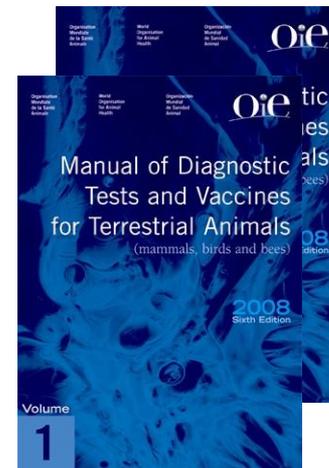


# The OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

OIE Workshop for OIE National Focal Points for Veterinary Products, Siem Reap, 29 June – 1 July 2011

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# Outline

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

# Introduction

# OIE's international standards

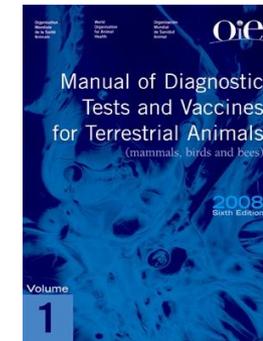
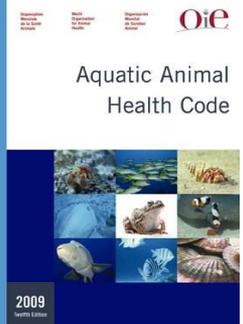
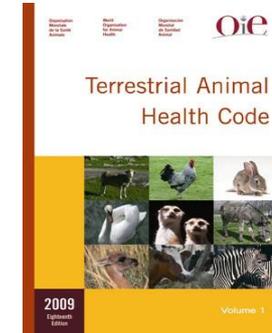
*Terrestrial Animal Health Code – mammals, birds and bees*

*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"

# *Terrestrial Manual*

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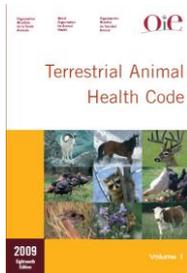
## Overview

# OIE *Terrestrial Manual*

## What is the *Terrestrial Manual*?

- 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*



# OIE *Terrestrial Manual*

## What is the *Terrestrial Manual*?

- First published in 1989 and since then produced every 4 years as printed version.
- The last printed version is the 2008 edition.
- Chapters are continuously updated and published on the OIE website after adoption by the World Assembly of Delegates during the General Session :  
[http://www.oie.int/eng/normes/mmanual/A\\_summry.htm](http://www.oie.int/eng/normes/mmanual/A_summry.htm)

# General Process for developing Chapter for the *Terrestrial Manual*





# OIE *Terrestrial Manual*

## 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)

# OIE *Terrestrial Manual*

## 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 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

Combined into one chapter in online version

### **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

# OIE *Terrestrial Manual*

## 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



# OIE *Terrestrial Manual*

## 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

**OIE *Terrestrial Manual***  
**and**  
**Diagnostic tests**

# Overview

Relevant parts in the *Terrestrial Manual*:

- Several introductory chapters of the *Terrestrial Manual* are relevant to diagnostic tests:
- general principles for the validation of diagnostic assays
- Biosafety and biosecurity in Veterinary laboratories
- Quality Management in Veterinary laboratories
- In each disease-specific chapter, **Part B** provides detailed descriptions of the internationally agreed diagnostic test methods for the disease described.



# Disease-specific chapter and diagnostic tests

Three possible categories of tests :

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

# Disease-specific chapter and diagnostic tests

- **Prescribed tests** are those that are required by the *Terrestrial Code* for the purpose of international trade of animals. Printed in **blue** in the relevant disease-specific chapters.
  - E.g. FMD – ELISA, VNT
- All the prescribed tests are listed in a table:  
« list of tests for international trade », page XI in each of the two volumes.

# Disease-specific chapter and diagnostic tests

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

# 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.

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

Wherever the *Terrestrial Code* requires that tests are carried out for international trade, 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):
- Principles of Veterinary Vaccine Production
- Tests for sterility and freedom from contamination of biological materials
- Guidelines for international standards for vaccine banks
- In the relevant disease-specific chapters, Part provides guidelines for the vaccine production for the disease described.

