agent in the absence of clinical signs. A value of 2% is selected.

- The test used is histopathology with immuno-staining techniques. This test is known to produce occasional false-positive results due to nonspecific staining, but is very sensitive. Published studies indicate values of 99.1% for sensitivity and 98.2% for specificity. No other practical tests are available. This means that it is not possible to definitively differentiate false positives from true positives, and that in a survey of any size, a few false positives are expected (i.e. 1.8%).

- The confidence is set at 95% and the power at 80%. In the previous examples, due to the assumed 100% specificity achieved by use of multiple tests, the effective power was 100%. In this case, with imperfect specificity, there will be a risk of falsely concluding that a healthy estuary is infected, so the power is not 100%. The choice of a relatively low figure (80%) means that there is a 1 in 5 chance of falsely calling an estuary infected when it is not infected, but it also dramatically decreases the survey costs, through a lower sample size.

Sample size

Based on the assumption that the sampling procedure will mimic simple random sampling, the sample size (number of oysters to sample per estuary) can be calculated with *FreeCalc*. The population size (number of oysters per estuary) is assumed to be very large. The calculated sample size, using the sensitivity, specificity and design prevalence figures given above, is 450. *FreeCalc* also reports that, based on this sample size and the specificity of the test, it is possible to get 10 or fewer false-positive test results, and still conclude that the population is free from disease. This is because, if the population were infected at 2% or greater, the anticipated number of positive reactors from a sample of 450 would be greater than 10. In fact, we would expect 9 true positives (450 × 2% × 99.1%) and 8 false positives (450 × 98% × 1.8%) or a total of 17 positives if the population were infected at a prevalence of 2%.

Appendix XXX (contd)

This illustrates how probability theory and adequate sample size can help differentiate between true- and false-positive results when there is no alternative but to use a test with imperfect specificity.

Sampling

The aim is to collect a sample of 450 oysters that represent an entire estuary. Simple random sampling depends on creating a sampling frame listing every oyster (not possible) and systematic sampling depends on being able to (at least conceptually) line up all the oysters (again, not possible). The authorities decide to use spatial sampling to approximate simple random sampling. Spatial sampling involves selecting random points (defined by coordinates), and then selecting oysters near the selected points. In order to avoid selecting many points with no oysters nearby, the estuary is first mapped (the fisheries authorities already have digital maps defining oyster leases available). To these maps areas with significant concentrations of wild oysters are also added, based on local expertise. Pairs of random numbers are generated such that the defined point falls within the defined oyster areas. Other schemes are considered (including using a rope marked at regular intervals, laid out on a lease to define a transect, and collecting an oyster adjacent to each mark on the rope) but the random coordinate approach is adopted.

Survey teams then visit each point by boat (using a GPS [Global Positioning System] unit to pinpoint the location). A range of approaches is available for selecting which oyster to select from a densely populated area, but it should involve some effort at randomness. Survey staff opt for a simple approach: when the GPS receiver indicates that the site has been reached, a pebble is tossed in the air and the oyster closest to the point where it lands is selected. Where oysters are arranged vertically (e.g. wild oysters growing up a post), a systematic approach is used to determine the depth of the oyster to select. First, an oyster at the surface, next, an oyster halfway down, and thirdly, an oyster as deep as can be reached from the boat.

This approach runs the risk of bias towards lightly populated areas, so an estimate of the relative density of oysters at each sampling point is used to weight the results (see *Survey Toolbox* for more details).

Testing

Specimens are collected, processed, and analysed following a standardised procedure. The results are classified as definitively positive (showing strong staining in a highly characteristic pattern, possibly with associated signs of tissue damage), probably positive (on the balance of probabilities, but less characteristic staining), and negative.

Analysis

The interpretation of the results when using a test with imperfect specificity is based on the assumption that, in order to conclude that the population is free from infection, any positive result identified is really a false positive. With a sample size of 450, up to 10 false positives may be expected while still concluding that the population is free from disease. However, if there is reasonable evidence that there is even a single *true* positive, then the population cannot be considered free. This is the reason for the classification of positive results into definitive and probable positives. If there are any definitive positives at all, the population in that estuary must be considered infected. The probable positives are consistent with false positives, and therefore up to 10 may be accepted. Using *FreeCalc* the actual confidence achieved based on the number of (presumed) false positives detected can be calculated. For instance, if 8 'probably positive' results were detected from an estuary, the confidence level for the survey would be 98.76%. On the other hand, if 15 'probably positive' results were detected, the confidence is only 61.9%, indicating that the estuary is likely to be infected.

Discussion

Normally, it may be safely assumed that a surveillance system aimed at demonstrating freedom from disease is 100% specific. This is because any suspected occurrence of disease is investigated until a definitive decision can be made. If the conclusion is that the case is truly a case of disease, then there is no issue of declaring freedom – the disease is known to be present. This example presents a different situation where, due to lack of suitable tests, it is not possible for the surveillance system to be 100% specific. This may represent an unusual situation in practice, but illustrates that methods exist for dealing with this sort of problem. In practice, a conclusion that a country (or estuary) is free from infection, in the face of a small (but statistically acceptable) number of positive results, will usually be backed up by further evidence (such as the absence of clinical disease).

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