

Animal

Fundada como OIE

Fondée en tant qu'OIE



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The Aquatic Animal Health Standards Commission



# Aquatic Animal Health Code





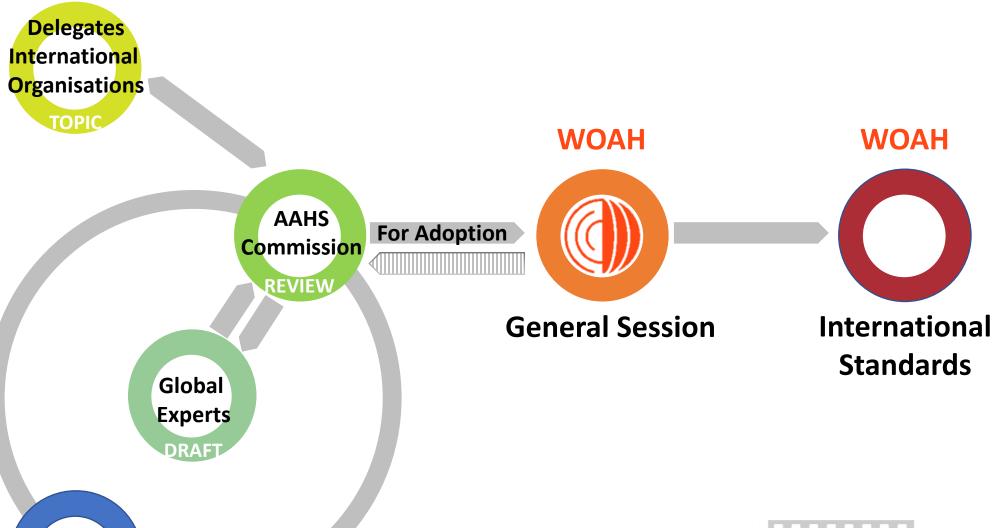
### Manual

of Diagnostic Tests for Aquatic Animals





The WOAH Standard setting process



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Delegates



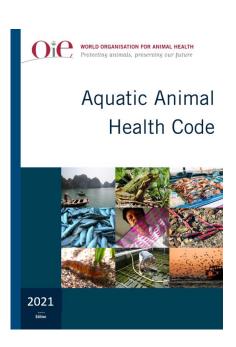


## The Aquatic Animal Health Code

## Provides standards for the improvement of aquatic animal health worldwide

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 also includes standards for the welfare of farmed fish and the use of antimicrobial agents in aquatic animals.

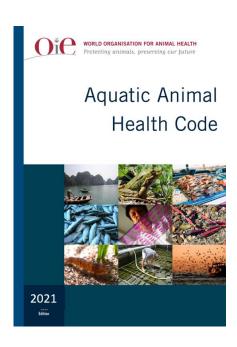


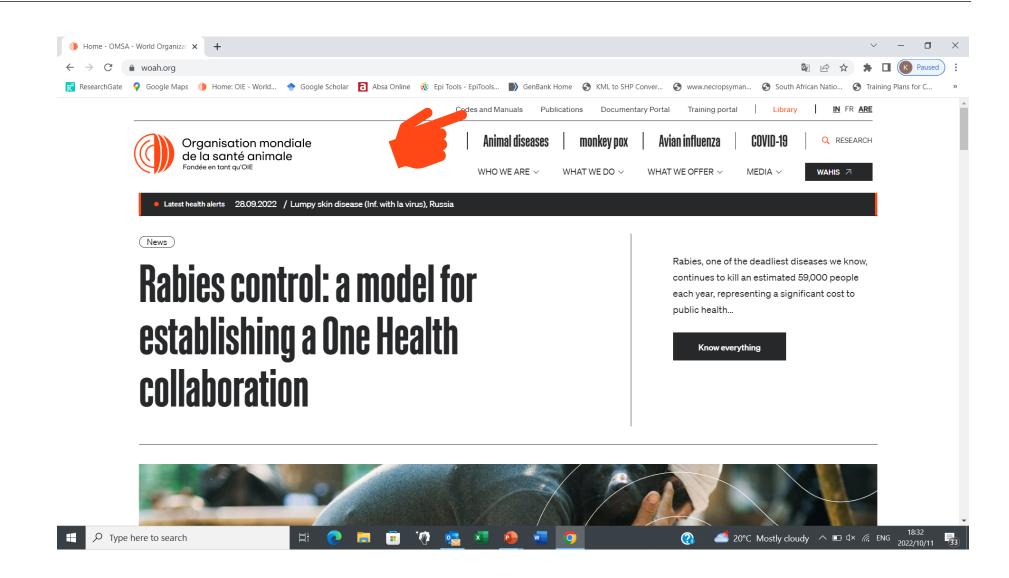
Recommends measures to be used by Veterinary Authorities or other Competent Authorities.

