

## USA COMMENTS

**General Comments:** The United States does not have specific suggestions for changes to the language in the proposed new chapter. Instead, we offer the following comments regarding whether the proposed new chapter is necessary or appropriate.

The United States notes that the apparent objective of this new chapter is to establish criteria for determining which aquatic animal species can become infected by (i.e. are susceptible to) an OIE notifiable disease-causing agent (pathogen), and to guide refinement of disease-specific chapters in the OIE Aquatic Code and Aquatic Manual. The proposed new chapter also intends to clarify that susceptible species includes species that are naturally or experimentally infected and includes both those that show clinical signs of disease or pathology and those that are asymptomatic carriers. Furthermore, the proposed new chapter attempts to address susceptibility to infection of taxonomically closely related host species.

The United States questions the need for this chapter and recommends that the issue be referred back to the Aquatic Animal Health Standards Commission (AAHSC) or the ad hoc group that drafted the chapter. The United States recommends that rather than creating a new chapter, which is confusing and somewhat ambiguous, the OIE consider revising its current definitions of “Infection” and “Susceptible Species” if such revision is needed for Member countries to better understand these terms.

The United States believes the proposed new chapter is unnecessary because it is intuitive and obvious that if an animal of a given species becomes infected with a specific infectious agent (pathogen) through natural or experimental pathways, then that species is susceptible to infection with that agent whether or not it shows overt clinical signs or pathology. As written, this chapter is ambiguous, uses terms not defined in the Aquatic Code glossary, or uses terms inconsistently (e.g. susceptible species vs host; pathogen vs aetiological agent). As such, the United States believes the proposed new chapter will be confusing for countries that seek to use it as an international standard.

The United States believes the following definitions in the Aquatic Code Glossary are adequate and accurate. However, should there be a need, then these definitions could be revised to accomplish the same intent as the proposed new chapter. Furthermore, if it might clarify issues related to diagnostic testing and tests, the following definitions could be added to the Definitions listed in the Aquatic Manual.

*Infection*—means the presence of a multiplying or otherwise developing or latent pathogenic agent in a host. This term is understood to include infestation where the pathogenic agent is a parasite in or on a host.

*Susceptible species*—means a species of aquatic animal in which infection has been demonstrated by natural cases or by experimental exposures to the pathogenic agent that mimics the natural pathways for infection. Each disease chapter in the Aquatic Code and the Aquatic Manual contains a list of currently known susceptible species.

The United States also believes that the current definition of “disease” in the Aquatic Code already addresses the issue of asymptomatic infected animal:

*Disease*—means clinical or non-clinical infection with one or more aetiological agents.

Furthermore, because the definition of *susceptible species* in the Aquatic Code addresses natural and experimental infections, it negates the necessity of Article X.X.3 and Article X.X.4 in the proposed new chapter.

The United States has additional and specific concerns regarding Article X.X.7 (“Outcome of the assessment”) and Article X.X.8 (“Taxonomic relationship of susceptible species”) in the proposed new chapter. Although it may be hypothesized that closely related species or genera may be infected with the same infectious agents (pathogen or parasite), there are numerous examples in veterinary medicine where this does not happen. The United States believes that, without empirical science-based evidence, it is inappropriate and unjustified to suggest that some species may be “possible susceptible species” or to suggest that, as written in Article X.X.8, given “aetiological agents with a wide host range, the taxonomic relationship of a species to other known susceptible species may be used to assume susceptibility [and] species can be classified as ‘possible’ susceptible species if they reside in a genus that includes at least two susceptible species and in which there is no strong evidence of resistance to infection.”

## ~~CHAPTER X.X~~

# ~~CRITERIA FOR DETERMINING SUSCEPTIBILITY OF AQUATIC ANIMALS TO SPECIFIC PATHOGENIC AGENTS~~

### ~~Article X.X.1~~

~~The purpose of this chapter is to provide criteria for determining which *susceptible species* are listed in Article X.X.2 of each disease specific chapter in the *Aquatic Code* and Article 2.2.1 of each disease specific chapter in the *Aquatic Manual*.~~

### ~~Article X.X.2~~

#### ~~Scope~~

~~This chapter provides criteria to determine which species should be listed as susceptible to infection with the aetiological agent of *listed diseases*. Susceptibility may include clinical or non-clinical *infection*. This chapter does not provide criteria for identifying mechanical vectors (i.e. species that may carry the pathogen without replication).~~

