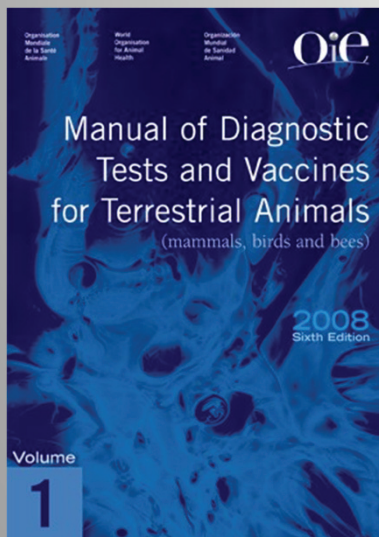
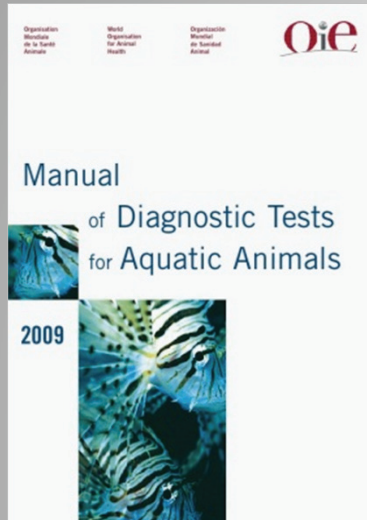


oie



THE OIE MANUAL OF DIAGNOSTIC TESTS AND VACCINES FOR TERRESTRIAL & AQUATIC ANIMALS

VMP Focal point training

Casablanca

6 - 8 December 2011

Dr Susanne Münstermann

OUTLINE

- The OIE Specialist Commissions and their mandate

- The Terrestrial Manual - overview
 - Diagnostic Tests
 - Vaccines

- The Aquatic Manual - overview
 - Diagnostic Tests
 - Vaccines

OIE'S INTERNATIONAL STANDARDS

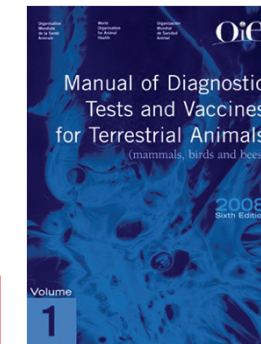
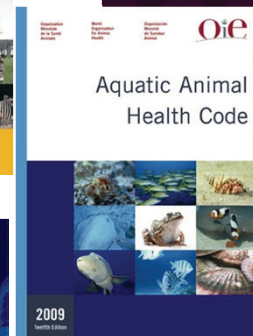
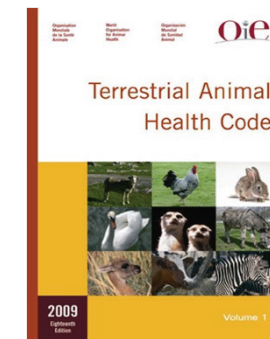
*Terrestrial Animal Health Code –
mammals, birds and bees*

*Aquatic Animal Health Code – fish,
molluscs and crustaceans*

*Manual of Diagnostic Tests and Vaccines
for Terrestrial Animals*

*Manual of Diagnostic Tests for
Aquatic Animals*

*OIE Quality Standard and Guidelines for
Veterinary Laboratories: Infectious
Diseases*



Specialist Commissions

Terrestrial Animal Health Standards Commission
"Code Commission"

Scientific Commission for Animal Diseases
"Scientific Commission"

Biological Standards Commission
"Laboratories Commission"

Aquatic Animal Health Standards Commission
"Aquatic Animals Commission"

Biological Standards Commission "Laboratories Commission"

- Six Members elected by the World Assembly of Delegates for a 3-year term
- Approves **OIE Reference Laboratories/OIE Collaborating Centres/Laboratory Twinning**
- Provides scientific advice for Standards related to diagnostics for eventual inclusion in the *Terrestrial Code*
- **Develops and sets International laboratory standards – diagnostics, vaccines, etc. (*Terrestrial Manual*)**
- Promotes the preparation and distribution of reagents



Terrestrial Manual

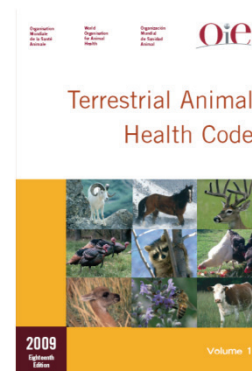
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Overview

PURPOSE

- Describes internationally agreed laboratory **standard** methods for disease **diagnosis**, and
- Describes also, when relevant, the requirements for the production and control of **vaccines** and other biological products

