# Japan's comments on the Report of the meeting of WOAH Aquatic Animal Health Standards Commission in February 2023

# The WOAH Aquatic Animal Health Code

Annex 15. Item 8.3. – Article 1.3.1. of Chapter 1.3. Diseases listed by WOAH - Listing of Infection with all genogroups of the virus species infectious spleen and kidney necrosis virus.

## Text

The Commission reiterated that the proposal for listing is to amend the name of the listed disease from infection with RSIV to infection with the virus species infectious spleen and kidney necrosis virus (ISKNV). This proposal would maintain the RSIV genogroup as a listed disease and would also include the ISKNV genogroup and the TRBIV genogroup. The Commission noted that while several Members supported the proposed change, a number did not. The Commission noted that the nomenclature of megalocytiviruses does cause some confusion. This is because "ISKNV" is the name of the virus species recognized by the ICTV and is also the name of one of the three recognised genogroups within the virus species. The Commission reviewed and updated the assessment of infection with the virus species ISKNV against the criteria in Chapter 1.2, Criteria for listing aquatic animal disease, to ensure clarity and consistency of terminology throughout with respect to the viral species ISKNV and the genogroup ISKNV. The Commission considered comments proposing that the name of the listing be "infection with Megalocytivirus". The Commission noted that the genus Megalocytivirus includes two recognized species, ISKNV and scale drop disease virus (SDDV). SDDV is not under consideration for listing and so the proposed disease name would be problematic as it would need to be defined to include the species ISKNV but exclude SDDV. The Commission proposed to alter the disease name in Article 1.3.1. to "Infection with all genogroups of the virus species ISKNV" to provide clarity on the scope of the listed disease.

#### Comments:

Japan does not support the proposal to amend the name of the listed disease from infection with RSIV to infection with ISKNV at this point, in terms of consistency in the virus name between WOAH and ICTV. In fact, ICTV is currently reviewing the classification and nomenclature of the genus Megalocytivirus, which may result in a different name than WOAH. In order to avoid confusion, we would like to suggest that WOAH wait until the review at ICTV is over.

# The WOAH Manual of Diagnostic Tests for Aquatic Animals

Annex 37. Item 11.1.4. – Chapter 2.2.9. Infection with yellow head virus genotype 1.

#### Text

(Omitted)

- 5.Test(s) recommended for surveillance to demonstrate freedom in apparently healthy populations
- : Clarified that the nested RT-PCR is recommended. The Commission is aware that a specific real-time PCR method has been validated and publication is pending. (Omitted)

## Annex 37

(Omitted)

5.Test(s) recommended for surveillance to demonstrate freedom in apparently healthy populations Nested RT-PCR (Protocol 3) is recommended for demonstrating freedom from YHV1 in an apparently healthy population. Sequencing of any amplified PCR products is required to determine the YHV genotype. Two-step PCR negative results are required for YHV1. (Omitted)

## Comments:

Japan agrees to the most part of Chapter 2.2.9 except following points.

First, the current draft describes three protocols as Conventional RT-PCR in 4.4.2, but those are not explicitly designated in Table 4.1 and section 6. To avoid confusion, those test protocols should be specified in the relevant sections.

Secondly, the current draft defines nested RT-PCR, one of the Conventional RT-PCR protocols, as the test recommended at the Table4-1 and section 5 and 6. However, the nested RT-PCR is considered unsuitable for a test method for demonstrating disease freedom generally, due to its strong possibility for contamination leading false positive. Therefore, Japan rather suggests the real-time PCR mentioned in the report, which probably has higher sensitivity and specificity than the conventional RT-PCR method, as the test recommended for surveillance, if the evaluation for the real-time PCR has been completed.

We suggest that the real-time PCR method be adopted as the recommended test with the description, "a method under development by the reference laboratory" if has not been published.

Table 4.1. WOAH recommended diagnostic methods and their level of validation for surveillance of apparently healthy animals and investigation of clinically affected animals

Method	A. Surveillance of apparently healthy animals				B. Presumptive diagnosis of clinically affected animals				C. Confirmatory diagnosis of a suspect result from surveillance or presumptive diagnosis	
	Early life stages	Juveniles	Adults	LV	Early life stages	Juveniles	Adults	LV	Early life stages	
Wet mounts										
Histopathology						++	++	1		<u> </u>
Cell culture										
Real-time RT-PCR										
Conventional RT- PCR	++	++	++	1	++	++	++	1		
Conventional PCR followed by amplicon sequencing									+	
In-situ hybridization						++	++	1		
Bioassay					+	+	+	1		
LAMP										
Ab-ELISA										
Ag-ELISA										
Other antigen detection methods										
Other methods <sup>3</sup>										*

- +++ = Methods are most suitable with desirable performance and operational characteristics.
- ++ = Methods are suitable with acceptable performance and operational characteristics under most circumstances.
- + = Methods are suitable, but performance or operational characteristics may limit application under some circumstances.

Shaded boxes = Not appropriate for this purpose.