



Organisation
Mondiale
de la Santé
Animale

World
Organisation
for Animal
Health

Organización
Mundial
de Sanidad
Animal

**Regional Seminar OIE National Focal Points for Veterinary Products
Entebbe, Uganda, 1-3 December 2015**

Terrestrial and Aquatic Manuals and mechanism of standard adoption

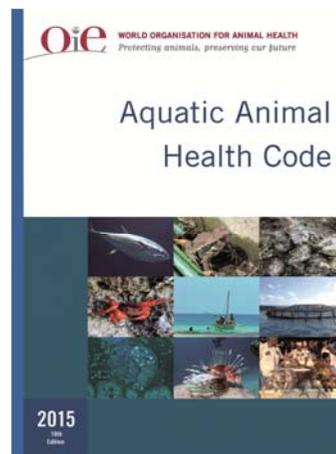
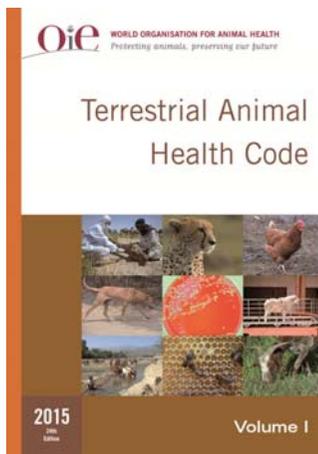
Dr Francois Diaz
Scientific and Technical Department, OIE Headquarters

OIE Standards



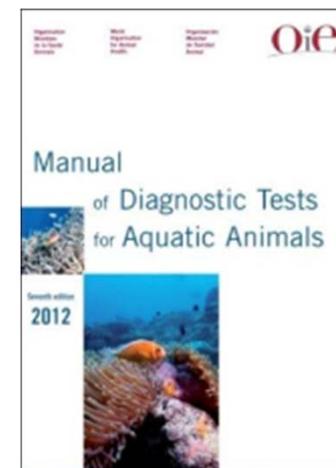
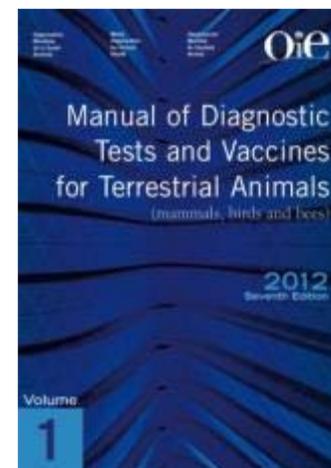
CODES

- Terrestrial
- Aquatic



MANUALS

- Terrestrial
- Aquatic



Codes and Manuals available on the OIE website

Specialist Commissions



Terrestrial Animal Health Standards Commission “Code Commission”

Responsible for updating the *Terrestrial Animal Health Code* annually; proposes new standards for adoption by the World Assembly of Delegates.

Responsible for ensuring that the Code reflects current scientific information.

Scientific Commission for Animal Diseases “Scientific Commission”

Assists in identifying the most appropriate strategies and measures for disease surveill., prevention, control

Examines Members’ request regarding their official animal health status, for MCs that wish to be included on the OIE official list of countries or zones free from certain diseases

Aquatic Animal Health Standards Commission “Aquatic Animals Commission”

Compiles information on aquatic diseases and recommends appropriate prevention and control methods for these diseases.

Responsible for updating the *Aquatic Code and Manual*; and for proposing new standards for adoption by the World Assembly of Delegates.

Biological Standards Commission “Laboratories Commission”

Establishes/approves methods for:

- diagnostic of terrestrial animals diseases
- defining quality criteria of biological products (vaccines)

Oversees production and adoption of the *Terrestrial Manual*. Advises the Director General in supervising the global network of OIE Reference Centers

Specialist Commissions



Terrestrial Animal Health Standards Commission “Code Commission”

Responsible for updating the *Terrestrial Animal Health Code* annually; proposes new standards for adoption by the World Assembly of Delegates.

