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

Paris, 5–9 March 2012

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

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

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

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

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

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

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

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

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

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

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

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

EU comments

The EU agrees in general with the proposed amendments to this chapter. However, the EU has a few comments on the text, inserted in Annex 17.

CHAPTER 6.1.

CONTROL OF HAZARDS IN AQUATIC ANIMAL FEEDS

EU comment

The EU agrees in general with the proposed amendments to this chapter, but has three comments, see Article 6.1.3 and 6.1.5.

Article 6.1.1.

Introduction

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

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

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

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

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

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

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

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

6. Hazards may be transmitted from *feed* to *aquatic animals* via direct or indirect means. Direct transmission occurs when the cultured species consumes *feed* containing a *pathogenic agent* (e.g. shrimp larvae consuming

rotifer contaminated with white spot syndrome virus) while indirect transmission refers to pathogens in *feed* entering the aquatic environment or infecting non target species, and thereby establishing a mechanism for indirect *infection* of the species of commercial interest. Pathogens that are less host-specific (e.g. white spot syndrome virus, *Vibrio* species) present a greater *risk* of indirect transmission as they can establish reservoirs of *infection* in multiple species.

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

Article 6.1.2.

Scope

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

Article 6.1.3.

General principles

1. Roles and responsibilities

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

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

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

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

2. Regulatory standards for feed safety

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

3. Risk analysis

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

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

4. Good practices

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

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

5. Relationship between prions and aquatic animal species

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

EU comment

In paragraph 5 of Article 6.1.3. the EU opposes the proposed amendment in the first part of the second sentence, which should be reverted to the previous text to read as follows:

"There is no evidence to suggest that the use of terrestrial animal by-products as ingredients in *aquatic animal feed* as currently practiced in *aquaculture* gives rise to public health *risks* in respect of prion *diseases* in fish".

Rationale

To our knowledge there is no scientific evidence to substantiate the proposed change, which would be unnecessarily alarming and may give wrong signals. Reference is made to the opinion of the European Food Safety Authority (EFSA) on the assessment of the health risks of feeding of ruminants with fishmeal in relation to the risk of TSE (*The EFSA Journal* (2007) 443, 1-26, http://www.efsa.europa.eu/en/efsajournal/doc/443.pdf). The EU kindly asks the OIE to share the scientific rationale for the proposed change.

6. Bioaccumulation

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

EU comment

In paragraph 6 of Article 6.1.3. the EU would propose the following amendment in the last sentence:

"In particular, the use of fish oil should be carefully considered because a high level of ~~dioxin-like PCB~~ chemical hazards can accumulate in it."

Rationale

The term "dioxin-like PCB" is a too narrow term.

7. Geographic and environmental considerations

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

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

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

8. Zoning and compartmentalisation

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

9. Sampling and analysis

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

10. Labelling

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

11. Design and management of inspection programmes

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

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

12. Assurance and certification

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

13. Hazards associated with aquatic animal feed

a) Biological hazards

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

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

b) Chemical hazards

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

c) Physical hazards

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

14. Contamination

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

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

15. Antimicrobial resistance

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

16. Management of information

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

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

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

Article 6.1.4.

Recommended approaches to risk mitigation

1. Commodities

a) Safe commodities

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

b) Commodities not listed as safe commodities

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

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

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

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

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

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

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

c) Whole fish (fresh or frozen)

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

2. Feed production

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

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

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

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

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

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

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

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

disease incidents, labelling should provide for identification by batch/lot and place and date of production.

3. Importing countries

Competent Authorities should consider the following measures:

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

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

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

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

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

4. Certification procedures

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

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

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

Article 6.1.5.

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

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

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

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

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

a) Direct exposure

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

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

b) Indirect exposure

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

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

EU comment

For clarity reasons, the EU proposes to reword the sentence above to read as follows:

"~~Use of~~ Wastewater and animal and human excreta as feed or as a source of nitrogen and nutrients for photosynthetic organisms are used in some aquaculture production systems. However, this may present a risk for transmission of some human pathogens e.g. bacteria, parasites, viruses, and chemical contaminants."