- For early detection, reporting and control of pathogenic agents in aquatic animals (amphibians, crustaceans, fish and molluscs).
- To prevent their spread via international trade in aquatic animals and their products, while avoiding unjustified sanitary barriers to trade.



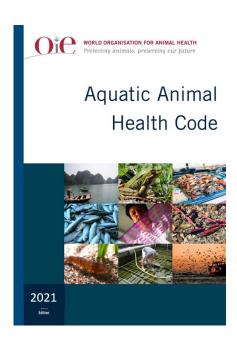
## The Aquatic Animal Health Code

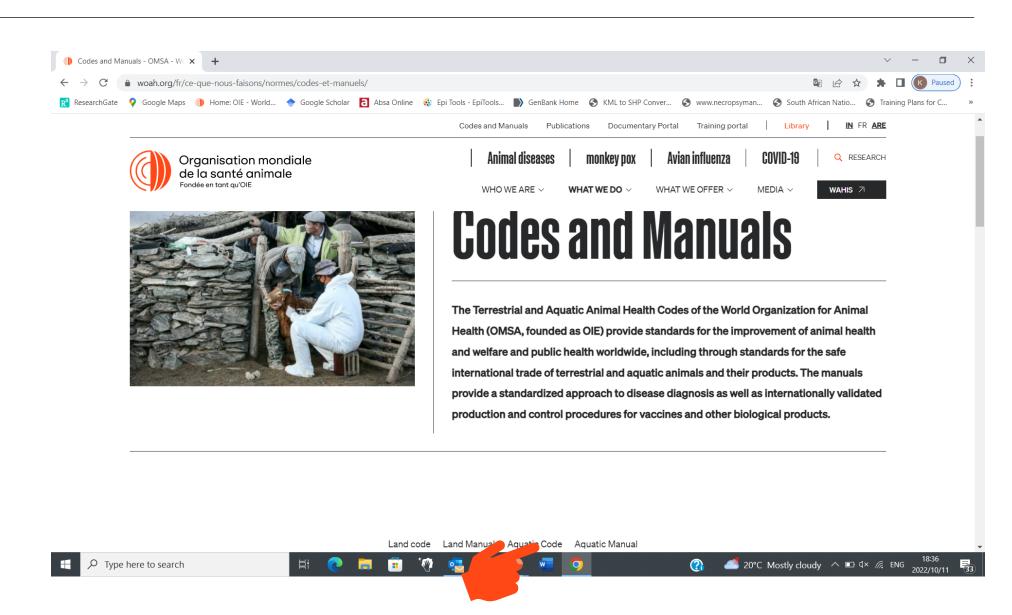




The Aquatic Animals Health Standards Commission

## The Aquatic Animal Health Code

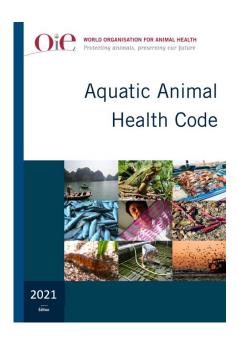


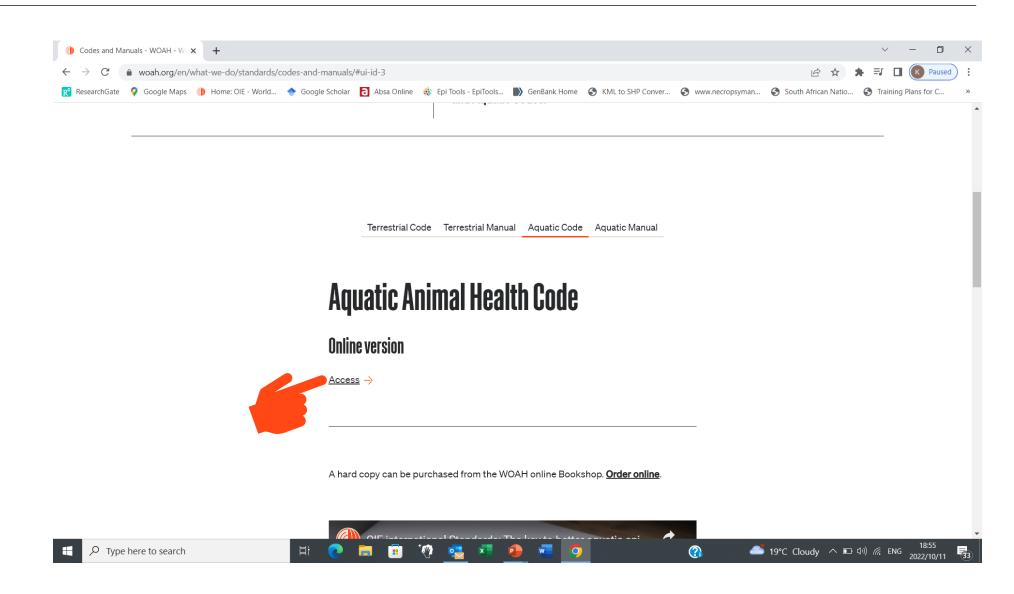


**The Aquatic Animals Health Standards Commission** 

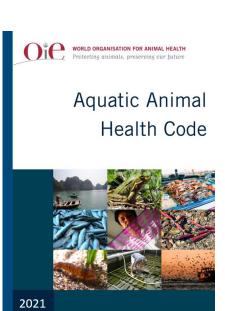