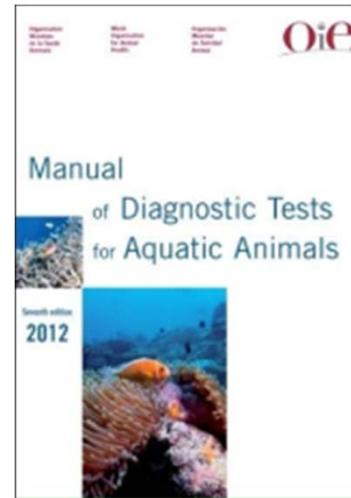
Responsible for ensuring that the Code reflects current scientific information.

Scientific Commission for Animal Diseases “Scientific Commission”

Assists in identifying the most appropriate strategies and measures for disease surveill., prevention, control

Examines Members’ request regarding their official animal health status, for MCs that wish to be included on the OIE official list of countries or zones free from certain diseases

Aquatic Animal Health Standards Commission “Aquatic Animals Commission”



Biological Standards Commission “Laboratories Commission”

Establishes/approves methods for:

- diagnostic of terrestrial animals diseases
- defining quality criteria of biological products (vaccines)

Oversees production and adoption of the *Terrestrial Manual*. Advises the Director General in supervising the global network of OIE Reference Centers

Specialist Commissions



Terrestrial Animal Health Standards Commission “Code Commission”

Responsible for updating the *Terrestrial Animal Health Code* annually; proposes new standards for adoption by the World Assembly of Delegates.

Responsible for ensuring that the Code reflects current scientific information.

Scientific Commission for Animal Diseases “Scientific Commission”

Assists in identifying the most appropriate strategies and measures for disease surveill., prevention, control

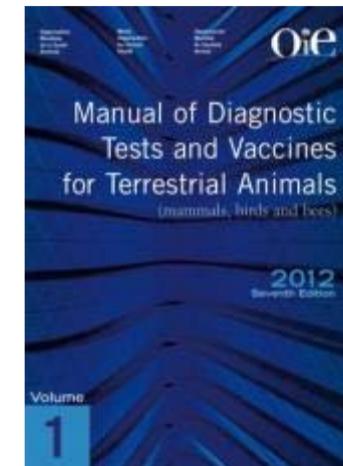
Examines Members’ request regarding their official animal health status, for MCs that wish to be included on the OIE official list of countries or zones free from certain diseases

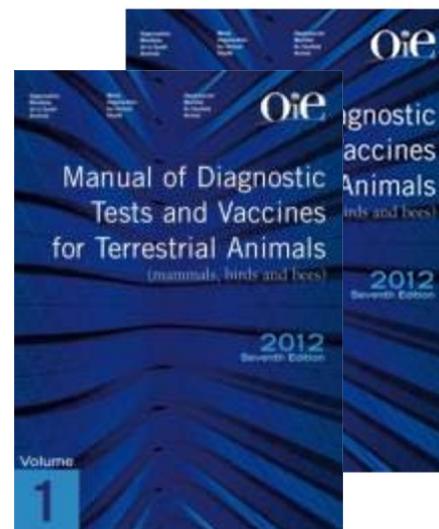
Aquatic Animal Health Standards Commission “Aquatic Animals Commission”

Compiles information on aquatic diseases and recommends appropriate prevention and control methods for these diseases.

Responsible for updating the *Aquatic Code and Manual*; and for proposing new standards for adoption by the World Assembly of Delegates.

Biological Standards Commission “Laboratories Commission”





