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GUIDANCE FOR THE ASSESSMENT OF AN AQUATIC ANIMAL DISEASE FOR A LISTING DECISION

This guidance document is intended to be used by the Aquatic Animals Health Standards Commission (AAHSC) or a WOAHA *ad hoc* Group when undertaking an assessment to make a listing decision for a pathogenic agent against the criteria for listing aquatic animal diseases in [Chapter 1.2.](#) of the *Aquatic Code*.

Objectives of a listing decision

The objective of a listing decision is to either add a new pathogenic agent to, or remove an existing pathogenic agent from, [Chapter 1.3.](#) of the *Aquatic Code*.

The objective of listing diseases in [Chapter 1.3.](#) is to support Members by providing information needed to take appropriate action to prevent the transboundary spread of important diseases of aquatic animals. This is achieved by transparent, timely and consistent notification.

To meet this objective there must be feasible actions under the mandate of the relevant Competent Authorities that, if effectively implemented, would reasonably be considered to prevent transboundary spread. Feasible actions that could be applied include the type of commodity traded, testing, and treatments prior to or after trade.

If there are pathways for transboundary spread beyond the risk management mandate of the relevant Competent Authorities, the case for listing should consider the significance of different potential pathways to the risk of transboundary spread, the feasibility of implementing risk management measures across all pathways, and the impact of implementation of risk management measures only on pathways under the mandate of the relevant Competent Authorities.

The above considerations should be considered before the assessment is undertaken.

The objective of the removal of a pathogenic agent from [Chapter 1.3.](#) in the *Aquatic Code* is to prevent unjustified trade barriers for pathogenic agents that no longer meet the criteria for listing.

Guidance provided in this document aims to support consistency and objectivity in the interpretation of the criteria by selected experts.

WOAH recognises that, for some pathogenic agents, different subspecies, lineages or strains may have different hosts, and differ in their impact on aquatic animals. Thus, it is possible that the listing criteria may only be satisfied for some of the subspecies, lineages or strains. To address this issue, WOAHA Headquarters will provide a clear description of the pathogenic agent to be assessed including, when relevant, information on type, subtype, lineage, etc. Experts should take this into consideration and perform the assessment accordingly.



Experts should substantiate their opinion for each criterion by providing a rationale and supporting sources of scientific evidence.¹

In cases where an expert finds it difficult to conclusively assess a criterion, the expert is requested to describe the problem, noting whether it resulted from insufficient information regarding the pathogenic agent, or from difficulty in interpreting or applying the criterion.

Criteria for listing aquatic animal diseases

Article 1.2.2. of [Chapter 1.2](#). 'Criteria for listing aquatic animal diseases' of the *Aquatic Code*, provided below, describes the criteria for the inclusion of a disease in the WOAHP list.

NOTE: all terms in [Chapter 1.2](#). that appear in italics are defined terms in the [Glossary](#) of the *Aquatic Code*.

Article 1.2.2.

The criteria for the inclusion of a [disease](#) in the WOAHP list are as follows:

1. International spread of the [pathogenic agent](#) (via [aquatic animals](#), [aquatic animal products](#), [vectors](#) or fomites) is likely.

AND

2. At least one country may demonstrate country or [zone](#) freedom from the [disease](#) in susceptible [aquatic animals](#), based on provisions of Chapter [1.4](#).

AND

3. A precise [case definition](#) is available and a reliable means of detection and [diagnosis](#) exists.

AND

4.
 - a. Natural transmission to humans has been proven, and human infection is associated with severe consequences.

OR

¹ Evidence utilised to assess the criteria can come from multiple different sources which can include immediate notifications through WAHIS, WOAHP Member country self-declarations, peer reviewed scientific literature, scientific reports, advice from reference laboratory experts, other expert advice, media reports, International Database on Aquatic Animal Diseases (CEFAS), the Food and Agriculture Organization of the United Nations (FAO), the Organisation for Economic Co-operation and Development (OECD), the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), among others.



- b. The [disease](#) has been shown to affect the health of cultured [aquatic animals](#) at the level of a country or a [zone](#) resulting in significant consequences e.g. production losses, morbidity or mortality at a [zone](#) or country level.

OR

- c. The [disease](#) has been shown to, or scientific evidence indicates that it would affect the health of wild [aquatic animals](#) resulting in significant consequences e.g. morbidity or mortality at a population level, reduced productivity or ecological impacts.

Guidance for interpreting criteria

The following section provides specific guidance for experts on how to interpret each criterion.

CRITERION 1. International spread of the *pathogenic agent (via aquatic animals, aquatic animal products, vectors or fomites)* is likely.

