**Annex 7. Item 6.2. – Draft new Chapter 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish'**

SECTION 4

# DISEASE PREVENTION AND CONTROL

CHAPTER 4.Z.

# CONTROL OF PATHOGENIC AGENTS IN TRADED GAMETES~~MILT~~ AND FERTILISED EGGS OF FISH

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| **Norway** | **Category:** General<br><br>**Proposed amended text:** not relevant<br><br>**Rationale:** Norway supports the proposed changes to this Chapter. We consider it a significant improvement compared to the current Aquatic Code.<br><br>The farming of salmonids is a growing industry, with production in many countries and a growing market for trade in both fertilised eggs and gametes. It is therefore of great importance to have standards in place that are relevant to the framework under which the industry operates.<br><br>The new chapter may also provide a framework for the development of similar standards for other farmed fish species.<br><br>**Supporting evidence:** not relevant |

**Article 4.Z.1.**

**Purpose**

To provide recommendations for trade of *gametes*~~milt~~ and *fertilised eggs* of fish intended for *aquaculture* purposes and to define *risk management*~~mitigation~~ for trade~~import~~ to a *free country*, *free zone* or *free compartment* when:

1) the intention is to grow out and harvest the ~~traded~~ fish from the traded *gametes* and *fertilised eggs* ~~imported *aquatic animals*~~; or

2) the intention is to establish a new stock for *aquaculture*.

For disease-specific recommendations, refer to Article 10.X.15. (and Article 10.4.20. for infection with ISAV)~~Section 10~~.

**Article 4.Z.2.**

**Scope**

This chapter describes general recommendations for safe trade in *gametes*~~milt~~ and *fertilised eggs* of fish from an area other than a *free country*, *free zone* or *free compartment*. These recommendations include the measures outlined in Article 4.Z.3. which cumulatively reduce the *risk* of transfer of *infection* to *aquatic animal* populations in a *free country, free zone* or *free compartment*.

Trade of *gametes*~~milt~~ and *fertilised eggs* of fish from a *free country*, *free zone* or *free compartment* should meet the requirements in Articles 10.X.9. (and Article 10.4.14. for infection with ISAV) of the fish disease-specific chapters, and is not addressed in this chapter.

**Article 4.Z.3.**

**Specific measures required for trade of gametes~~milt~~ and fertilised eggs of fish**

Trade of *gametes*~~milt~~ and *fertilised eggs* of fish from a country, *zone* or *compartment* not declared free from infection with the *listed diseases* of concern should meet the following requirements:

1) the health status of the broodstock at the *aquaculture establishment* of origin must~~should~~ be determined. Only populations of broodstock which are demonstrated to be ~~test~~ free from the *pathogenic agents* of concern, as described in point 3 of Article 4.Z.4., are suitable for movement~~supply~~ to *collection and incubation centres*~~, as described in Article 4.Z.4.~~;

2) *gametes*~~milt~~ and *fertilised eggs* must~~should~~ originate~~come~~ from a *collection and incubation centre* which has been approved for that purpose by the *Competent Authority* of the place of origin, and which operates in compliance with the conditions described in Articles 4.Z.5., 4.Z.6. and 4.Z.7.;

3) in the event of a positive detection in a *collection and incubation centre*, the *Competent Authority* of the *importing country* should assess the *risks* associated with importation of *gametes* and *fertilised eggs* from that establishment, taking all relevant factors into account, including the *biosecurity plan* which is applied to prevent cross contamination of gametes and fertilised eggs from individual parents which have tested negative;

4~~3~~) ~~the~~ *fertilised eggs* must~~should~~ be~~have been~~ surface disinfected prior to the export using a method proven to inactivate *pathogenic agents*, for salmonid eggs as described in Chapter 4.5.~~ and in accordance with the recommendations in the fish disease-specific chapters (Articles 10.X.15. for infection with SAV, infection with IHNV, and infection with VHSV; Article 10.4.20. for infection with ISAV)~~;

5~~4~~) when intended for *international trade*, the consignment must~~should~~ be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* stating~~which should state~~ that the *gametes*~~milt~~ and the *fertilised eggs* originate~~come~~ from parents which have been individually tested and are negative for ~~tested free from~~ the relevant *pathogenic agent*~~disease~~, and which meet the requirements in points 1~~, and~~ 2 and 4.

Application of the measures recommended in this chapter should comply with the requirements of Chapters 5.1., 5.2. and 5.3.

**Article 4.Z.4.**

**Health status of broodstock at the aquaculture establishment~~place~~ of origin**

*Aquaculture establishments* keeping broodstock for movement to a *collection and incubation centre* for the production of~~and~~ *gametes*~~milt~~ and *fertilised eggs* of fish ~~from a country, *zone* or *compartment* not declared free from infection with a *listed disease*,~~ should meet the following requirements:

1) the *aquaculture establishment* ~~it~~ should be approved for that purpose by the *Competent Authority* and be under its official control;

2) ~~it should implement~~have in place a *biosecurity plan* should be implemented which has been developed ~~drawn up~~ in accordance with Chapter 4.1.;

3) the broodstock to be transferred should be sampled and tested for the *pathogenic agents* of concern no more than 30 days before the broodstock's entry to ~~the date on which they enter~~ ~~prior to entry to~~ the *collection and incubation centre* using a sample size that is sufficiently large to demonstrate with 95% confidence that the *pathogenic agent* would be detected if present above a prevalence of 2%, using the diagnostic methods provided in the *Aquatic Manual*. If the results of this testing produce a positive result, the broodstock should not be moved to the *collection and incubation centre*;

4) broodstock intended for movement to a *collection and incubation centre* should be clinically healthy at the time of movement, should not originate~~be~~ from a population experiencing recent or ongoing mortality, and should not be exposed to animals or other sources of *disease* that can~~of a~~ lower their health status following the testing referred to in~~at~~ point 3.

