The OIE relevant Standards and Guidelines to Veterinary Medicinal Products

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Outline

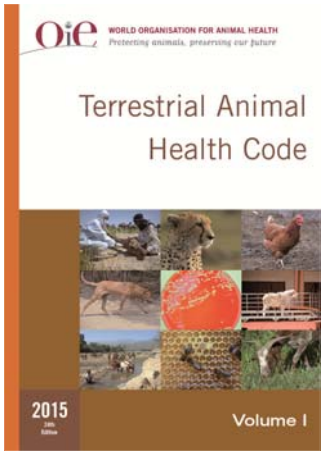
- Veterinary legislation Chapter 3.4- article 3.4.11-Veterinary Medicines and biologicals
- Standards and guidelines related to Veterinary Medicinal Products, including Vaccines
- Standards and guidelines related to antimicrobial resistance (AMR)
- No-standards and guideline related to antiparasitic

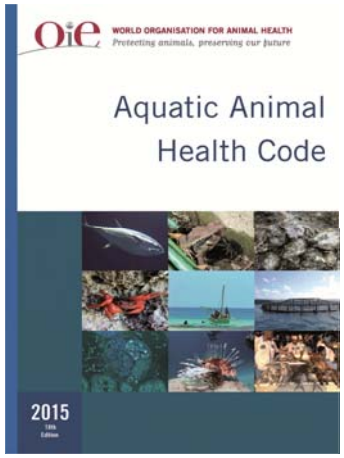
Standards and guidelines related to Vaccines

The OIE Standards

CODES

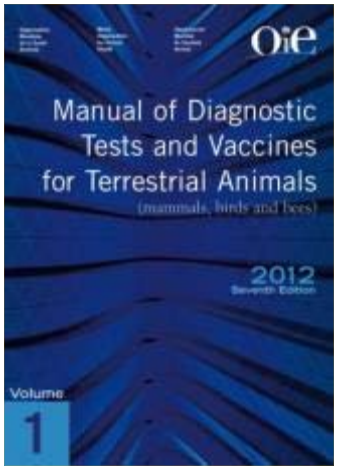
- Terrestrial
- Aquatic

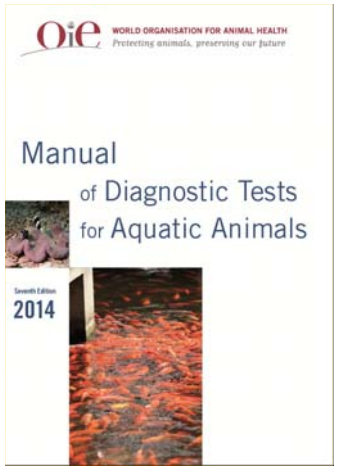




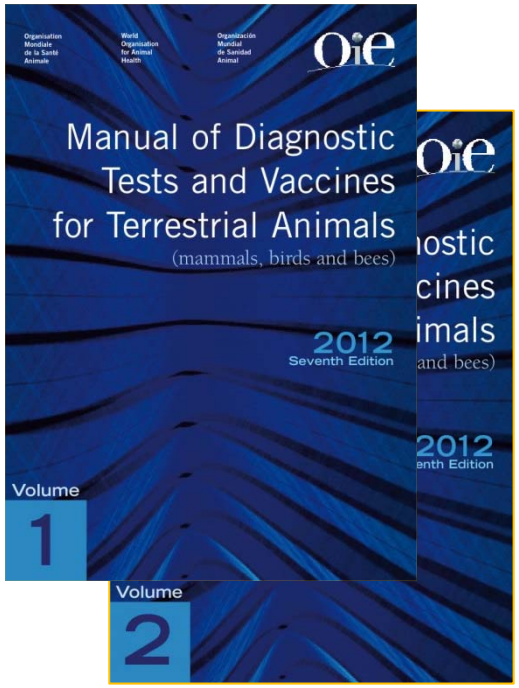
MANUALS

- Terrestrial
- Aquatic





Terrestrial Manual



Requirements for the production and control of vaccines and other biological products