OIE
Terrestrial Manual
-
Overview

Terrestrial manual - Purpose

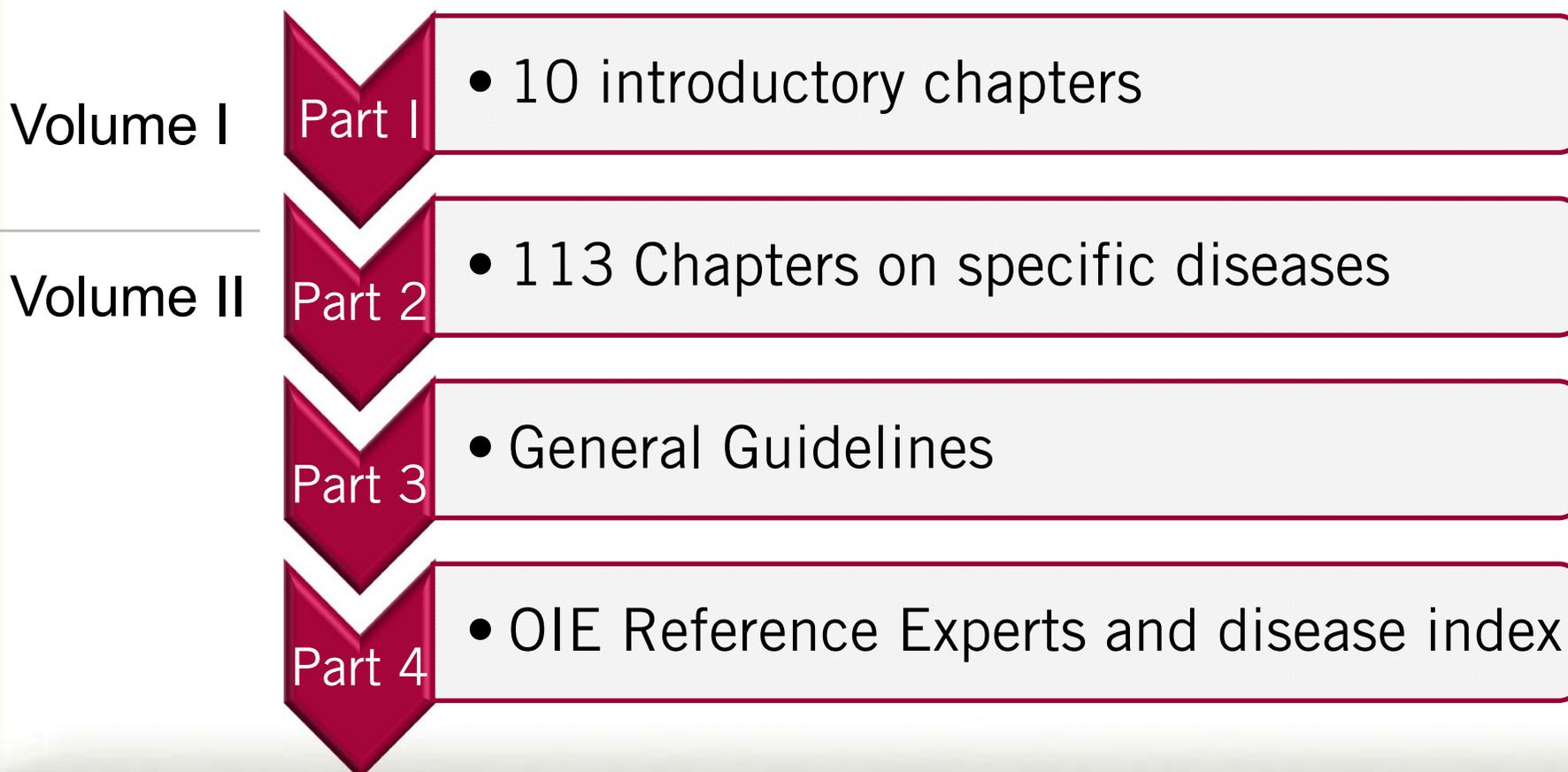


- Describes internationally agreed **standard** laboratory methods for disease **diagnosis**
- Describes requirements for the production and control of **vaccines** and other biological products
- First published in 1989, updated every 4 years, most recent print: 7th edition of 2012
- Available in full and up to date on line in English and Spanish at <http://www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/>

Terrestrial Manual



Terrestrial manual – structure → Divided into 4 parts, presented in 2 volumes:



Terrestrial Manual – Before part 1



- Introduction (How to use this *Terrestrial Manual*)
- List of tests for International trade
- Common abbreviations used in this *Terrestrial Manual*
- Glossary of terms
- Contributors

