USA COMMENTS

AQUATIC ANIMAL HEALTH STANDARDS COMMISSION – FEBRUARY 2017 REPORT

CHAPTER 1.5.

CRITERIA FOR LISTING SPECIES AS SUSCEPTIBLE TO INFECTION WITH A SPECIFIC PATHOGEN

Article 1.5.1.

The purpose of this chapter is to provide criteria for determining which species are listed as susceptible in Article 1.5.2.X.X.2 of each disease-specific chapter in the Aquatic Code.

Article 1.5.2.

Scope

Susceptibility may include clinical or non-clinical infection but does not include species that may carry the pathogenic agent without replication.

The decision to list an individual species as susceptible in disease-specific chapters should be based on a finding that the evidence is definite in accordance with Article 1.5.3. All species in a taxonomic group may be listed as susceptible when certain criteria are met in accordance with Article 1.5.9.

However, possible susceptibility of a species is also important information and this should also be included in Section 2.2.1, 2.2.2, Species with incomplete evidence for susceptibility entitled «Susceptible host species» of the relevant disease-specific chapter of the Aquatic Manual.

Article 1.5.3.

Approach

A three-stage approach is outlined in this chapter to assess susceptibility of a species to infection with a specified pathogenic agent and is based on:

1) criteria to determine whether the route of transmission is consistent with natural pathways for the infection (as described in Article 1.5.4.);

2) criteria to determine whether the pathogenic agent has been adequately identified (as described in Article 1.5.5.);

3) criteria to determine whether the evidence indicates that presence of the pathogenic agent constitutes an infection (as described in Article 1.5.6.).

Article 1.5.4.

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

The evidence should be classified as transmission through:
1) natural occurrence; includes situations where infection has occurred without experimental intervention e.g. infection in wild or farmed populations; or

2) non-invasive experimental procedures; includes cohabitation with infected hosts, infection by immersion or ingestion; or

3) 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) mimic natural pathways for disease transmission. Consideration should also be given to environmental factors as these may affect host resistance or transmission of the pathogen.

Article 1.5.5.

Stage 2: criteria to determine whether the pathogenic agent has been adequately identified

The pathogenic 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.

Article 1.5.6.

Stage 3: criteria to determine whether the evidence indicates that presence of the pathogenic agent constitutes an infection

A combination of the following criteria should be used to determine infection (see Article 1.5.7.):

A. the pathogenic agent is multiplying in the host, or developing stages of the pathogenic agent are present in or on the host;

B. viable pathogenic agent is isolated from the proposed susceptible species, or infectivity is demonstrated by way of transmission to naive individuals;

C. clinical 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 pathogenic agent and potential host species under consideration.

Article 1.5.7.

Outcomes of the assessment

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

1) transmission has been obtained naturally or by experimental procedures that mimic natural pathways for the infection in accordance with Article 1.5.4.;

AND

2) the identity of the pathogenic agent has been confirmed in accordance with Article 1.5.5.;

AND
3) There is evidence of infection with the pathogenic agent in the suspect host species in accordance with criteria A to D in Article 1.5.6. 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 1.5.8.**

Species for which there is incomplete evidence for susceptibility

The decision to list a species as susceptible in Article 1.5.2. of each disease-specific chapter should be based on a finding that the evidence is definite.

However, where there is insufficient evidence to demonstrate susceptibility through the approach described in Article 1.5.3. because transmission does not mimic natural pathways of infection, or the identity of the pathogenic agent has not been confirmed, or infection is only partially supported, information will be included in the relevant disease-specific chapter in the Aquatic Manual.

If there is insufficient evidence to demonstrate susceptibility of a species, the Competent Authority should assess the risk of spread of the pathogen under consideration, in accordance with the recommendations in Chapter 2.1., prior to the implementation of import health measures.

**Article 1.5.9.**

**Listing susceptible species at a taxonomic ranking higher than species**

*Pathogenic agents with a broad host range*

For pathogenic agents with a broad host range, it may be appropriate for the outcome of the assessment to be made at a taxonomic ranking higher than species (e.g. genus, family). It may be appropriate for the outcome of the assessment to be made at a taxonomic classification higher than species for a pathogenic agent that has a broad host range. A pathogenic agent will be considered to have a broad host range when it has been demonstrated as susceptible in at least three families.

1) A decision to conclude susceptibility for a taxonomic level above species should only be made where:

   **A.** Susceptibility has been demonstrated in at least one species from within each of three or more families;

   **AND**

   **AB.** More than one species within the family taxonomic ranking has been found to be susceptible in accordance with the criteria above;

**Rationale:** The Linnaeus classification system organizes organisms based on their similarities, usually physical characteristics. Those physical similarities do not necessarily correlate with disease susceptibility. Additionally, the phrase in 1A, above, supersedes the conditions described in 1B. Having at least one species from within each of three or more families (1A) encompasses “more than one species within the taxonomic ranking” (1B).

**AND**

**BC.** No species within the taxonomic group ranking has been found to be refractory to infection, and evidence exists to support this claim.

**Rationale:** Absence of effort or surveillance to detect diseased animals should not imply evidence of species being refractory to infection. Such evidence to be determined through study.

The taxa taxonomic ranking chosen should be the lowest level supported by this evidence.
2) Evidence that a species is refractory to infection may include:

   A. absence of infection in a species exposed to the pathogenic agent in natural settings where the pathogen is known to be present and it has caused disease in susceptible species;

   B. absence of infection in species exposed to the pathogenic agent through a controlled challenge using experimental procedures.