**Article 4.Z.5.**

**Collection and incubation centres**

*Collection and incubation centres* should be approved for that purpose by the *Competent Authority*, and be under its official control. ~~for that purpose on the basis that the~~ The *collection and incubation centre* should meet the following requirements ~~should~~:

1) bei~~s~~be under the supervision of an *Aquatic Animal Health Professional* or *veterinarian*, who takes overall responsibility for *aquatic animal* health at the establishment ~~its operation~~;

2) have implemented ~~have~~ a *biosecurity plan* which has been developed ~~drawn up~~ in accordance with Chapter 4.1.;

3) bei~~s~~be structured to contain epidemiologically separate individual broodstock or groups of broodstock;

4) have~~has~~have in place a ~~valid traceability~~ system in place to ensure that *gametes* ~~milt~~~~each batch of *gametes*~~ or *fertilised eggs* can be traced back to an epidemiologically separate individual or group as relevant, and which includes~~include~~ documentation ~~and auditing~~ of test~~ing~~ results~~, *disease* history and movements of *aquatic animals*~~;

~~5) is be separated into dedicated areas for:~~

~~a) holding broodstock prior to *gamete* collection;~~

~~ba) a collection of room for eggs and milt;~~

~~c) milt testing and storage;~~

~~d) disinfection of *fertilised eggs*;~~

~~eb) an incubation of centre for *fertilised eggs*;~~

~~c) a milt laboratory and milt storage area;~~

~~fd) administration offices.~~

5~~6~~) is~~be~~ subject to inspections carried out ~~and pass audits~~ by the *Competent Authority* or a ~~an approved~~ third party approved by the *Competent Authority* at a frequency sufficient to ensure that the *collection and incubation centre* is in compliance with ~~least once per year against the requirements of~~ this chapter.

**Article 4.Z.6.**

**Biosecurity conditions applicable to collection and incubation centres**

*Collection and incubation centres* must have a *biosecurity plan* which has been developed in accordance with Chapter 4.1. To further minimise the risk of contamination of *gametes* and *fertilised eggs* by common microorganisms, some which may be pathogenic, the following measures should be taken:

1) the *collection and incubation centre* should be separated into dedicated areas for:

a) holding broodstock prior to *gamete* collection;

b) collection of *gametes*;

c) milt testing and storage;

d) disinfection of *fertilised eggs*;

e) incubation of *fertilised eggs*;

f) collection of *aquatic animal products* and waste;

g) administration.

2) water used, including for production and shipment (such as ice), should be free from *pathogenic agents* of concern;

3) only fish directly associated with the production of *gametes* should be permitted to enter the *collection and incubation centre*;

4) when collecting *gametes* from broodstock, all necessary precautions should be taken to prevent the risk of contamination from the skin, surface, or blood;

5) procedures should include the use of sterile equipment, gloves and any other appropriate contamination-prevention measures to maintain the sanitary integrity of the *gametes* or *fertilised eggs*;

6) incubators should be cleaned and disinfected before and after each use;

7) each broodstock should be euthanized after removal of eggs or after the last collection of milt;

8) the system described in point 4 of Article 4.Z.5. should ensure that *gametes* or *fertilised eggs* can be traced back to the individual parent and the associated screening results;

9) where the system only allows tracking to the group and not to the individual, the measures referred to in point 5 of Article 4.Z.7. should apply to the group;

10) if *fertilised eggs* from multiple parents are incubated together and a positive individual is detected, all *fertilised eggs* that were incubated together should be discarded.

**Article 4.Z.76.**

**Testing of broodstock at the collection and incubation centre**

Broodstock for the production of~~and~~ *gametes*~~milt~~ and *fertilised eggs* of fish, should meet the following requirements at the *collection and incubation centre*:

1) stripping and sampling should be carried out under the oversight~~supervision~~ of the *Aquatic Animal Health Professional* or *veterinarian* who has responsibility for the *collection and incubation centre*;

2) at stripping the broodstock should be individually sampled, and tested for the *listed diseases* of concern, in accordance with the methods for diagnosis provided in the *Aquatic Manual,* in a laboratory that has been approved by the *Competent Authority*;

3~~2~~) fish that test positive, and any *gametes* or *fertilised eggs*~~milt or eggs~~ derived from them should not be traded;

4) details of the results from testing relevant cohorts of broodstock as described in point 2 ~~paragraph 1~~ should be provided to the *Competent Authority* of an *importing country* on request;

5) in accordance with the *biosecurity plan* for the *collection and incubation centre*,~~and~~ all *gametes*, *fertilised eggs* and fish from the~~that~~ epidemiological group that tested positive should be disposed of in a biosecure manner. Affected facilities should be disinfected to ensure that cross-contamination of other batches of *gametes* or *fertilised eggs*~~milt or eggs~~ does not occur;

6) *fertilised eggs* should be surface disinfected using a method proven to inactive *pathogenic agents*, for salmonid eggs in accordance with the protocol ~~as~~ described in Article 4.5.2.;~~Chapter 4.5.~~

7) any broodstock mortality should be investigated to determine cause of death.

**Article 4.Z.8~~7~~.**

**Conditions applicable to the collection and storage of milt and preparation of milt samples ~~in the laboratory~~**

The following conditions should be in place ~~at the laboratory~~ for milt collection and storage:

1) the integrity of the traceability system as described in Article 4.Z.5. should be maintained at all times;

2) receptacles used to freeze milt should be sterilized before use;

3) diluents should be pathogen free ~~produced in a way to protect against contamination with *pathogenic agents*~~;

4) frozen milt should be stored in hermetically sealed containers at a species-specific optimal temperatures to maintain their viability in a separate room.