Available in full and up to date on line at:

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

Terrestrial Manual - Relevant standards:

Provides generic and specific guidance on vaccine quality:

- Principles of veterinary vaccine production (including diagnostic biologicals)- Chapter 1.1.6 (new version adopted in 2015)
- *Tests of biological materials for sterility and freedom from contamination* - Chapter 1.1.7. *(consultation phase)*
- *Minimum requirements for vaccine production facilities* -Chapter 1.1.8 *(consultation phase)*
- *Quality control of vaccines* Chapter 1.1.9.*(consultation phase)*
- In the relevant disease-specific chapters, the Part C is on the Requirements for Vaccines and Diagnostic Biologicals

Terrestrial Manual : Chapter 1.1.6 (1)

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 and assured quality
- Contents: General requirements and procedures
- 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”

Terrestrial Manual : Chapter 1.1.6 (2)

Summary of the contents:

VACCINE PRODUCTION :

1. Quality Assurance
2. Production facilities
3. Documentation of manufacturing process and record keeping
4. Production
5. Process validation
6. Stability tests
7. Test to demonstrate safety and efficacy of a vaccine

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.06_VACCINE_PRODUCTION.pdf

Terrestrial Manual : Chapter 1.1.6 (3)

Summary of the contents (contd)

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.06_VACCINE_PRODUCTION.pdf

Terrestrial Manual : Chapter 1.1.6 (4)

Summary of the contents (contd)

Quality Controls (QC) in vaccine production :

1. **Principle** (The independence of quality control from production is considered FUNDAMENTAL to the satisfactory operation)
2. **Batch/serial release for distribution**
   - 2.1. Batch/serial purity test
   - 2.2. Batch/Serial safety test
   - 2.3. Batch/Serial potency test
3. **Other tests**
   - 3.1. Test on the finished product
     - 3.2.1. Purity
     - 3.2.2. Test of the detection of TSE agent

INSPECTION of Production Facilities: The inspections should be carried out on a regular basis and should allowed the assessment of manufacturing sites with regards GMP standards.

Terrestrial Manual : Chapter 1.1.6 (5)

Summary of the contents (contd)

Two appendices:

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

   Introduction – Principles – Manufacturing practices –Information to be submitted when applying for MA in the importing country – Categorisation of veterinary vaccines – Vaccinovigilance – Risk communication

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.06_VACCINE_PRODUCTION.pdf

Terrestrial Manual : Proposed Chapter 1.1.7

- TESTS FOR STERILITY AND FREEDOM FROM CONTAMINATION OF BIOLOGICAL MATERIALS

- DEFINITION : Sterility is defined as the absence of living organisms. It is achieved by heating, by filtration, by treatment with ethylene oxide or by ionising irradiation, and by conducting any subsequent processes aseptically. Freedom from contamination is defined as the absence of specified living organisms.

Comment should be sent to adresse s.linnane@oie.int the before 16.01.2016

Proposed Chapter 1.1.7

Structure:

A. GENERAL PROCEDURES

B. LIVING VIRAL VACCINES FOR ADMINISTRATION BY INJECTION

C. LIVING VIRAL VACCINES FOR ADMINISTRATION THROUGH DRINKING WATER, SPRAY, OR SKIN SCARIFICATION

D. INACTIVATED VIRAL VACCINES

E. LIVING BACTERIAL VACCINES

F. INACTIVATED BACTERIAL VACCINES

G. SERA and DIAGNOSTIC AGENTS FOR ADMINISTRATION TO ANIMALS

H. EMBRYOS, OVA, SEMEN AND GENETICALLY MODIFIED ORGANISM

I. PROTOCOL EXAMPLES

Terrestrial Manual

- Chapter 1.1.7., 1.1.8. and 1.1.9. was sent to OIE Member Countries for comment in October
- Deadline for comments: 2016 January
- Your role in providing comments is very important, more than welcome!