~~The decision to list a species as susceptible should be based on a finding that the evidence is definite. However, possible susceptibility of a species is also important information and this should also be included in Section 2.2.1 of the disease chapter of the *Aquatic Manual*.~~

### ~~Article X.X.3~~

#### ~~Approach~~

~~There are three stages outlined in this chapter to assessing susceptibility of a species to *infection* with a specified aetiological agent:~~

- ~~1) determine whether the route of infection used is consistent with natural pathways for the infection as described in Article X.X.4.;~~
- ~~2) determine whether the aetiological agent has been identified using a technique as described in Article X.X.5.;~~
- ~~3) determine whether the evidence indicates that presence of the aetiological agent constituted an *infection* using the criteria in Article X.X.6.~~

### ~~Article X.X.4~~

#### ~~Stage 1: criteria for transmission of infection~~

~~The evidence should be classified as transmission through: i) natural occurrence, ii) non-invasive experimental procedure, or iii) invasive experimental procedure.~~

~~Consideration needs to be given to whether experimental procedures (e.g. inoculation, infectivity load, host stress) mimic natural pathways for *disease* transmission.~~

#### ~~Article X.X.5~~

##### ~~Stage 2: criteria for identification of the aetiological agent~~

~~The aetiological agent should be identified and confirmed in accordance with the methods described in Section 7 (corroborative diagnostic criteria) of the relevant disease chapter in the *Aquatic Manual*, or other methods that have been demonstrated to be equivalent.~~

~~Under some circumstances the presumptive identification of the aetiological agent has been made but not confirmed in accordance with the *Aquatic Manual*.~~

#### ~~Article X.X.6~~

##### ~~Stage 3: criteria to determine infection~~

~~The following criteria should be used to determine *infection*:~~

- ~~A. the aetiological agent is multiplying in the host, or that developing or latent stages of the aetiological agent are present in or on the host;~~
- ~~B. viable aetiological agent is isolated from the proposed *susceptible species*, or viability demonstrated via transmission to naive individuals (by natural routes);~~
- ~~C. clinical and/or pathological changes are associated with the *infection*;~~
- ~~D. the specific location of the pathogen corresponds with the expected target tissues.~~

~~The type of evidence to demonstrate infection will depend on the aetiological agent and potential host species under consideration.~~

#### ~~Article X.X.7~~

##### ~~Outcomes of the assessment~~

~~*Susceptible species* can be classified as 1) Possible or 2) Definite.~~

##### ~~1. Possible susceptible species:~~

- ~~a) the presumptive identification of the aetiological agent has been made but may not have been confirmed in accordance with Article X.X.5.;~~

~~AND~~

- ~~b) there is evidence of infection with the aetiological agent in the suspect species in accordance with Article X.X.6. At least one of criteria A, B, C or D in Article X.X.6. is required.~~

##### ~~2. Definite susceptible species:~~

- ~~a) transmission has been obtained by natural or experimental procedures that mimic natural pathways of infection in accordance with Article X.X.4.;~~

~~AND~~

- ~~b) the identity of the aetiological agent has been confirmed in accordance with X.X.5;~~

~~AND~~

- ~~c) there is evidence of infection with the aetiological agent in the suspect host species in accordance with Article X.X.6. Evidence to support criterion A alone is sufficient to determine infection. In the absence of evidence to meet criterion A, satisfying at least two of criteria B, C or D would be required to determine infection.~~

~~Article X.X.8.~~

~~Taxonomic relationship of susceptible species~~

~~Defining species as possible susceptible on the basis of a taxonomic relationship at levels higher than genus requires solid evidence that the pathogen has a very wide host range.~~

~~For aetiological agents with a wide host range, the taxonomic relationship of a species to other known *susceptible species* may be used to assume susceptibility. Species can be classified as 'possible *susceptible species*' if they reside in a genus that includes at least two *susceptible species* and in which there is no strong evidence of resistance to *infection*.~~

~~Evidence of resistance would include the following:~~

- ~~1) Appropriate testing reveals no evidence of *infection* when animals are exposed to the pathogen in natural setting where the pathogen is known to be present and to cause disease in *susceptible species*.~~
  - ~~2) Appropriate testing reveals no evidence of infection when animals are exposed through controlled challenges by natural routes.~~
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