Terrestrial Manual – Part 1



General standards

Section 1.1.	Introductory Chapters
Chapter 1.1.0.	<u>Management of veterinary laboratories</u>
Chapter 1.1.1.	<u>Collection, submission and storage of diagnostic specimens</u>
Chapter 1.1.2.	<u>Transport of specimens of animal origin</u>
Chapter 1.1.3.	<u>Biosafety and biosecurity: standard for managing biological risk in the veterinary diagnostic laboratory and animal facilities</u>
Chapter 1.1.4.	<u>Quality management in veterinary testing laboratories</u>
Chapter 1.1.5.	<u>Principles and methods of validation of diagnostic assays for infectious diseases</u>
Chapter 1.1.6.	<u>Principles of veterinary vaccine production (including diagnostic biologicals)</u>
<i>Chapter 1.1.7.</i>	<u>Tests for sterility and freedom from contamination of biological materials</u>
<i>Chapter 1.1.8.</i>	<i>Minimum requirements for vaccine production facilities (under study)</i>
Chapter 1.1.9.	<i>Quality control of vaccines (under study)</i>
Chapter 1.1.10.	<u>International standards for vaccine banks</u>

Terrestrial Manual – Part 2



- 113 Chapters on specific diseases:
OIE listed diseases + other diseases of importance to international trade
 - Subdivided by:
 - Multiple species (7)
 - Apinae (1)
 - Aves (3)
 - Bovinae (3) *(end vol.1)*
 - Equidae (1)
 - Leporidae (1)
 - Caprinae (2)
 - Suidae (1)
 - Other Diseases (4)
- (x) = updated in 2015*

Terrestrial Manual – Part 2



Structure of the guidelines on specific diseases

- Each disease chapter (except FMD) is developed following this template:
 - Summary
 - A. Introduction
 - B. Diagnostic techniques
 - C. Requirements for vaccines and diagnostic biologicals
 - References

Terrestrial Manual – Part 2



Structure of the guidelines on specific diseases

- Each disease chapter (except FMD) is developed following this template:
 - **Summary**
 - A. Introduction
 - B. Diagnostic techniques
 - C. Requirements for vaccines and diagnostic biologicals
 - References

Terrestrial Manual – Part 2



Structure of the guidelines on specific diseases

- Each disease chapter (except FMD) is developed following this template:
 - Summary
 - **A. Introduction**
 - B. Diagnostic techniques
 - C. Requirements for vaccines and diagnostic biologicals
 - References

Terrestrial Manual – Part 2



Structure of the guidelines on specific diseases

- Each disease chapter (except FMD) is developed following this template:
 - Summary
 - A. Introduction
 - **B. Diagnostic techniques**
 - C. Requirements for vaccines and diagnostic biologicals
 - References

Diagnostic techniques in disease specific chapters



Three possible categories of tests are described in Part B of the disease-specific chapters:

1. Prescribed tests,
2. Alternative tests, and
3. Other tests

Prescribed tests

- **Prescribed tests** are required by the *Terrestrial Code* for the testing of animals before they are moved internationally.
- Printed in **blue** in the relevant disease-specific chapters.
- All prescribed tests are listed in the table: « *list of tests for international trade* », page XI in each of the two volumes of the *Terrestrial Manual*.

Alternative tests / Other tests



- Alternative tests are suitable for the diagnosis of disease within a local context, and can also be used in the import/export of animals after bilateral agreement.
- The alternative tests are also listed in the table: « *list of tests for international trade* », page XI in each of the two volumes.
- Often other tests are described, which may be of practical value in local situations or which may still be under development.

Diagnostic tests – fitness for purpose *new approach*



Table 1. Test methods available for the diagnosis of equine infectious anaemia and their purpose

Method	Purpose			
	Population freedom from infection/ efficiency of eradication policies	Individual animal freedom from infection	Confirmation of clinical cases	Prevalence of infection – surveillance
Agar gel immunodiffusion	++	++	++	++
Enzyme-linked immunosorbent assay	++	++	+	+
Immunoblot	-	++	++	-
Polymerase chain reaction	-	+/-	+	-
Virus isolation/horse inoculation	-	-	+	-

Key: +++ = recommended method; ++ = suitable method; + = may be used in some situations, but cost, reliability, or other factors severely limits its application; - = not appropriate for this purpose.

