UNITED STATES’ COMMENTS IN RED BELOW

Annex 42. Item 7.2. – 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

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

2) *gametes*~~milt~~ and *fertilised eggs* 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* 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 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 tested free from the relevant *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* forthe 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) 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 which has been drawn up in accordance with Chapter 4.1.;

3) prior to entering the *collection centre* and/or the *incubation centre*, the broodstock should demonstrate equal or higher health status for the *pathogenic agents* of concern; this may be accomplished by either:

a) ~~be~~ test~~ed~~ the broodstock for the pathogenic agents of concern as close as possible 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*; or

b) source the broodstock from *aquaculture establishments* that have demonstrated freedom from the *pathogenic agents* of concern in accordance with the *Aquatic Code* at the premises, compartment, zone, or country level.

**RATIONALE**

We disagree with the intent of statement 3 as written. In our view, the important point we are trying to make here is that any broodstock entering the collection/incubation center should be sourced from a population with a known health status for the pathogens of concern AND that health status should be equal or higher to the health status of the animals in the collection/incubation center. This could be accomplished via testing prior to movement (as suggested) or based on freedom claims at the premises/compartment/zone/country levels. One example for not testing prior to movement (as suggested) could be due to the value of the broodstock; in many cases, broodstock are a highly valuable life stage and, since there are not many non-lethal methods available, would therefore require lethal sampling for the pathogens of concern prior to movement.

We therefore suggest amending the language in statement 3 to maintain the premise that all animals entering a collection/incubation center should have an equivalent or higher health status compared to the animals already in the center, while also allowing flexibility in how this equivalency is determined.

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 by the Competent Authority for that purpose on the basis that the collection and incubation centre ~~should~~:

1) is~~be~~ under the supervision of an *Aquatic Animal Health Professional* or *veterinarian*, who takes overall responsibility for its operation;

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

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

4) has~~have in place~~ a ~~valid traceability~~ system in place to ensure that milt~~each batch of~~ *~~gametes~~* or *fertilised eggs* can be traced back to an epidemiologically separate individual or group, 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;

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

c) milt testing and storage;

d) disinfection of *fertilised eggs*;

e~~b~~) ~~an~~ incubation of~~centre for~~ *fertilised eggs*;

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

f~~d~~) administration ~~offices~~.

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.

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 supervision of the *Aquatic Animal Health Professional, Aquatic Animal Health Services* or *veterinarian* who has responsibility for the *collection and incubation centre*;

**RATIONALE**

We suggest removing “stripping and” because not all broodstock testing may include/require stripping. Additionally, and we recommend expanding the level of supervision to include aquatic animal health services, in addition to a veterinarian or aquatic animal health professional, to allow more flexibility to member countries regarding who supervises this activity on behalf of the Competent Authority.

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*;

**RATIONALE**

We suggest the edits above because not all broodstock testing may include/require stripping and, depending on the pathogen of concern, the pooling of samples for testing may be permissible based on the pathogen-specific guidance provided in the *Aquatic Manual*.

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 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 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 as described in Chapter 4.5.

Article 4.Z.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 produced in a way to protect against contamination with *pathogenic agents*;

4) frozen milt should be stored in hermetically sealed containers in a separate room.

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