Comment should be sent to adresse s.linnane@oie.int the before 16.01.2016

Outline of vaccine section of the diseases chapters(1)

1. Background

2. Outline of production and minimum requirements for vaccines

2.1. Characteristics of the seed

1. Biological characteristics
2. Quality criteria (*sterility, purity, freedom from extraneous agent*)
3. Validation of the vaccine strain
4. Emergency procedure for provisional acceptance of new master seed virus

2.2. Method of manufacture

- Procedure
- Requirements for ingredients
- In process controls
- Final product batch tests (*sterility, identity, safety, bath potency*)

2.3. Requirements for authorisation/registration/licencing

3. Specific topics (the e.g. oral vaccine, toxoid, specific requirements for biotechnology based vaccines)

Outline of vaccine section of the diseases chapters (2)

Production and minimum requirements for vaccines

2.3. Requirements for authorisation/registration/licencing

2.3.1. Manufacturing process

2.3.2. Safety requirements

2.3.3. Efficacy requirements

2.3.4. Vaccines permitting DIVA strategy (detection of infection in vaccinated animals

2.3.5. Duration of immunity

2.3.6. Stability

Terrestrial Manual – Part 3 related to veterinary medicinal products

General Guidelines in Part III only available online

3.1. Laboratory methodologies for bacterial antimicrobial susceptibility testing

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

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

Standards and guidelines related to antimicrobial resistance (AMR)

Standards and guideline related to antimicrobial resistance

OIE Terrestrial Animal Health Code

- Chapter.6.6.
  Introduction to the recommendations for controlling antimicrobial resistance
- Chapter 6.7.
  Harmonisation of national antimicrobial resistance surveillance and monitoring programmes
- Chapter 6.8.
  Monitoring of the quantities and usage patterns of antimicrobials agents used in food producing animals
- Chapter 6.9.
  Responsable and prudent use of antimicrobial agents in veterinary medicines
- Chapter 6.10.
  Risk analysis for antimicrobial resistance arising from the use of antimicrobial agents in animals

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http://www.oie.int/international-standard-setting/terrestrial-code/access-online

Standards and guideline related to antimicrobial resistance

OIE Standards - Aquatic Animal Health Code

Antimicrobial use in aquatic animals in section 6

- Chapter.6.1. Introduction to the recommendation for controlling antimicrobial resistance
  Chapter 6.2. Principles for responsible and prudent use of antimicrobial agents in aquatic animals
- Chapter 6.3. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals
- Chapter 6.4. Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals
- Chapter 6.5. Risk analysis for antimicrobial resistance arising from the use of antimicrobial agents in aquatic animals

http://www.oie.int/international-standard-setting/aquatic-code/access-online line

Standards and guideline related to antimicrobial resistance

- The OIE International Committee unanimously adopted the List of Antimicrobial Agents of Veterinary Importance at its 75th General Session in May 2007 (Resolution No. XXVIII).
- This list was further updated and adopted in May 2013 and May 2015 by the World Assembly of OIE Delegates.
- List of antimicrobial agents of veterinary importance :

http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Eng_OIE_List_antimicrobials_May2015.pdf

Standards and guideline related to antimicrobial resistance

- **Criterion 1.** Response rate to the questionnaire regarding Veterinary Important Antimicrobial Agents

- **Criterion 2.** Treatment of serious animal disease and availability of alternative antimicrobial agents

Standards and guideline related to antimicrobial resistance

- Veterinary Critically Important Antimicrobial Agents (VCIA): are those that meet BOTH criteria 1 AND 2
- Veterinary Highly Important Antimicrobial Agents (VHIA): are those that meet criteria 1 OR 2
- Veterinary Important Antimicrobial Agents (VIA): are those that meet NEITHER criteria 1 OR 2

Antiparasitics

Antiparasitics

- Trypanocides .....**Specific Monograph**

http://web.oie.int/boutique/index.php?page=ficprod&id_prec=1309&id_produit=1458&lang=en&fichrech=1&PHPSESSID=9374551d777d42d410d15c3c97ddd102

- Future plan based on the feed back of previous Focal Point trainings : work on a prudent use of antiparasitics

Thank you for your attention!

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