Guidance

When assessing a pathogenic agent against this criterion, the criterion should be considered met if:

1. international trade in aquatic animal species susceptible to the disease exists or is likely to develop;

AND

2. under international trading practices, the entry and establishment of the disease is likely;

OR

3. if there has been a disease occurrence associated with international movements.

The criterion does not require that international spread of a pathogenic agent has been proven because this would not be consistent with WOA's mandate to prevent disease transmission through trade. This is especially important for aquatic animal diseases because eradication is often not possible once they have spread.

CRITERION 2. At least one country may demonstrate country or zone freedom from the *disease* in susceptible *aquatic animals*, based on provisions of Chapter 1.4.

Guidance

When assessing a pathogenic agent against this criterion, there should be evidence to indicate that at least one country may be declared 'free' of the disease (at country or zone level) if the surveillance principles outlined in Chapter 1.4. of the *Aquatic Code* were to be applied.



The criterion does not require that a country has declared freedom from the disease (at country or zone level), but that one or more countries has the potential to do so. The minimum requirement would be information from surveillance (including results from disease investigations, if available) indicating the absence of clinical disease in countries with susceptible species and conditions conducive to expression of the disease.

Information demonstrating the disease-free status for a country or zone for the disease, or ongoing programmes to achieve free status (including preliminary results of surveillance) should be considered.

CRITERION 3. A precise case definition is available and a reliable means of detection and diagnosis exist.

Guidance

When assessing a pathogenic agent against this criterion, the evaluators should consider the definitions for 'case' and 'case definition'; as per the Glossary of the *Aquatic Code*, i.e. :

- 'case' means an individual *aquatic animal* infected by a *pathogenic agent*, with or without clinical signs.
- 'case definition' is a set of criteria used to distinguish a *case animal* or an *epidemiological unit* from a non-case.

NOTE: 'aquatic animal', 'pathogenic agent' and 'epidemiological unit' are also Glossary defined terms in the *Aquatic Code*.

The case definition needs to be formulated to combine test results and other factors to reliably identify cases of the disease and distinguish them from non-cases and other diseases. The assessment should take into account all variants of the pathogenic agent, including those that do not cause clinical signs of disease. This definition should be supported by documented scientific evidence.

A diagnostic test should be widely available and preferably have undergone a formal standardisation and validation process using routine field samples (in accordance with [Chapter 1.1.2.](#) of the *Aquatic Manual*). In order to provide critical evaluation of this criteria and make very obvious any challenges with the available test methods, the assessment should include a table that summarizes all test methods available, degree of validation that tests have undergone (sensitivity/specificity etc.), limitations, suitability for different purposes (apparently healthy versus clinically affected), and surveillance for freedom at the country zone or compartment level.

CRITERION 4.

- a) **Natural transmission to humans has been proven, and human infection is associated with severe consequences.**

Guidance



When assessing a pathogenic agent against this criterion, this criterion should be considered met if there is clear scientific evidence that the pathogenic agent is zoonotic, and that the disease has severe consequences in humans. The public health impact of the disease should be taken into consideration at the population, not only at the individual level. One-off occurrence of disease in humans is not sufficient to consider the criterion met.

- b) **The *disease* has been shown to affect the health of cultured *aquatic animals* at the level of a country or a zone resulting in significant consequences e.g. production losses, morbidity or mortality at a zone or country level.**

Guidance

When assessing a pathogenic agent against this criterion, the assessment of this criterion must include evidence that the pathogenic agent being assessed will result in losses in susceptible species. Evidence that the pathogenic agent is the causal agent of the morbidity or mortality, and that the losses are not the result of management or environmental factors (e.g. loss of production due to spawning failure) should be provided. There may be a direct economic impact of the disease or other indirect impacts such as an effect on product quality.

- c) **The *disease* has been shown to, or scientific evidence indicates that it would, affect the health of wild *aquatic animals* resulting in significant consequences e.g. morbidity or mortality at a population level, reduced productivity or ecological impacts.**

Guidance

When assessing a pathogenic agent against this criterion, the assessment using this criterion should include any evidence of declines in capture fisheries and/or negative impact on biodiversity of wild aquatic animals associated with the disease being assessed. It should also include evidence available of mortality events in wild populations² caused by the disease, if available.

² Wild aquatic animal populations can be populations that are commercially harvested (wild fisheries) and hence are an economic asset. However, consideration should also be given to impacts on populations that have ecological or environmental significance. For example, the population could consist of an endangered species of aquatic animal or declines in aquatic animals could result in significant ecological disruption.