## The Aquatic Animal Health Code





Information available in the Aquatic Animal Health Code



Zoning & compartmentalisation

Guidelines for risk analysis

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Quality of Aquatic Animal Health Services

Conditions for trade

Model export certificates

Transport of farmed fish

Disease prevention and control

Surveillance for disease

Criteria for disease

freedom

Disease reporting obligations

OIE listed diseases

Disinfection of aquaculture establishments and equipment

Procedures for aquatic animal waste disposal

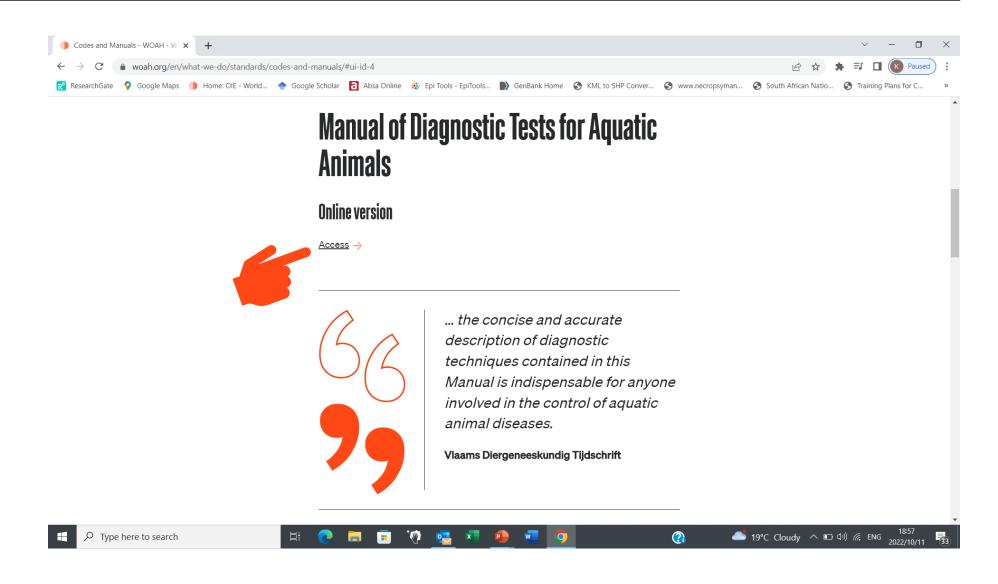
Responsible and prudent use of antimicrobial agents

