



STANDARD OPERATING PROCEDURE FOR DETERMINING WHETHER AN AQUATIC ANIMAL DISEASE SHOULD BE CONSIDERED AN EMERGING DISEASE

The aim of this Standard Operating Procedure (SOP) is to facilitate the notification to the World Organisation for Animal Health (WOAH) of emerging diseases¹ of aquatic animals by WOAH Members.

The SOP documents the process and defines the roles and responsibilities of the Aquatic Animal Health Standards Commission, subject-matter experts, WOAH Headquarters, and Members.

Standard Operating Procedure

Scope:	<p>This SOP describes the process to be followed for determining if an aquatic animal disease meets the <i>Aquatic Code</i> definition of an 'emerging disease', and subsequent actions.</p> <p>The procedure is composed of four components:</p> <ul style="list-style-type: none">A. Identification of an aquatic animal disease to be considered;B. Decision to initiate the process of assessment;C. Assessment of an emerging disease;D. Actions for a disease recognised as an emerging disease by the AAHSC;E. Actions for diseases no longer considered as emerging diseases by the AAHSC;F. actions for diseases assessed as not meeting the definition of an emerging disease by the AAHSC.
Related documents:	Guidance for the interpretation of the <i>Aquatic Code</i> definition of emerging disease (' Annex 1 ').
List of acronyms:	<p><i>Aquatic Code</i>: <i>Aquatic Animal Health Code</i></p> <p>AAHSC: Aquatic Animal Health Standards Commission</p> <p>HoD: Head of Department</p> <p>WAHIAD: WOAH World Animal Health Information and Analysis Department</p> <p>WAHIS: World Animal Health Information System</p>

¹ *Emerging disease* means a *disease*, other than *listed diseases*, which has a significant impact on *aquatic animal* or public health resulting from: a change of known *pathogenic agent* or its spread to a new geographic area or species; or a newly recognised or suspected *pathogenic agent* (as defined in the *Aquatic Code*, 2022 edition).

A. IDENTIFICATION OF AN AQUATIC ANIMAL DISEASE TO BE CONSIDERED

Step	Time Reference	Responsible	Action	Reference Document
A-1	Before the next AAHSC meeting	AAHSC, Secretariat	A member of the AAHSC or the WOAH Secretariat proposes a disease to be considered for assessment for meeting the definition of an 'emerging disease ¹ '. Go to B-1.	
A-2	Before the next AAHSC meeting	WOAH Member, Reference Centre expert, <i>ad hoc</i> Groups	Submits a request to WOAH Secretariat AAC.Secretariat@woah.org that a disease be considered for assessment for meeting the definition of an 'emerging disease ¹ ' Go to B-1	
A-3	Before the next AAHSC meeting	WAHIAD	WAHIAD prepares a report: i) of possible diseases to be considered for assessment by the AAHSC based on rumours, other reports or notifications received; ii) summarising the immediate notifications received for previously assessed emerging diseases through WAHIS to be considered by the AAHSC. Go to A-1.	

B. DECISION TO INITIATE THE PROCESS OF ASSESSMENT

Step	Time Reference	Responsible	Action	Reference Document
B-1	Before the next AAHSC pre-meeting preparatory call	Secretariat	Presents any requests received for diseases to be considered as meeting the definition of an 'emerging disease ¹ ' to the AAHSC. Go to B-2.	
B-2		AAHSC at pre-meeting preparatory call	Decides whether to include the request on the agenda of its next meeting. - If Yes, go to C-1; - If No, go to B-3.	
B-3		Secretariat	The Secretariat informs the submitter, as relevant, of the rationale for not proceeding with further considerations.	