➤ **Is the companion volume to the *Terrestrial Animal Health Code***

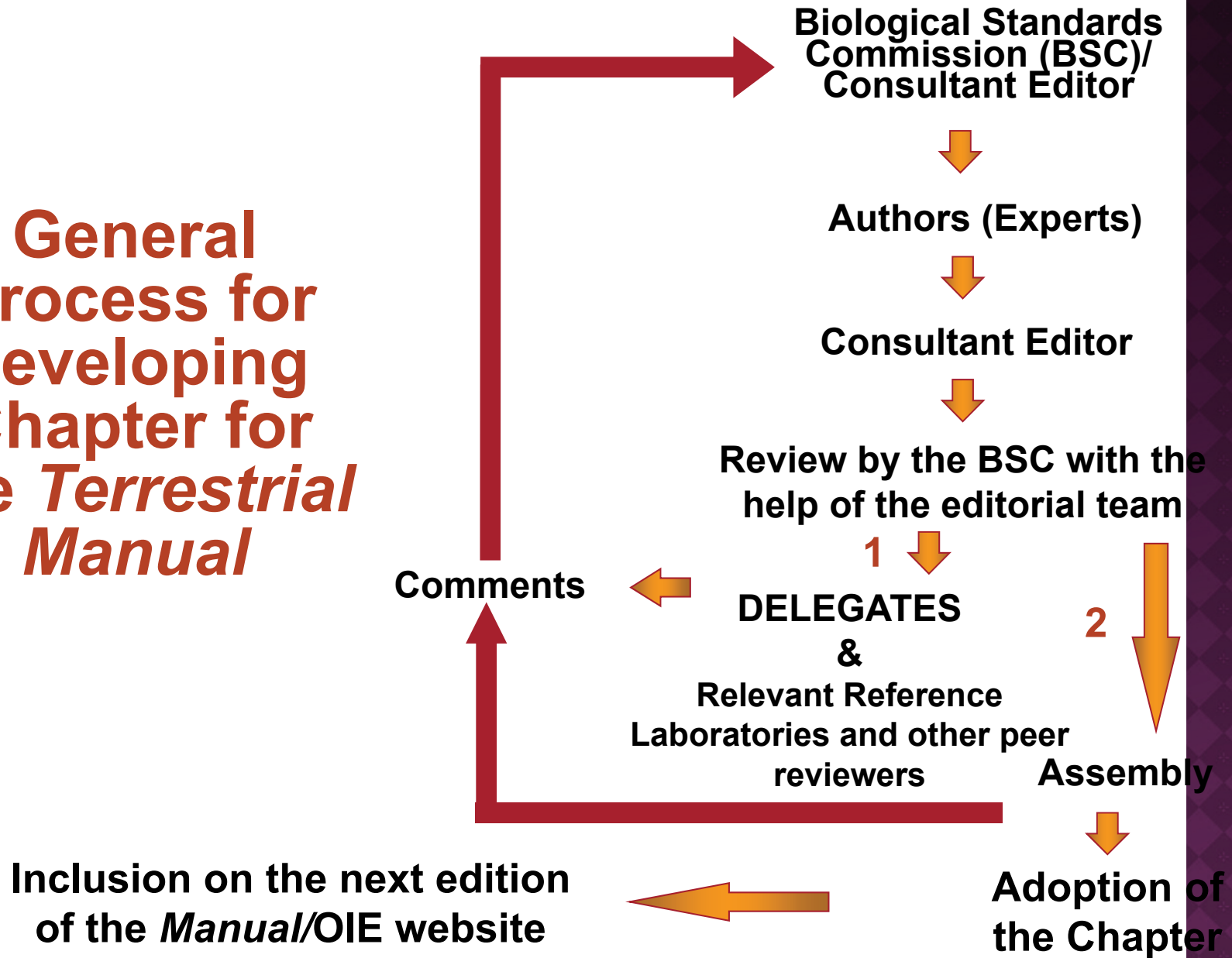


PURPOSE

- First published in 1989 and since then every 4 years in paper version.
- The last version is the 2008 edition.
- Available on the OIE website - include all updated chapters:

<http://www.oie.int/international-standard-setting/terrestrial-manual/access-online/>

General Process for developing Chapter for the *Terrestrial Manual*



Structure

Divided into **two parts** :

- **Part 1:** 11 introductory chapters on general issues of interest to veterinary laboratories
- **Part 2:** 113 Chapters on specific diseases (OIE listed diseases and other diseases of public health or trade importance)

Structure

Combined into
one chapter

Part 1 – Introductory chapters:

