

Japan's comments on the Report of the meeting of WOAHA Aquatic Animal Health Standards Commission in September 2023

The WOAHA Aquatic Animal Health Code

Annex 7 and 8. Item 6.4. – Article 1.3.1. of Chapter 1.3. Diseases listed by WOAHA - Listing of Infection with all genogroups of the virus species infectious spleen and kidney necrosis virus.

The Commission reviewed comments and noted that the majority of comments were supportive of the proposed change to the listed name of infection with RSIV to infection with the virus species infectious spleen and kidney necrosis virus.

The Commission concluded that the information provided in the assessment of infection with the virus species infectious spleen and kidney necrosis virus against the criteria in Chapter 1.2. Criteria for listing aquatic animal disease was robust and reiterated that the assessment supported the listing of all genogroups, including RSIV, ISKNV, and TRBIV.

The Commission considered comments that the International Committee on Taxonomy of Viruses (ICTV) is currently reviewing the classification and nomenclature of the genus *Megalocytivirus* and that the listing of the disease should use a new proposed name to avoid confusion between ISKNV species and ISKNV genogroup. The Commission confirmed that new nomenclature is under consideration by the ICTV but noted a decision and publication is pending. The Commission will continue to monitor this issue and adopt new nomenclature once published by the ICTV.

The Commission agreed that there are some limitations on the validation of diagnostic tests for detection of the TRBIV genogroup due to the availability of TRBIV-infected tissues. However, the Commission reiterated that there are a variety of methods that are inclusive of all three genogroups (Kawato et al., 2021a, Koda et al., 2023 and Kim et al., 2022). Further diagnostic accuracy studies are warranted, in particular using TRBIV-infected tissues, however, this is not an impediment to this criterion being met.

(Omitted)

Comments:

Japan agrees with the Commission's plan to adopt new nomenclature for this disease once published by the ICTV. It helps to prevent confusion due to two different names and avoids the work toward unifying them. It would be more reasonable if we temporarily maintain the WOAHA's current nomenclature until the final one is fixed in ICTV, since frequent changes may cause confusion in related legal regulations and trade administration procedures, as well as confusion in academic fields when referring to the history of outbreaks. We propose to continuously contact ICTV for coordination toward a unified nomenclature. It would be helpful to grasp their work schedule at first in order to set up our working plan.

Annex 9. Item 6.5 – Chapter 4.3 Application of compartmentalisation – discussion paper

The Commission highlighted that compartmentalisation provides an opportunity to trade disease-free aquatic animal commodities from zones or countries that are not declared free from the diseases of concern. While compartmentalisation has particular relevance for aquatic animal diseases - because eradication is often not possible - it has not been implemented or recognised widely among Members. The Commission emphasised that the revision of Chapter 4.3. aims to provide clarity on the requirements of compartments, improve acceptance and make private sector investment in it more attractive.

The discussion paper proposes a range of purposes for applying compartments, high-level principles to guide their application and the concept of dependent and independent compartments. Together these proposals are intended to increase clarity on the application of compartments for effective risk management, while also broadening the range of circumstances where they might be applied.

This discussion paper has been informed by Member responses to a short questionnaire provided in the Commission's September 2022 meeting report, as well as feedback from Focal Point workshops.

The Commission explained that questions are included throughout the discussion paper to prompt responses from Members on issues of particular importance to the direction of the chapter's revision. Members are invited to submit comments on the discussion paper, including responses to the questions posed and other matters relevant to the revision of Chapter 4.3.

(Omitted)

Answers:

1) Are the above principles (points A-E) to guide revision of Chapter 4.3. Compartmentalisation appropriate? If not, please suggest alternatives.

No objection.

2) Do these purposes encompass the principal reasons for establishing a compartment, defined by product type, pathway and end use? If not, please provide alternative suggestions.

No objection.

3) Do you support including the concepts of independent and dependent compartments in the revised Chapter 4.3? What are your reasons?

No objection. Having "dependent compartment" in this chapter is reasonable, since the status of each compartment should be determined by a number of epidemiological factors.

4) Should a dependent compartment be able to supply live aquatic animals for aquaculture or restocking? If yes, under what conditions should this trade be allowed (e.g. epidemiological separation, targeted surveillance)?

Yes, we believe that this should be possible. As for the conditions supplying additional assurance, use of pathogen-free feed, proper cleaning and disinfection of equipment, and prevention of vector invasion are also important, in addition to the epidemiological separation and targeted surveillance as exemplified. However, since the actual situations in each country and region differ, such conditions should be provided as examples but not requirements for all countries so that export/import countries can set specific conditions in the course of bilateral

discussions referring to the listed conditions in this chapter.

5) Do the general principles of compartmentalisation described above provide an appropriate high-level framework for the establishment and recognition of a compartment? Please suggest any amendments or additional principles that should be considered?

No objection except No. 6. Please refer to Question 7.

6) Do you support the revision of article 4.3.2. to include the principles in section 6 above (as modified based on member comments)? Are there any additional key issues or requirements that should be addressed within a set of principles?

No objection.

7) Do you support the recommended approach to revision of article 4.3.6., including requirements for independence, accreditation and mandatory laboratory reporting? Please provide rationale or further comments.

We support the approach to revising the requirements for independence and mandatory laboratory reporting. As for accreditation, we believe that the reliability of diagnostic tests should be ensured at a certain level. This could be achieved by quality management systems for laboratories currently in place at each member, in addition to the application of ISO 17025 or equivalent.

8) Do you support the proposed revision of article 4.3.8., including division into two articles: one on quality of Aquatic Animal Health Services and one on Competent Authority oversight? Please provide rationale or further comments.

No objection.

Annex 16. Item 6.8. – Draft new Chapter 5.X. Movement of ornamental aquatic

Article 5.X.4

Eligibility for the international movement of ornamental aquatic animals

Prior to considering the aquatic animal health risks associated with the import of a species of ornamental aquatic animal, the Competent Authority of an importing country should consult **relevant national regulations** and international obligations to determine that the species is eligible for import.

Species of ornamental aquatic animal may be subject to controls on international movement or trade due to their conservation status (e.g. listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)). These controls may prohibit international movement or may necessitate additional import documentation.

Species of ornamental aquatic animals (or taxonomic groups of species) may also be identified as invasive by a Competent Authority or other authority of an importing country. Such species may be prohibited to be traded, owned or farmed due to the risks they present to biodiversity, ecosystems, industry or public amenity in the importing country.

Comments

Regarding "relevant national regulations", referred to in the 1st paragraph of the Article 5.X.4, we understand that importing country is assumed to consult relevant national regulations when determining the import eligibility and thus there is no need to specifically mention it in the Code. In addition, "relevant national regulations" is ambiguous and it is unclear what kind of regulations should be consulted. We would like the commission to clarify what kind of regulations are assumed in this phrase.