## 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:** 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.

# Chapter 1.1.8.

## Principles of Veterinary Vaccine Production

- **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

# Chapter 1.1.8.

## Principles of Veterinary Vaccine Production

- **Summary of the content (contd):**

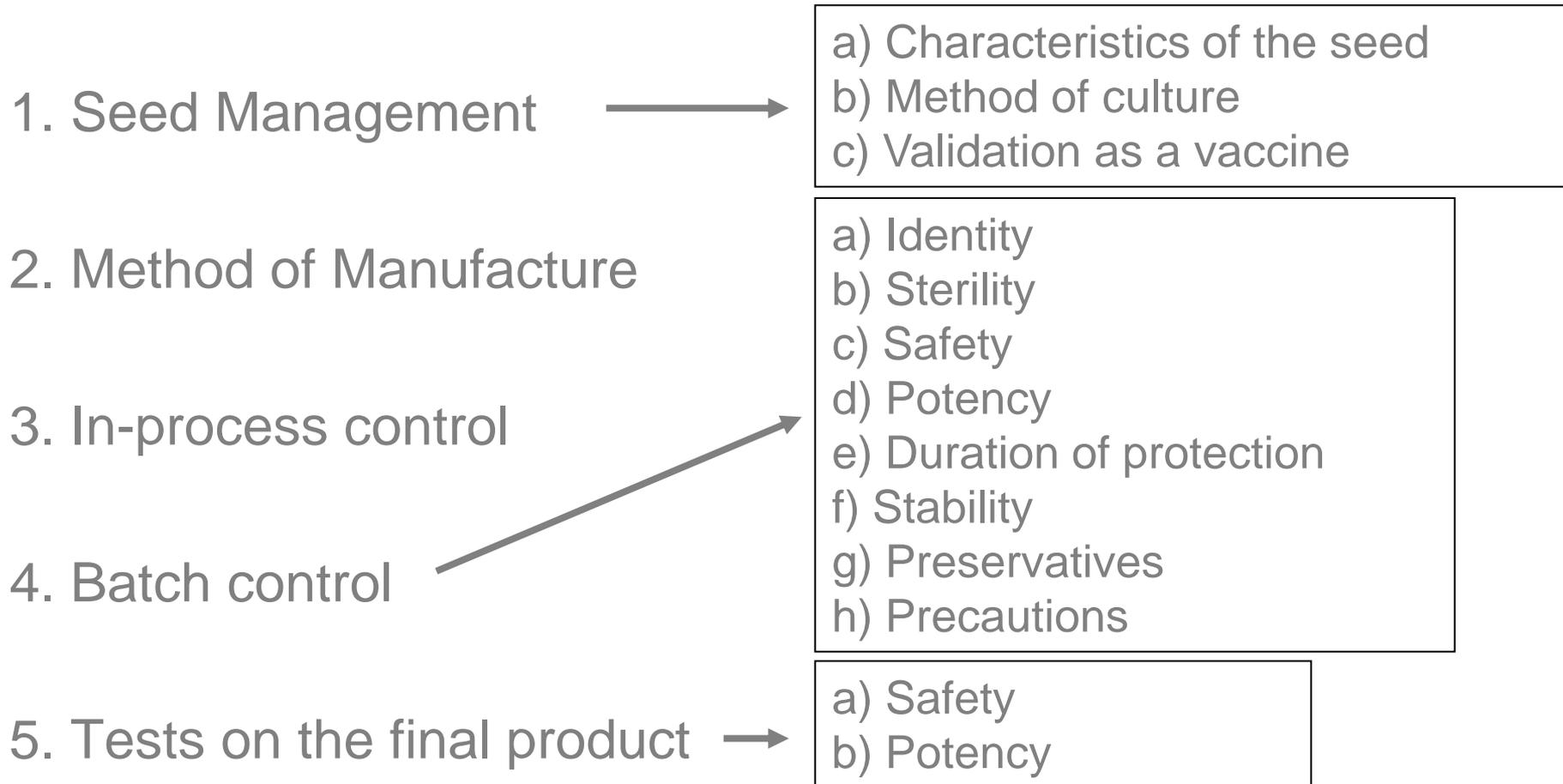
Two appendixes are provided at the end of the chapter providing guidelines for risk analysis for veterinary biologicals and especially vaccines in the framework of the international trade:

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 – 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



# Disease-specific chapter and vaccines

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

# Disease-specific chapter and vaccines

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

# Thank you for your attention



Organisation Mondiale  
de la Santé Animale

World Organisation  
for Animal Health

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