- 1.1.1. Collection and shipment of diagnostic specimens
- 1.1.2. Biosafety and biosecurity in the veterinary microbiology laboratory and animal facilities
- 1.1.3. Quality Management in veterinary testing laboratories
- 1.1.4. Principles of validation of diagnostic assays for infectious diseases
- 1.1.5. Validation and quality control of polymerase chain reaction methods used for the diagnosis of infectious diseases
- 1.1.6. Laboratory methodologies for bacterial antimicrobial susceptibility testing

Structure

Part 1 – Introductory chapters (contd):

- 1.1.7. Biotechnology in the diagnosis of infectious diseases and vaccines development
- 1.1.8. Principles of veterinary vaccine production
- 1.1.9. Tests for sterility and freedom from contamination of biological materials
- 1.1.10. Guidelines for international standards for vaccine banks
- 1.1.11. The role of official bodies in the international regulation of veterinary biologicals

Structure

Part 2 – 113 Chapters on specific diseases:

OIE listed diseases + other diseases of global importance:

Subdivided by:

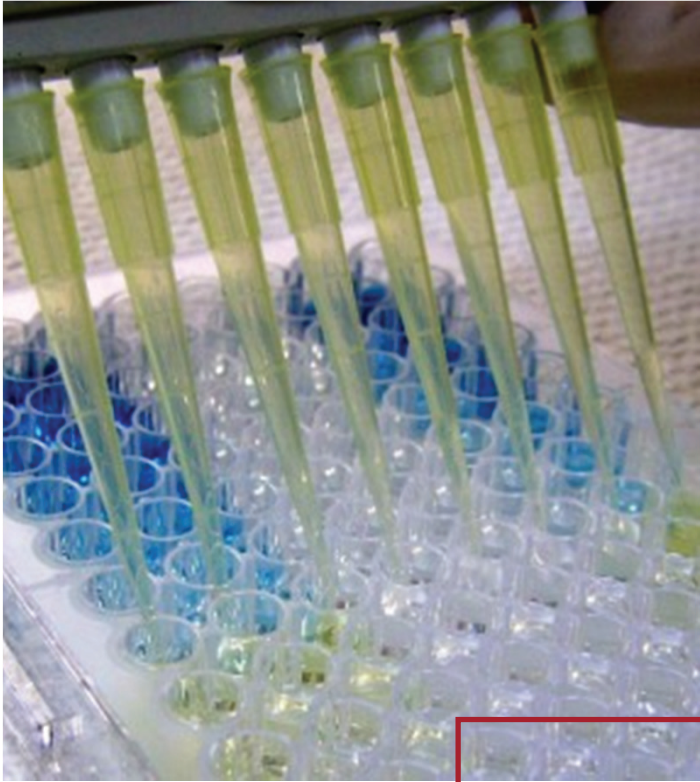
- Multiple species
- Apidae
- Aves
- Bovidae
- Equidae
- Lagomorpha
- Ovidae and Capridae
- Suidae
- Other Diseases

Structure

Part 2 – Chapters 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



OIE *Terrestrial Manual*
and
Diagnostic tests

OVERVIEW

Relevant parts in the *Terrestrial Manual*:

- ⦿ Several **introductory chapters** of the *Terrestrial Manual* are relevant for diagnostic tests.
- ⦿ Considering the importance to validate diagnostic tests, the introductory chapters on the **general principles for the validation of diagnostic assays** are of special interest.
- ⦿ In each disease-specific chapter, the **Part B** is on the diagnostic techniques and provides detailed descriptions of the **prescribed** and alternative tests.

STRUCTURE

Three possible categories of tests described in the 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 the prescribed tests are listed in the table: « *list of tests for international trade* », page XI in each of the two volumes.

ALTERNATIVE TESTS

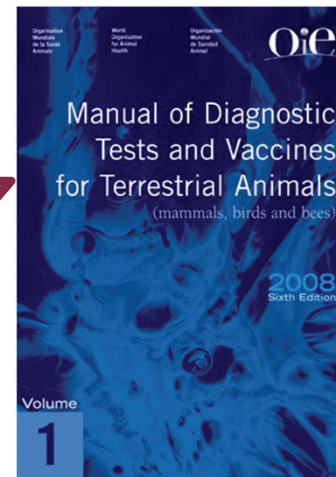
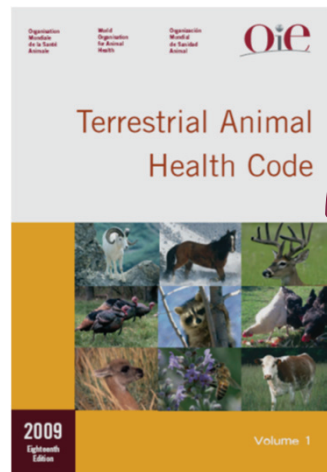
- **Alternative tests** are suitable for the diagnosis of disease within a local context, and can also be used in the import/export of animals after bilateral agreement.
- The alternative tests are also listed in the table: « *list of tests for international trade* », page XI in each of the two volumes.