C. ASSESSMENT OF AN EMERGING DISEASE

Step	Time Reference	Responsible person/entity	Action	Reference Document
C-1	Before the AAHSC meeting	AAHSC	For each disease, one of the members of the AAHSC is selected to lead, and is expected to: <ul style="list-style-type: none"> - collect available information about the disease (with assistance of the Secretariat). 	
C-2	During the AAHSC meeting	AAHSC	The AAHSC lead presents the findings and the AAHSC considers this together with any other available information, and agrees that either: <ul style="list-style-type: none"> i. the disease meets the definition of an emerging disease (Go to C-3 i.); OR ii. further information is required and agrees to reassess the disease at its next meeting if new information is available (Go to C-3 ii); OR iii. the disease does not meet the definition (Go to F-1). 	
C-3	During the AAHSC meeting	AAHSC	The considerations and conclusions (see C-2) are presented in the AAHSC report: <ul style="list-style-type: none"> i. for diseases that meet the definition of an emerging disease Members are informed that the disease should be reported to WOA in accordance with Article 1.1.4. of the <i>Aquatic Code</i>. OR ii. for diseases where further information is needed Members are requested to submit any available information on the disease to AAC.Secretariat@woah.org for the AAHSC to consider at a subsequent meeting (go to C-4). <p>Go to D.</p>	
C-4	Subsequent AAHSC meeting	AAHSC	Any new scientific information provided by Members or experts is reviewed to reassess the disease as an emerging disease. Go to C-1.	

C-5	During the AAHSC meeting	AAHSC	<p>Reviews all emerging diseases previously assessed as an emerging disease (i.e. on the WOAH Register) to decide if they:</p> <ul style="list-style-type: none"> i) Continue to meet the definition for an emerging disease (go to C-1); OR ii) Based on new evidence the disease should be assessed against the listing criteria in accordance with Chapter 1.2. of the <i>Aquatic Code</i> and the SOP for Listing (go to SOP for listing); OR iii) If a disease does not meet i. or ii above (go to E1). <p>For diseases that have been re-assessed at 6 consecutive meetings (i.e. a 3 year period) to determine if the disease continues to meet the definition for emerging disease, it should move to either ii or iii, without continuing the cycle of C5 to C1 indefinitely.</p>	SOP for listing
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D. ACTIONS FOR DISEASES CONSIDERED AS EMERGING DISEASES BY THE AAHSC

Step	Time Reference	Responsible person/entity	Action	Reference Document
D-1	Immediately after the AAHSC meeting	Secretariat	<p>Informs the data owner in WAHIAD of the disease(s) assessed and the outcome of the assessment(s) (see C-2).</p> <ul style="list-style-type: none"> - provide name of pathogenic agent and any reported susceptible species. 	
D-2		WAHIAD – Data owner	Adds the emerging disease (see C-1) to the WAHIS Register of Emerging Diseases table and in the codification system.	
D-3		Secretariat HoD – Standards Department	The Secretariat requests HoD to validate the addition of the new emerging disease to the ‘Animal Disease Portal’ on the WOAH webpage and requests Communication Department to create the link for the new emerging disease.	
D-4		Communication Department	Create the appropriate link to the new emerging disease on the Animal Disease Portal	
D-5		Secretariat and AAHSC	<p>Develops a technical disease card for the emerging disease, which is uploaded onto the AAHSC webpages, and the Animal disease portal on the WOAH website.</p> <p>Disease cards are updated at every meeting of the AAHSC.</p>	

			Informs WAHIAD when the technical disease card is published.	
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E. ACTIONS FOR DISEASES NO LONGER CONSIDERED AS EMERGING DISEASES BY THE AAHSC

Step	Time Reference	Responsible person/entity	Action	Reference Document
E-1	Immediately after the AAHSC meeting	Secretariat	Informs the WAHIAD data owner of the disease(s) assessed which are no longer considered an emerging disease(s) Requests Communication Department remove the disease from the 'Animal Disease Portal' on the WOAHP webpage and maintain the technical disease card on the AAHSC webpage for Member support.	
E-2		WAHIAD – Data Owner	Changes the status of the disease in the WAHIS Reference table and in the codification system (including assessment date).	
E-3		WAHIAD	Contacts Members with on-going or stable events to inform them that the disease is no longer considered an emerging disease.	
E-4		Communication Department	Delete the existing links on the 'Animal Disease Portal'.	

F. ACTIONS FOR DISEASES ASSESSED AS NOT MEETING THE DEFINITION OF AN EMERGING DISEASE BY THE AAHSC

Step	Time Reference	Responsible person/entity	Action	Reference Document
F-1	Immediately after the AAHSC meeting	Secretariat	Informs the WAHIAD data owner of the disease(s) assessed that did not meet the definition of an emerging disease (see C-2III).	
F-2		WAHIAD – Data Owner	Adds this disease(s) to the WAHIS Register of emerging diseases (with date assessed and appropriate links).	

