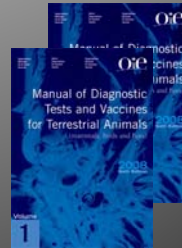


# The OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

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Séminaire régional de formation pour points focaux OIE pour les produits vétérinaires  
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## Summary of the Presentation

The Biological Standards Commission (BSC) and the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)*

- **Terrestrial Manual – Overview**
- **Terrestrial Manual – Diagnostic tests**
- **Terrestrial Manual – Vaccines**

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## BSC and *Terrestrial Manual*



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## Specialized 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"

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## 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*







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## 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*
- Promotes the preparation and distribution of reagents
- Develop and set International laboratory standards – diagnostics, vaccines, etc. (*Terrestrial Manual*)



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# Biological Standard Commission

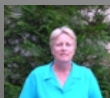
**Prof. Vincenzo Caporale**  
(President)  
Istituto Zooprofilattico Sperimentale de Teramo  
ITALY



**Dr Medhi El Harrak**  
(Secretary General)  
Biopharma  
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**Dr Beverly Schmitt**  
(Vice-President)  
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UNITED STATES OF AMERICA



**Dr Alejandro Schudel**  
(Member)  
ARGENTINA



**Dr Paul Townsend**  
(Member)  
Veterinary Laboratories Agency  
UNITED KINGDOM



**Dr Hualan Chen**  
(Member)  
National Avian Influenza Reference Laboratory  
Animal Influenza Laboratory of the Ministry of Agriculture  
CHINA (PEOPLE'S REP. OF)

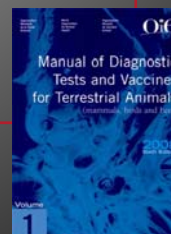


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## Terrestrial Manual

## - Overview

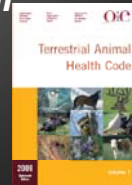
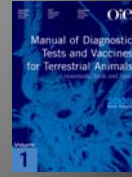


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## What is the OIE *Terrestrial Manual*?

- Describes internationally agreed laboratory standard methods:
  - For disease diagnosis,
  - For production and control of vaccines and diagnostic biologicals, when relevant.
- **Is the companion volume to the *Terrestrial Animal Health Code***



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## The relation between the OIE *Terrestrial Manual* and the OIE *Terrestrial Code*

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

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## What is the OIE Terrestrial Manual?

All the OIE Standards for diagnostic methods and vaccines are published in the *Terrestrial Manual*

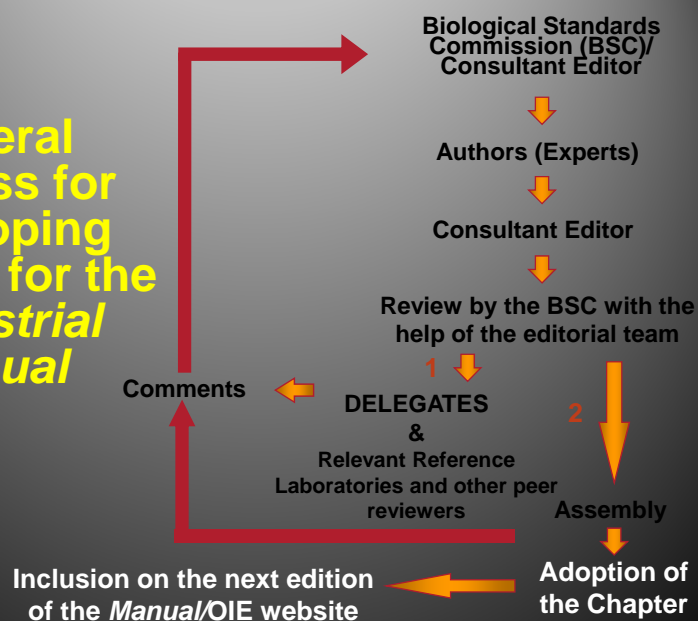
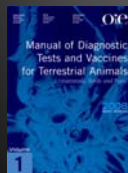
- First published in 1989 and since then every 4 years in paper version.
- The last version is the 2008 edition.
- It is also available on the OIE website where, in addition, the chapters updated annually after adoption by the World Assembly of Delegates during the General Session are also available:

[www.oie.int/eng/normes/mmanual/A\\_summry.htm](http://www.oie.int/eng/normes/mmanual/A_summry.htm)