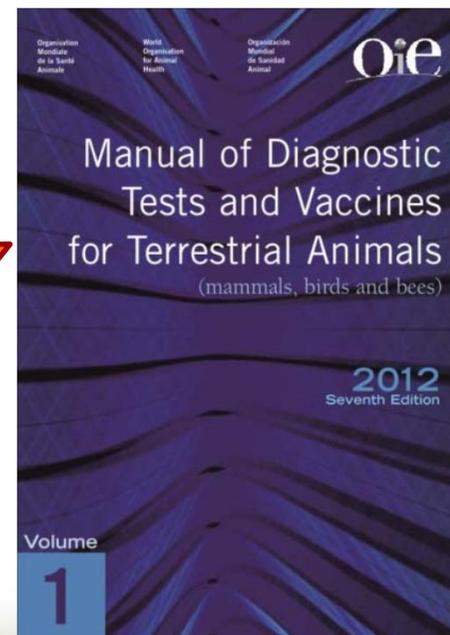
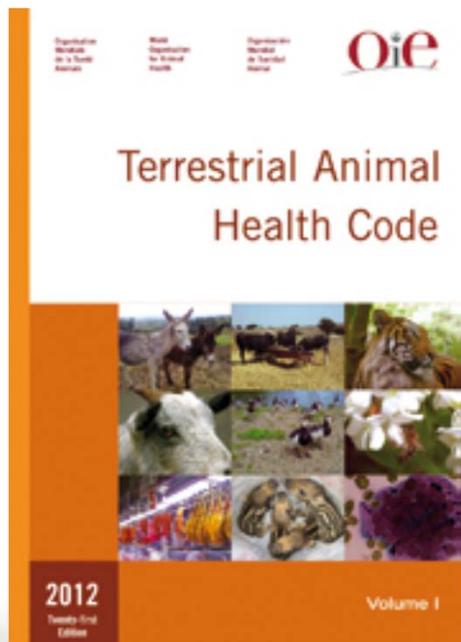
Although not all of the tests listed as category +++ or ++ have undergone formal standardisation and validation, their routine nature and the fact that they have been used widely without dubious results, makes them acceptable.

Example: Equine Infectious Anaemia

Relation between *Manual* and *Code*



Where the *Terrestrial Code* requires that tests are carried out for international movement, the *Terrestrial Manual* should provide a recommended laboratory method.



Terrestrial Manual – Part 2



Structure of the guidelines on specific diseases

- Each disease chapter (except FMD) is developed following this template:
 - Summary
 - A. Introduction
 - B. Diagnostic techniques
 - **C. Requirements for vaccines and diagnostic biologicals**
 - References

Terrestrial Manual – Part 2



Structure of the guidelines on specific diseases

- Each disease chapter (except FMD) is developed following this template:
 - Summary
 - A. Introduction
 - B. Diagnostic techniques
 - C. Requirements for vaccines and diagnostic biologicals
 - **References**

General Guidelines

- 3.1 Laboratory methodologies for bacterial antimicrobial susceptibility testing
- 3.2 Biotechnology in the diagnosis of infectious diseases
- 3.3 The application of biotechnology to the development of veterinary vaccines
- 3.4 The role of official bodies in the international regulation of veterinary biologicals
- 3.5 Managing biorisk: examples of aligning risk management strategies with assessed biorisks *
- 3.6 OIE Validation Guidelines *