Stunning and killing of farmed fish for human consumption



# The Manual of Diagnostic Tests for Aquatic Animals







### The Manual of Diagnostic Tests for **Aquatic Animals**



#### Manual

of Diagnostic Tests for Aquatic Animals



### The Manual provides:

1. Internationally agreed recommendations to support effective laboratory testing capacity.

2. Specific methods for disease diagnosis.

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3. Presents a network of WOAH reference laboratories and collaboration centers.

# The Manual of Diagnostic Tests for Aquatic Animals



#### Manual

of Diagnostic Tests for Aquatic Animals

2021



Table 4.1. OIE recommended diagnostic methods and their level of validation for surveillance of apparently healthy animals and investigation of clinically affected animals

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Method	A. Surveillance of apparently healthy animals				B. Presumptive diagnosis of clinically affected animals			C. Confirmatory diagnosis¹ of a suspect result from surveillance or presumptive diagnosis				
	Early life stages <sup>2</sup>	Juveniles <sup>2</sup>	Adults	LV	Early life stages <sup>2</sup>	Juveniles <sup>2</sup>	Adults	LV	Early life stages <sup>2</sup>	Juveniles <sup>2</sup>	Adults	LV
Wet mounts												
Histopathology <sup>3</sup>						++	++	1				
Cell culture						++	++	1				
Real-time PCR	+++	+++	+++	3	+++	+++	+++	3				
Conventional PCR					++	+++	+++	3 <sup>5</sup>	++	++	++	35
Conventional nested PCR	+	+	+	NA	++	++	++	NA	+	+	+	NA
Amplicon sequencing <sup>4</sup>									+++	+++	+++	1
<i>In-situ</i> hybridisation												
Bioassay												
LAMP						+++	+++	1				
IFAT						+	+	1				
ELISA												
Other antigen detection methods												
Other method												

LV = level of validation, refers to the stage of validatio



; LAMP = loop-mediated isothermal amplification; ively.

<sup>1</sup>For confirmatory diagnoses, methods need to be carried out in combination (see Section 6). <sup>2</sup>Susceptibility of early and juvenile life stages is described in Section 2.2.3.

# The Manual of Diagnostic Tests for Aquatic Animals



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of Diagnostic Tests for Aquatic Animals





#### 6.1. Apparently healthy animals or animals of unknown health status 1

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Apparently healthy populations may fall under suspicion, and therefore be sampled, if there is an epidemiological link(s) to an infected population. Geographic proximity to, or movement of animals or animal products or equipment, etc., from a known infected population equate to an epidemiological link. Alternatively, healthy populations are sampled in surveys to demonstrate disease freedom.

#### 6.1.1. Definition of suspect case in apparently healthy animals

The presence of infection shall be suspected if: a positive result has been obtained on at least one animal from at least one of the following diagnostic tests:

- A positive result from a real-time PCR assay
- A positive result from a conventional nested PCR assay.

#### 6.1.2. Definition of confirmed case in apparently healthy animals

The presence of infection with KHV is considered to be confirmed if at least one of the following criteria is met:

- Detection of KHV in tissue samples by real-time PCR followed by conventional PCR and sequencing of the amplicon
- Detection of KHV in tissue samples by real time PCR followed by conventional nested PCR and sequencing of the amplicon

#### 6.2. Clinically affected animals

No clinical signs are pathognomonic for infection with KHV however, they may narrow the range of possible diagnoses.