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## General Process for developing Chapter for the Terrestrial Manual



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## Structure of the *Terrestrial Manual*

Divided into **two parts** :



- Part 1: Eleven 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)

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## Structure of the *Terrestrial Manual*

**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 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

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## Structure of the *Terrestrial Manual*

### 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

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## Structure of the *Terrestrial Manual*

### Part 2 – 113. Chapters on specific diseases:

OIE listed diseases + other diseases of global importance

Classified following the subdivision detailed below:

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



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## Structure of the *Terrestrial Manual*

**Part 2** – Chapters on specific diseases:

Each disease chapter (with one exception) is developed following this template:

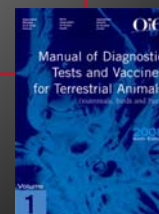
- Summary
- A. Introduction
- B. Diagnostic techniques
- C. Requirements for vaccines and diagnostic biologicals
- References



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## OIE *Terrestrial Manual* and Diagnostic tests



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## Overview

Relevant parts in the *Terrestrial Manual*:

- Several introductory chapters of the *Terrestrial Manual* are relevant for the diagnostic tests.
- Considering the importance to have diagnostic tests validated, the introductory chapters on the general principles for the validation of diagnostic assays are of special interests.
- In each disease-specific chapter, the Part B is on the diagnostic techniques and provides detailed descriptions of the internationally agreed diagnostic test methods for the disease described.

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## Disease-specific chapter and diagnostic tests

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

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



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## Disease-specific chapter and diagnostic tests

- **Prescribed tests** are those that 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 a table: «list of tests for international trade», page XI in each of the two volumes.



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## Disease-specific chapter and diagnostic tests

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

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## Disease-specific chapter and diagnostic tests

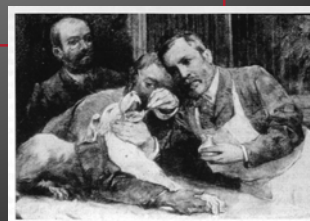
- There are often other tests described in the chapters, which may also be of some practical value in local situations or which may still be under development.



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## OIE *Terrestrial Manual* and Vaccines



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## Overview

Relevant parts in the *Terrestrial Manual*



- Several introductory chapters of the *Terrestrial Manual* are relevant for 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. Mainly this part provides guidelines for the vaccine production for the described disease.

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## Principles of Veterinary Vaccine Production

### Chapter 1.1.8.

- **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:** describes requirements and procedures intended to be general in nature and to be consistent with published standards that are generally available for guidance in the production of veterinary vaccines.

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## Principles of Veterinary Vaccine Production

### Chapter 1.1.8.

- **Summary of the content:**
- **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”
- The other relevant issues addressed are in particular 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

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## Principles of Veterinary Vaccine Production

### Chapter 1.1.8.

- **Summary of the content (contd):**
- Two appendixes are provided at the end of the chapter providing guidelines for risk analysis for veterinary biologicals and especially vaccines in the framework of the international trade:
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 – Categorization of veterinary vaccines – Vaccino vigilance – Risk communication

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## Vaccine in disease-specific chapters

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		a) Identity b) Sterility c) Safety d) Potency e) Duration of protection f) Stability g) Preservatives h) Precautions
3. In-process control	↗	
4. Batch control	↘	
5. Tests on the final product	→	a) Safety b) Potency

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## Vaccines in disease-specific chapters

New General Template of the Part C which is now in use for all the new or updated disease-specific chapters

1. Background: (a) rationale and intended use of the product

2. Outline of production and minimum requirements for conventional vaccines

3. Vaccines based on biotechnology: (a) Vaccines available and their advantages; (b) Special requirements for biotechnological vaccines, if any

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## Vaccines in disease-specific chapters

New General Template of the Part C which is now in use for all the new or updated disease-specific chapters

### 2. Outline of production and minimum requirements for conventional vaccines

- a) Characteristics of the seed: (i) Biological characteristics; (ii) Quality criteria.
- b) Method of manufacture: (i) Procedure; (ii) Requirements for substrates and media; (iii) In process controls; (iv) Final product batch tests
- c) Requirements for authorisation: (i) Safety requirements; (ii) Efficacy requirements; (iii) Stability

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## Thank you for your attention



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