GUIDANCE FOR THE INTERPRETATION OF THE AQUATIC CODE DEFINITION OF AN EMERGING DISEASE

This guidance document is intended to be used by the Aquatic Animal Health Standards Commission and other WOAHA selected experts when undertaking an assessment to determine if a disease meets the *Aquatic Code* definition of an '**emerging disease**'.

The definition of emerging disease does not apply to diseases included in Chapter 1.3. Diseases listed by the OIE.

AVAILABILITY AND QUALITY OF INFORMATION

Before undertaking the assessment, one should assess if the strength of the available scientific evidence² is sufficient for taking an informed decision. To be sufficient, the available scientific information should provide evidence on the susceptibility, virulence, and impact in the aquatic animal host and epidemiological findings on the potential role it could play in the disease epidemiology, including on disease transmission and distribution and impact on human or animal health. Information should come from a reliable source.

CURRENT DEFINITION OF EMERGING DISEASE

According to the Glossary of the *Aquatic Code* (2022 edition):

EMERGING DISEASE

means a *disease*, other than *listed diseases*, which has a significant impact on *aquatic animal* or public health resulting from:

- a) a change of known *pathogenic agent* or its spread to a new geographic area or species; or
- b) a newly recognised or suspected *pathogenic agent*.

[NOTE: terms in italics are defined terms in the Glossary of the *Aquatic Code*]

GUIDANCE FOR THE INTERPRETATION OF SOME KEY TERMS USED IN THE DEFINITION

Disease / Pathogenic agent

1. the infectious aetiology of the disease should be proven; OR
2. a pathogenic agent is strongly associated with the disease, but the aetiology is not yet known. Infectious diseases of unknown aetiology can have equally high-risk implications as those diseases where the infectious aetiology is proven. Whilst disease occurrence data are gathered, research should be conducted to elucidate the aetiology of the disease and the results be made available within a reasonable period of time.

Significant impact

In general, the significant impact should take into account the direct impact of the new occurrence of the *disease* in aquatic animals, or its consequential impact on public health.

² The provision of evidence is defined as follows: 'peer-reviewed publications, official reports, grey literature or science-based evidence provided by subject-matter experts'.

An impact can be defined as ‘**significant**’ if at least one of the following conditions is met:

1. *The disease has been shown to have a significant impact on the health of farmed aquatic animals at the level of a country or a zone taking into account the occurrence and severity of the clinical signs, including significant morbidity, mortality and/or associated direct production losses.*
 - this condition should be considered met if the assessment includes evidence¹ that the pathogenic agent is the causal agent of the mortality or morbidity, including associated loss of production, or productivity impacts such as a reduction in the quantity or quality of animal products from susceptible species. Indirect losses due to disease control activities, environmental impact (e.g. disposal, disinfection) or trade restrictions should not be considered when assessing the impact; OR
2. *The disease has been shown to, or scientific evidence indicates that it would, have a significant impact on the health of wild aquatic animals taking into account the occurrence and severity of the clinical signs, including direct economic losses and mortality, and any threat to the viability of a wild aquatic animal population.*
 - this condition should be considered met if the assessment includes any evidence¹ of actual or potential mortality or morbidity in susceptible wild aquatic animal populations and/or negative impacts on the biodiversity of wild aquatic animal associated with the disease being assessed. Consideration should also be given to impacts on populations that have ecological or environmental significance. For example, the involvement of endangered species, or mortalities in wild aquatic animal populations that could result in significant ecological disruption.
3. *Natural transmission from aquatic animals to humans is suspected, and human infection is associated with severe consequences.*
 - this condition should be considered met if there is clear scientific evidence¹ 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, and not at only at the individual, level (e.g., according to WHO-DALYs). One-off occurrence of disease in humans is not sufficient to consider the condition as met.

Change of a known pathogenic agent

- the change of a known non-WOAH-listed pathogenic agent should be interpreted as a change in the epidemiological behaviour (e.g., occurrence in a new species or change of host species range, change of transmission pathways, or unexpected increased morbidity or mortality) of the pathogenic agent itself, or the appearance of a new strain of a pathogenic agent having a significant impact on aquatic animals or public health.

New geographical area

- the spread of a non-WOAH-listed pathogenic agent to a geographical area where the disease has never been reported before. There is information suggesting that the entry and transmission of the pathogenic agent is associated with domestic or international movement of aquatic animals (including natural and non-commercial movements, such as migrations) or aquatic animal products (and associated movement of fomites), or vectors, or through passive transport through water.