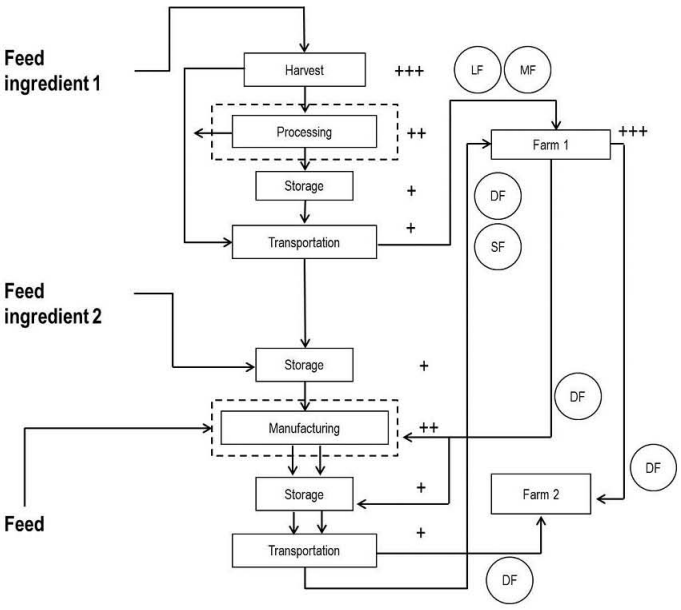
Figure 1 illustrates the possible pathways for transmission of pathogens within the *feed* production and utilisation process.

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

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

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

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



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

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– Text deleted

Annex 18

CHAPTER 1.3.

DISEASES LISTED BY THE OIE

EU comment

The EU would reiterate its previous comments regarding the question of listing HPR0 forms of ISAV in the OIE Code:

Prior to concluding on the different options, it is necessary to further assess the risks associated with HPR0 ISA taking into account:

1. The capability of HPR0 ISA to cause disease;

2. The risk of HPR-deleted ISA emerging from HPR0 ISA and, if relevant, indicating the risk factors causing such an emergence.

As mentioned earlier, the European Commission has requested the European Food Safety Authority (EFSA) for an opinion on this matter. An opinion is expected in autumn of 2012.

Therefore, the EU at this stage does not wish to conclude on the matter.

However, as a general principle, notification should be made compulsory only for diseases or agents for which it is necessary to adopt sanitary measures for international trade. If the purpose is to gather data, means other than compulsory disease notification should be used, for the following reasons:

1. Compulsory disease notification may in practice result in distortion of international trade, as disease agents normally are only listed when trade standards are needed.

2. Compulsory disease notification may not be the best tool to gather epidemiological data on agents that do not cause clinical disease.

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

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

Article 1.3.1.

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

– Epizootic haematopoietic necrosis

– Epizootic ulcerative syndrome

– Infection with *Gyrodactylus salaris*

– Infectious haematopoietic necrosis

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

– Koi herpesvirus disease

– Red sea bream iridoviral disease

– Spring viraemia of carp

– Viral haemorrhagic septicaemia.

[…]

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— Text deleted

Annex 19

CHAPTER 10.5.

INFECTIOUS SALMON ANAEMIA

EU comment

The EU refers to its comments made on Chapter 1.3.

Article 10.5.1.

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

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

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

Article 10.5.2.

Scope

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

Article 10.5.3.

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

1. *Competent Authorities* should not require any ISA related conditions, regardless of the ISA status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *aquatic animals* and *aquatic animal products* from the species referred to in Article 10.5.2. intended for any purpose and complying with Article 5.3.1.:

   a) heat sterilised, hermetically sealed fish products (i.e. a heat treatment at 121˚C for at least 3.6 minutes or any time/temperature equivalent);

   b) pasteurised fish products that have been subjected to a heat treatment at 90˚C for at least 10 minutes (or to any time/temperature equivalent which has been demonstrated to inactivate ISAV);

   c) mechanically dried, eviscerated fish (i.e. a heat treatment at 100˚C for 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate ISAV);

   d) fish oil;

   e) fish *meal*; and

   f) fish skin leather.

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

country, *zone* or *compartment*.

3. When considering the importation or transit of *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of ISA of a species not covered in Article 10.5.2. but which could reasonably be expected to pose a *risk* of transmission for ISA, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

Article 10.5.4.

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

~~In Article 10.5.4, all statements referring to HPR-deleted ISA are only for detectable ISA virus identified as other than HPR0.~~ A country may make a *self-declaration of freedom* from ~~HPR-deleted~~ ISA if it meets the conditions in points 1, 2, 3 or 4 below.

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

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

OR

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

OR

3. A country where the last observed occurrence of the *disease* was within the past ten years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to clinical expression as described in the corresponding chapter of the *Aquatic Manual*) may make a *self-declaration of freedom* from ~~HPR-deleted~~ ISA when:

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

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

OR

4. A country that has made a *self-declaration of freedom* from ~~HPR-deleted~~ ISA but in which the *disease* is subsequently detected may make a *self-declaration of freedom* from ~~HPR-deleted~~ ISA again when the following conditions have been met:

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

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

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

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

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

~~Article 10.5.5.~~

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

~~In Article 10.5.5, all statements referring to ISA are for any detectable ISA virus, including HPR0. A country may make a *self-declaration of freedom* from ISA (including HPR0) if it meets the conditions in points 1, 2, 3 or 4 below.~~

~~If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from ISA (including HPR0) if all the areas covered by the shared water are declared ISA (including HPR0) free countries or *zones* (see Article 10.5.5.).~~