### The Manual of Diagnostic Tests for Aquatic Animals



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#### 6.2.1. Definition of suspect case in clinically affected animals

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The presence of infection shall be suspected if at least one of the following criteria is met:

- Gross pathology or clinical signs associated with infection with KHV as described in this chapter, with or without elevated mortality
- Histopathological changes consistent with infection with KHV as described in this chapter ii)
- KHV typical CPE in cell culture iii)
- A positive result by a real-time PCR iv)
- A positive result by a conventional (single round or nested) PCR V)
- A positive result by LAMP assay vi)
- A positive result by IFAT vii)

#### 6.2.2. Definition of confirmed case in clinically affected animals

The presence of infection shall be confirmed if at least one of the following criteria is met:

- KHV isolation in cell culture followed by virus identification by conventional PCR or conventional nested PCR and sequencing of the amplicon
- Detection of KHV in tissue samples by real-time PCR followed by conventional PCR or ii) conventional nested PCR and sequencing of the amplicon
- A positive result by LAMP assay followed by conventional PCR or conventional nested PCR and sequencing of the amplicon
- iv) A positive result by IFAT followed by conventional PCR or conventional nested PCR and sequencing of the amplicon

## Highlights of recent work

#### DISEASES LISTED BY THE OIE

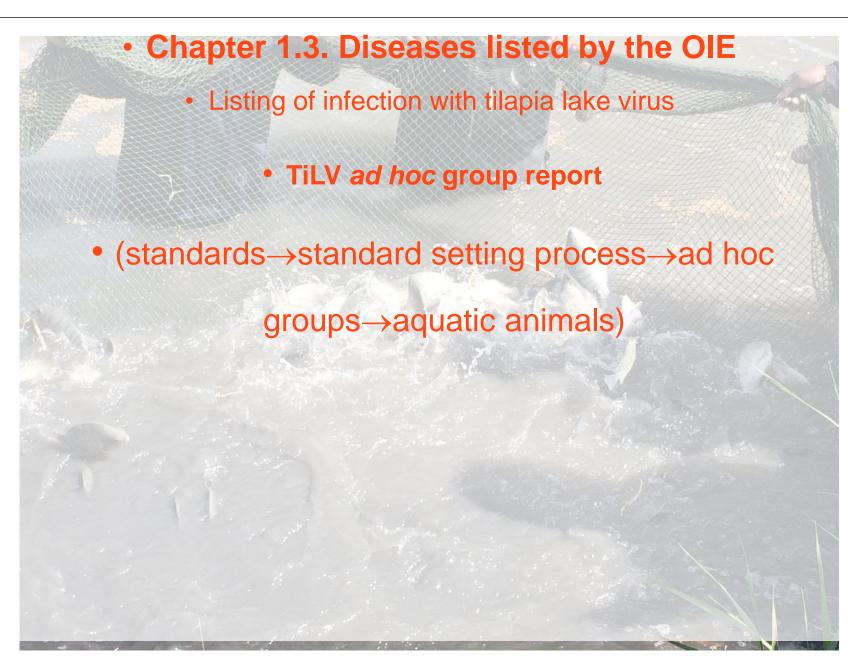
The diseases in this chapter have been assessed in accordance with Chapter 1.2. and constitute the OIE list of aquatic animal diseases.

In case of modifications of this list of aquatic animal diseases adopted by the World Assembly of Delegates, the new list comes into force on 1 January of the following year.

Article 1.3.1.

The following diseases of fish are listed by the OIE:

- Infection with Aphanomyces invadans (epizootic ulcerative syndrome)
- Infection with epizootic haematopoietic necrosis virus
- Infection with Gyrodactylus salaris
- Infection with HPR-deleted or HPR0 infectious salmon anaemia virus
- Infection with infectious haematopoietic necrosis virus
- Infection with koi herpesvirus
- Infection with red sea bream iridoviru
- Infection with salmonid alphavirus
- Infection with spring viraemia of carp virus
- Infection with tilapia lake virus
- Infection with viral haemorrhagic septicaemia virus.



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## Highlights of recent work

### Chapter 1.4. Aquatic Animal Disease Surveillance

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#### CHAPTER 1.4.

#### AQUATIC ANIMAL DISEASE SURVEILLANCE

#### Article 1.4.1.

#### .....

This chapter provides guidance on the surveillance approaches to be used by a Competent Authority to make and maintain a self-declaration of freedom from disease or to confirm the occurrence of a listed disease or an emerging disease.