** Approved in May 2015*

Terrestrial Manual – Part 3



OIE Validation Guidelines

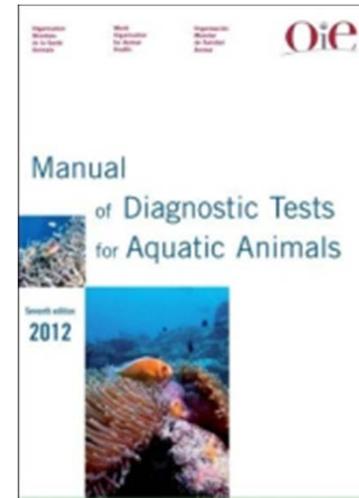
- 3.6.1 Development and optimisation of antibody detection assays
- 3.6.2 Development and optimisation of antigen detection assays
- 3.6.3 Development and optimisation of nucleic acid detection assays
- 3.6.4 Measurement uncertainty
- 3.6.5 Statistical approaches to validation
- 3.6.6 Selection and use of reference samples and panels
- 3.6.7 Principles and methods for the validation of diagnostic tests for infectious diseases applicable to wildlife
- 3.6.8 Comparability of assays after minor changes in a validated test method (under study)*

Terrestrial Manual – Part 4



OIE Reference Experts and Disease Index

- List of OIE Reference Laboratories
- Alphabetical list of diseases



OIE
Aquatic Manual
-
Overview

Manual of diagnostic tests for aquatic animals



- **Describes internationally agreed standard laboratory methods for disease diagnosis**
- Manual is produced every 1 - 2 years, updates are published on-line in real time
- Available in full and up to date on line in English and Spanish at:
<http://www.oie.int/en/international-standard-setting/aquatic-manual/access-online//>



Aquatic Manual - Structure



- **Part 1:** general chapters for veterinary laboratories
 - Quality management in veterinary testing laboratories
 - Principles and methods of validation of diagnostic assays for infectious diseases
 - Methods for disinfection of aquaculture establishments
- **Part 2:** specific disease chapters by
 - Amphibians: 2 diseases
 - Crustaceans: 10 diseases (1 new in 2014)
 - Fish: 12 diseases (4 new in 2014)
 - Molluscs: 9 diseases (1 new in 2014)



Aquatic manual – structure of disease chapters

Chapters of **Part 2** follow this structure:

- Scope
- Disease information
- Sampling
- Diagnostic methods
- Rating of tests against purpose of use
- Tests recommended for the declaration of disease freedom
- Corroborative diagnostic criteria

