Annex 12. Item 6.7. – Draft new Chapter 4.Z. Control of pathogenic agents in traded milt and fertilised eggs of fish

SECTION 4

DISEASE PREVENTION AND CONTROL

**USA COMMENTS IN RED FONT**

CHAPTER 4.Z.

CONTROL OF PATHOGENIC AGENTS IN TRADED MILT AND FERTILISED EGGS OF FISH

**General comments:** We appreciate the Commission’s work drafting this important new chapter. As written, this chapter proposes activities and responsibilities of Competent Authorities and farming communities that would require tremendous resources, while not addressing some of the fundamental scientific guidance on the risk of vertically transmitted pathogens versus those that are not transmitted vertically. Also, this chapter suggests redundant animal testing in a manner that demonstrates a lack of understanding of how aquatic animal health testing and animal/gamete movement is conducted. The edits and comments below are intended to clarify our interpretation of this new chapter.

Article 4.Z.1.

Purpose

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

**RATIONALE:** Change from “mitigation” to “management” to better align with Chapter 2.1. Also, “risk management” is a defined term in the Aquatic Code Glossary.

1) the intention is to grow out and harvest the imported *aquatic animals*; or

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

For disease-specific recommendations, refer to Section 10.

Article 4.Z.2.

Scope

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

Trade of 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 milt and fertilised eggs of fish

Trade of 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 should be determined. Only populations of broodstock which test free from the *pathogenic agents* of concern are suitable for supply to *collection and incubation centres*, as described in article 4.Z.4.;

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

3) the fertilised eggs should ~~have been~~ be 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);

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 whichshould state that the milt and the fertilised eggs come from ~~parents~~ broodstock which have tested free from the relevant *diseases* or originate from a broodstock population that is free from the relevant *diseases* and meet the requirements in points 1 and 2.

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

**RATIONALE:**

(2) Competent Authorities of all Member Countries may not have the authority to “approve” incubation centers simply for operational purposes. Under bullet (4), if a trading partner requires oversight by the Competent Authority of these breeding centers, then that requirement could be verified under that requirement; this change would then remove the stipulation that ALL aquatic animal breeding facilities be audited and inspected by the Competent Authority, just those participating in international trade.

(3) Edited for grammar.

(4) Wording change to “broodstock” rather than “parents” as broodstock is a more accurate term for use in animal production scenarios and will avoid an interpretation that individual testing of each parent is intended. Additional edits provide the option to either test the individual broodstock or source the animals from a population that has been determined to be free of relevant diseases.

Article 4.Z.4.

Health status of broodstock ~~at the place of origin~~ to be used for traded milt and eggs

**RATIONALE:** The term “at place of origin” is confusing because this article outlines criteria for broodstock either in a country which does not have demonstrated freedom from the listed diseases, or sourced from a country which does not have demonstrated freedom from the listed diseases. The edits to this heading clarify that the concern we are addressing in this section is the health status of the broodstock prior to entering a breeding center.

*Aquaculture establishments* keeping broodstock for the production ~~and~~ of 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:

**RATIONALE:** Editorial correction.

~~1) be approved by the~~ *~~Competent Authority~~*~~;~~

**RATIONALE:** Remove “approved by the Competent Authority” as some Competent Authorities may not have the authority or ability to approve these types of facilities. If a trading partner requires this level of oversight, then that requirement may be defined in an import permit.

2) have in place a biosecurity plan in accordance with Chapter 4.1.;

3) the broodstock should be tested for the pathogenic agents of concern prior to entry to the collection and incubation centre 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 be from a population experiencing recent or ongoing mortality, and should not be exposed to animals of a lower health status following the testing at point 3.

Article 4.Z.5.

Collection and incubation centres

Collection and incubation centres ~~should be approved by the Competent Authority on the basis that the collection and incubation centre~~ should:

1) be under the supervision of an *Aquatic Animal Health Professional* or *veterinarian*;

2) have a biosecurity plan in accordance with Chapter 4.1.;

3) be structured to contain epidemiologically separate groups of broodstock;

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

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

a) ~~a~~ collection ~~room~~ area for eggs and milt;

b) an incubation centre for fertilised eggs;

c) a milt laboratory and milt storage area;

d) administration offices.

6) ~~be be subject to and pass audits by the~~ *~~Competent Authority~~* ~~or an approved third party when required to meet trade requirements.at least once per year against the requirements of this chapter.~~

RATIONALE: Edits to support changes made to the previous articles regarding approval by the Competent Authority.

(4) Edited for clarity since it was not clear what was meant by a “valid traceability” and “audit”.

(5) Edited for clarity and more flexibility for the design of these centers.

(6) Removal of text relates back to the activities and oversight of the Competent Authority. Not all Competent Authorities will have this ability or authority to audit these facilities. The review for compliance with trade requirements is more commonly done prior to export.

Article 4.Z.6.

Testing of broodstock at the collection and incubation centre

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

**RATIONALE:** Editorial correction.

1) ~~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*;

2) fish that test positive, and any milt or eggs derived from them should not be traded and all gametes and fish from that epidemiological group should be disposed of in a biosecure manner. Affected facilities should be disinfected to ensure that cross-contamination of other batches of milt or eggs does not occur.

**RATIONALE:** Edits made to broaden how and when broodstock are tested once in the breeding center. Testing at stripping may not always be possible or reasonable as gametes or fertilized eggs may need to move faster than results may be attained. Also, these edits therefore allow the flexibility for testing to be done at any time while animals are in the center.

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.

**RATIONALE:** The term laboratory is confusing in this context and is not needed. Not all facilities may use the phrase “milt laboratory”. For example, milt collection could be conducted in conjunction with collection prior to spawning, and then evaluated with equipment on site (and not necessarily in a laboratory).

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