

CHAPTER X.X
USA COMMENTS
CRITERIA FOR LISTING SPECIES AS
SUSCEPTIBLE TO INFECTION WITH A SPECIFIC
PATHOGEN DETERMINING SUSCEPTIBILITY OF
AQUATIC ANIMALS TO
SPECIFIC PATHOGENIC AGENTS

The United States does not believe that this chapter is a needed addition to the Aquatic Code. 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. Additionally, the AAHSC should consider that there is no such parallel chapter in the OIE Terrestrial Code. The United States kindly requests that the AAHSC provide OIE Members its specific reasons for recommending this chapter to the Aquatic Code.

Article X.X.1.

The purpose of this chapter is to provide criteria for determining ~~which susceptible species that~~ are listed as susceptible 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 but does not provide criteria for identifying include mechanical vectors (i.e. species that may carry the pathogen aetiological agent 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 approach is outlined in this chapter to assessing susceptibility of a species to infection with a specified aetiological agent:~~

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

Article X.X.4.

~~Stage 1: criteria to determine whether the route of infection used is consistent with natural pathways for the infection for transmission of infection~~

~~The evidence should be classified as transmission through: a) natural occurrence, b) non-invasive experimental procedure, or c) invasive experimental procedure.~~

- a) natural occurrence; includes all situations where infection has arisen without direct experimental intervention e.g. infection arising in wild or farmed populations;
- b) non-invasive experimental procedure; includes cohabitation with infected hosts, infection by immersion or ingestion; or
- c) invasive experimental procedure; includes injection, exposure to unnaturally high loads of pathogen, or exposure to stressors (e.g. temperature) not encountered in the host's natural or culture environment.

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 to determine whether the aetiological agent has been adequately identified 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 whether the evidence indicates that presence of the aetiological agent constituted an infection to determine infection

A combination of The following criteria should be used to determine *infection* (see Article X.X.7):

- 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~~ **infectivity is demonstrated via** by way of 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.

Question about Article X.X.6.A.: the meaning of “developing stages” in reference to an aetiological agent is not clear. Clarification is requested.

Article X.X.7.

Outcomes of the assessment

The decision to list a species as susceptible should be based on a finding that the evidence is definite. Evidence should be provided for the following:

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

1. Definite susceptible species:

- 1a) Transmission has been obtained ~~by~~ naturally or by experimental procedures that mimic natural pathways of *infection* in accordance with Article X.X.4.;

AND

2b) the identity of the aetiological agent has been confirmed in accordance with Article X.X.5;

AND

3e) there is evidence of *infection* with the aetiological agent in the suspect host species in accordance with criteria A to D in 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*.

Species for which there is incomplete evidence for susceptibility

Where evidence exists but is insufficient to demonstrate susceptibility of a species because either transmission does not mimic natural pathways of infection, or the identity of the aetiological agent has not been confirmed, or *infection* is only partially supported, the information will be included in the relevant disease chapter in the *Aquatic Manual*.

Where these species could reasonably be expected to pose a risk of transmission for the pathogen under consideration, Competent Authorities should conduct a risk analysis in accordance with the recommendations in the *Aquatic Code*.

2- 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.~~

~~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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