OTHER TESTS

- There are often **other tests** described in the chapters, which may also be of some practical value in local situations or which may still be under development.

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.





**OIE *Terrestrial Manual*
and
Vaccines**

OVERVIEW

Relevant parts in the *Terrestrial Manual*:

- ⦿ Several *introductory chapters* of the *Terrestrial Manual* are relevant for the vaccines (production and quality).
- ⦿ Chapter 1.1.8., *Principles of Veterinary Vaccine Production* is of special interest.
- ⦿ In the relevant *disease-specific chapters*, the **Part C** is on the Requirements for Vaccines and Diagnostic Biologicals

CHAPTER 1.1.8.

PRINCIPLES OF VETERINARY VACCINE PRODUCTION

- ◉ **Background:** A reliable supply of pure, safe, potent and effective vaccines is essential for maintenance of animal health and the successful operation of animal health programmes
- ◉ **Objective:** to ensure the production and availability of uniform and consistent vaccines of high quality
- ◉ **Content:** General requirements and procedures

CHAPTER 1.1.8.

Summary of the content:

- ① Nomenclature: for this chapter, the term “vaccine” includes “all products designed to stimulate active immunisation of animals against disease, without regard to the type of microorganism or microbial toxin from which they may be derived or that they contain”
- ① Quality Assurance / Production facilities & the importance of their inspection / Master Seed & Master Cell Stocks / Ingredients / Consistency of Production / Safety & Efficacy Tests / Batch/serial release for Distribution / Labelling / Biotechnology-derived vaccines

CHAPTER 1.1.8.

Summary of the content (contd):

Two appendixes:

1. Risk analysis for biologicals for veterinary use
(provides only general considerations)
2. Risk analysis for veterinary vaccines:

Introduction - Principles - Manufacturing practices -
Registration in the importing country - Categorisation
of veterinary vaccines - Vaccinovigilance - Risk
communication

DISEASE-SPECIFIC CHAPTER AND VACCINES

General Template of the Part C which was used until now and is still present in some disease-specific chapters

1. Seed Management



- a) Characteristics of the seed
- b) Method of culture
- c) Validation as a vaccine

2. Method of Manufacture

3. In-process control

4. Batch control



- a) Identity
- b) Sterility
- c) Safety
- d) Potency
- e) Duration of protection
- f) Stability
- g) Preservatives
- h) Precautions

5. Tests on the final product

- a) Safety
- b) Potency

Organisation
Mondiale
de la Santé
Animale

World
Organisation
for Animal
Health

Organización
Mundial
de Sanidad
Animal



Manual of Diagnostic Tests for Aquatic Animals



2009



MANUAL OF DIAGNOSTIC TESTS FOR AQUATIC ANIMALS

- ◉ **Objective:** a uniform approach to the diagnosis of aquatic diseases listed in the Aquatic **Code**
- ◉ Diagnostic tests are used to comply with standards for international movement / trade of aquatic animals
- ◉ Manual is produced every 2-3 years, updates are on-line
- ◉ Available in English and Spanish



GENERAL CONSIDERATIONS

- ◉ Unlike terrestrial animals, crustaceans, amphibians, fish and molluscs don't often show specific clinical disease signs
- ◉ Therefore the best suited diagnostic is detection of the **pathogen**
- ◉ The methods are mainly **direct**, indirect methods, e.g. antibody detection, are generally not accepted

- ◉ Molluscs and crustaceans don't produce antibodies
- ◉ General approach: pathogen isolation and identification, or
- ◉ Antigen detection by immunological or molecular techniques
- ◉ PCR is recommended for detection and confirmation but not for screening to prove absence of disease



STRUCTURE

Divided in two parts:

- **Part 1:** 3 chapters of general interest for veterinary laboratories

- **Part 2:** specific diseases
 - Amphibians: 2 diseases (approved 2011)
 - Crustacéans: 7 diseases
 - Fish: 9 diseases
 - Molluscs: 7 diseases (2 approved 2011)

PART 1 - GENERAL CHAPTERS

- ◉ 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 DISEASES

The 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



ENZOOTIC HAEMATOPOIETIC NECROSIS

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

Thank you for your attention

Oie