#### Article 1.4.2.

#### Introduction and scope

This chapter supports a Competent Authority to meet the requirements for self-declaration of freedom from disease at the level of a country, zone or compartment, and for maintenance of freedom, that are presented in each disease-specific chapter. It also provides a Competent Authority with guidance to meet the requirements of notification of a listed disease or an emerging disease in accordance with Chapter 1.1.

This chapter is not intended to provide detailed technical guidance on surveillance design or analysis. Competent Authorities are encouraged to consult published literature and seek appropriate expertise to design and analyse surveillance programmes that meet the requirements of the Aquatic Code.

- 1) The general requirements of a surveillance system necessary to support a self-declaration of freedom from disease
- The criteria that have been used to set the periods specified in each disease-specific chapter for basic biosecurity
  conditions to be in place, or for targeted surveillance that should be undertaken, prior to claiming freedom, are
  included in Articles 1.4.9, and 1.4.10.
- The requirements for each of the four pathways for claiming freedom, and for maintaining freedom, are introduced in Article 1.4.3. and described in detail in Articles 1.4.11. to 1.4.15.
- Guidance on the design of surveys to demonstrate freedom from disease, and for combining multiple sources of surveillance information are provided in Articles 1.4.16. and Article 1.4.17., respectively.
- 5) Article 1.4.18. provides guidance on diagnostic confirmation of listed diseases or an emerging disease.

Competent Authorities should refer to the relevant disease-specific chapter of the Aquatic Manual for recommendations on sample collection and appropriate diagnostic methods for surveillance and diagnosis of listed diseases. The relevant disease-specific chapter of the Aquatic Manual should also be consulted for the necessary information on epidemiology and diagnostic performance of assays required for surveillance programme design.

#### Article 1.4.3.

#### Pathways for demonstrating freedom from disease

Competent Authorities may use one of four pathways to make a self-declaration of freedom from disease. Each pathway outlines the aquate aimfal health circumstances and requirements that should be met for a self-declaration to be made. Any one of these four pathways may be utilised; however, a Competent Authority should provide evidence that all relevant requirements to demonstrate disease freedom have been met as described in this chapter and the relevant disease-specific chapter of the Aquatic Code including when water bodies are shared with other countries or are under the control of different Competent Authorities. The four pathways are:

Pathway	Primary Evidence	Secondary Evidence	Level of application
1. Absence of susceptible species	Surveys, Historical data, Import records, Environmental information	None	Country, Zone
2. Historical freedom	Passive surveillance (Early Detection System)	Targeted surveillance	Country, Zone
3. Targeted surveillance	Targeted surveillance	Passive surveillance	Country, Zone, Compartment
4. Returning to freedom	Targeted surveillance	Passive surveillance	Country, Zone, Compartment

## Highlights of recent work

# Chapter 4.1., Biosecurity for Aquaculture Establishments

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(new chapter)

SECTION 4.

DISEASE PREVENTION AND CONTROL

CHAPTER 4.1.

### BIOSECURITY FOR AQUACULTURE ESTABLISHMENTS

Article 4.1.1.

#### Purpose

To provide recommendations on the development and implementation of biosecurity measures primarily to mitigate the risk of the introduction of specific pathogenic agents into aquaculture establishments, and if pathogenic agents are introduced, to mitigate the risk of further spread within, or release from, the aquaculture establishment.



# Environmental DNA methods for aquatic animal disease surveillance

https://www.woah.org/en/document/the-use-of-environmental-dna-methods-for-detection-of-woah-listed-aquatic-animal-diseases/

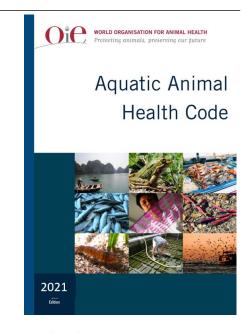




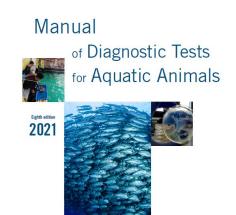
## New work of the commission

- Chapter 4.3. Application of compartmentalisation
- New Chapter 5.X. Ornamental aquatic animals
- New Chapter 5.Y. Trade of genetic materials
- New Chapter Emergency Disease Preparedness

Section 2.2. Diseases of molluscs







### Thank you