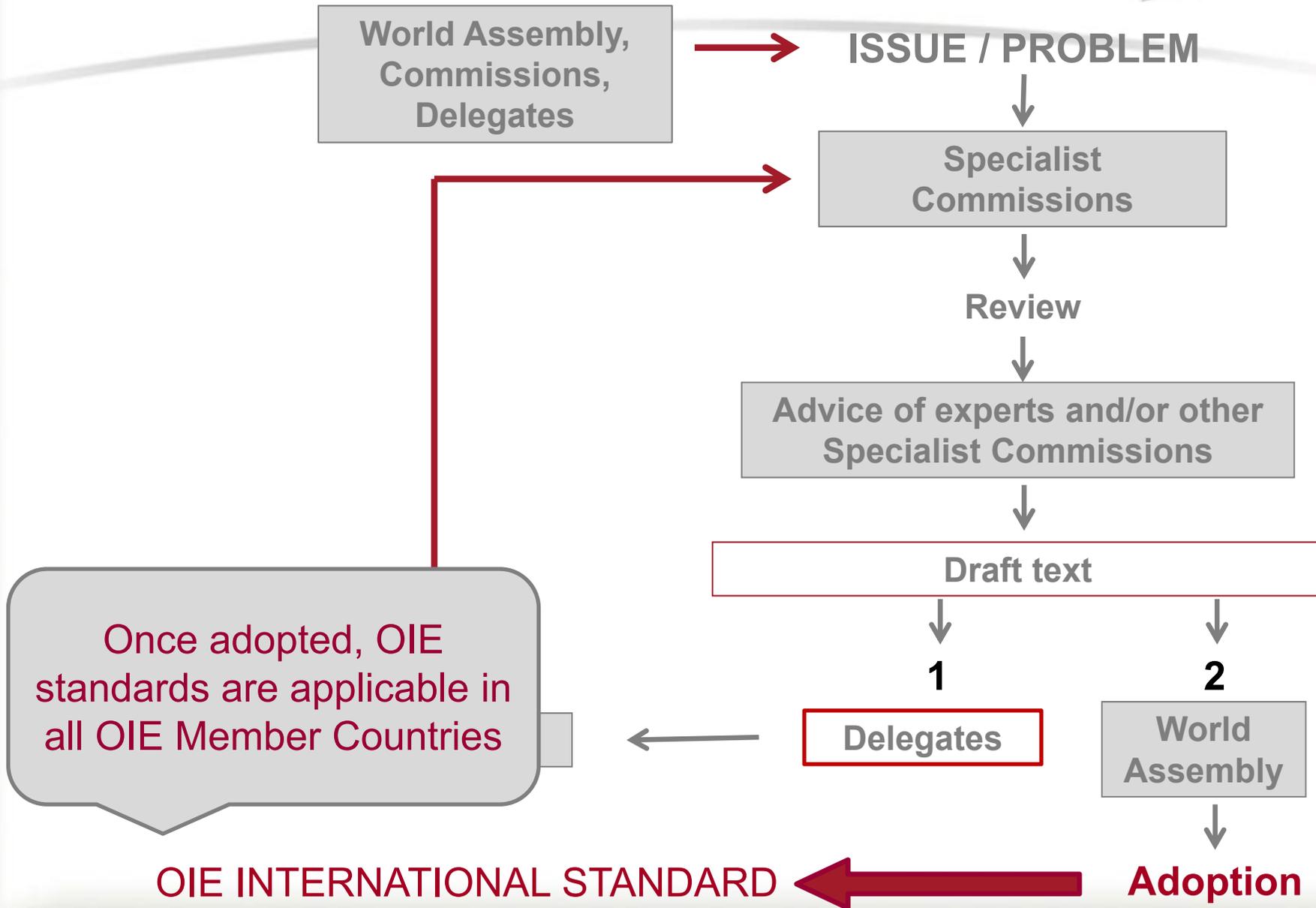


Rating of tests against purpose

Table 5.1. Methods for targeted surveillance and diagnosis

Method	Targeted surveillance				Presumptive diagnosis	Confirmatory diagnosis
	Ova/milt	Fry/fingerlings	Juveniles	Adults		
Gross signs	na	d	d	d	d	d
Histopathology	na	d	d	d	b	d
Immunoperoxidase stain	na	c	c	c	c	c
Transmission EM	na	d	d	d	c	b
Immuno-EM	na	d	d	d	c	b
Cell culture	na	a	a	a	a	b
Antigen-capture ELISA	na	a	a	a	a	a
Antibody-capture ELISA	na	d	d	c	c	d
PCR-REA	na	d	a	d	c	a
PCR sequence analysis	na	d	d	d	c	a

OIE Standard Setting Process



Where to find the Manuals on line?



For the media

- Public health and animal health experts review knowledge of SARS-CoV
 - Update August 2014 - Questions & Answers on Middle East Respiratory Syndrome Coronavirus (MERS-CoV)
 - Evaluating the relationship between human and animal health
- [+View all press releases](#)
[+Access all media](#)

Highlights

A new film explaining Animal Health Information (WAHIS)



Overview

- Application of compartmentalisation
- Introduction to Specialist Commissions
- Devising import measures
- Commodity-based approach
- Standard-Setting: The Code
- Legal rights and obligations

Terrestrial code

[Access online](#)

Terrestrial manual

[Access online](#)

Aquatic code

[Access online](#)

Aquatic manual

[Access online](#)

Specialists commission

Code Commission & Reports

Laboratories Commission & Reports

Working Groups & Reports

Implications of private standards

Editorial

Protecting bees to safeguard our future



Beekeeping is an integral part of farming in every region of the world, as either a core or side-line business. Often it is small-scale and, in many

Most recent issues:

* Animal welfare: focusing on the future, Vol. **33** (1), April 2014

* Coordinating surveillance policies in animal health and food safety 'from farm to fork', Vol. **32** (2), August 2013

Available free of charge

Available in EN, SP

Thank you for your attention



Organisation
Mondiale
de la Santé
Animale

World
Organisation
for Animal
Health

Organización
Mundial
de Sanidad
Animal

12 rue de Prony, 75017 Paris, France – www.oie.int – oie@oie.int