~~1. A country where none of the *susceptible species* is present may make a *self-declaration of freedom* from ISA (including HPR0) when *basic biosecurity conditions* have been continuously met in the country for at least the past two years.~~

~~OR~~

~~2. A country where the species referred to in Article 10.5.2. are present but there has been no detectable occurrence of the any ISA virus (including HPR0) may make a *self-declaration of freedom* from ISA (including HPR0) when:~~

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

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

~~OR~~

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

~~a) on detection of any ISA virus (including HPR0), the affected area was declared an *infected zone* and a *protection zone* was established; and~~

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

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

~~In the meantime, part of the non-affected area may be declared a free *zone* provided that such part meets the conditions in point 3 of Article 10.5.5.~~

Article 10.5.~~5.6~~5.

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

~~In Article 10.5.6, all statements referring to HPR-deleted ISA are only for detectable ISA virus identified as other than HPR0.~~ A *zone* or *compartment* within the *territory* of one or more countries not declared free from ~~HPR-deleted~~ ISA may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

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

OR

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

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past ten years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to clinical expression as described in the corresponding chapter of the *Aquatic Manual*) may be declared free from ~~HPR-deleted~~ ISA when:

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

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

OR

4. A *zone* previously declared free from ~~HPR-deleted~~ ISA but in which the *disease* is detected may be declared free from ~~HPR-deleted~~ ISA again when the following conditions have been met:

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

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

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

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

~~Article 10.5.7.~~

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

~~In Article 10.5.7, all statements referring to ISA are for any detectable ISA virus, including HPR0. A *zone* or *compartment* within the *territory* of one or more countries not declared free from ISA may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.~~

~~1. A *zone* or *compartment* where none of the *susceptible species* is present may be declared free from ISA (including HPR0) when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past two years.~~

~~OR~~

~~2. A *zone* or *compartment* where the species referred to in Article 10.5.2. are present but there has been no detectable occurrence of ISA virus (including HPR0) may be declared free from ISA (including HPR0)~~

~~when~~

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

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

~~OR~~

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

~~a) on detection of ISA virus (including HPR0), the affected area was declared an *infected zone* and a *protection zone* was established; and~~

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

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

Article 10.5.~~6~~87.

Maintenance of ~~HPR-deleted~~ free status

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

A country, *zone* or *compartment* that is declared free from ~~HPR-deleted~~ ISA following the provisions of point 3 of Articles 10.5.4. or 10.5.~~5~~6. (as relevant) may discontinue *targeted surveillance* and maintain its status as ~~HPR-deleted~~ ISA free provided that conditions that are conducive to clinical expression of ISA, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

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

~~Article 10.5.9.~~

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

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

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

Article 10.5.~~7~~109.

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

When importing live *aquatic animals* of the species referred to in Article 10.5.2. from a country, *zone* or *compartment* declared free from ISA, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing*

country certifying that, on the basis of the procedures described in Articles 10.5.4. or 10.5.5. (as applicable), the place of production of the *aquatic animal* is a country, *zone* or *compartment* declared free from ISA.

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

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

Article 10.5.~~8~~.~~11~~10.

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

1. When importing, for *aquaculture*, live *aquatic animals* of the species referred to in Article 10.5.2. from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:

    a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and

    b) the treatment of all effluent and waste materials in a manner that ensures inactivation of ISAV.

2. If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.

3. For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: http://www.ices.dk/pubs/Miscellaneous/ICESCodeofPractice.pdf) may be summarised to the following points:

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

    b) evaluate stock health/disease history;

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

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

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

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

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

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

4. With respect to point 3e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

Article 10.5.~~9~~.~~12~~1.

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

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

1. the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 10.5.3., or products described in point 1of Article 10.5.12., or other products authorised by the *Competent Authority*; and

2. all effluent and waste materials from the processing are treated in a manner that ensures inactivation of ISAV or is disposed in a manner that prevents contact of waste with *susceptible species*.

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

Article 10.5.~~10~~.132.

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

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

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

2. all effluent and waste materials from the processing are treated in a manner that ensures inactivation of ISAV.

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

Article 10.5.~~11~~.143.

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

When importing *aquatic animal products* of the species referred to in Article 10.5.2. from a country, *zone* or *compartment* declared free from ISA, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 10.5.4., ~~or~~ or 10.5.5~~,~~ 10.5.6. or 10.5.7. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from ISA.

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

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

Article 10.5.~~12~~.154

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

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

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

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

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

Article 10.5.~~13~~.165.

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

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

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

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

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

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

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

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

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

3. When importing disinfected eggs of the species referred to in Article 10.5.2. for aquaculture, from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that the procedures described in point 2 of Article 10.5.~~13~~163. have been fulfilled.

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