THE OIE RELEVANT STANDARDS AND GUIDELINES FOR VETERINARY MEDICINAL PRODUCTS

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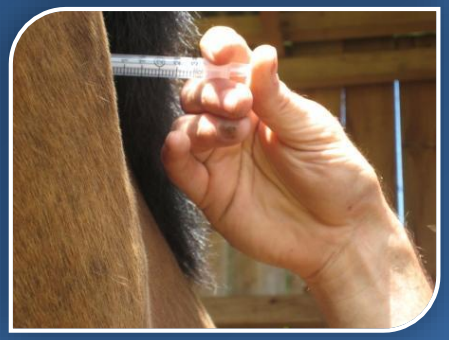
Outline

- **Veterinary legislation** Chapter 3.4 The role of Official Bodies in the International Regulation of Veterinary biologicals (Terrestrial Manual)
- Standards and guidelines related vaccines and recent updates
- Standards and guidelines related to antimicrobial resistance (AMR)
- Currently no OIE standards or guidelines related to antiparasitic products

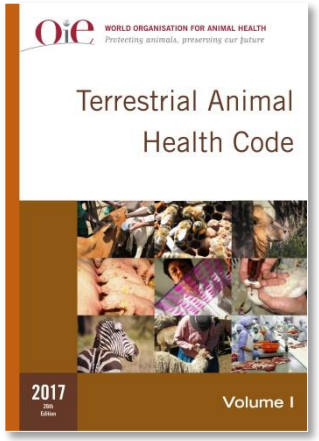


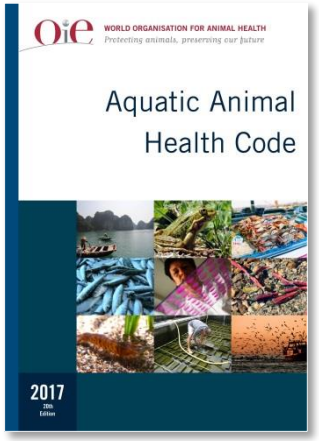
Standards and Guidelines Related to Vaccines

The OIE Standards

CODES

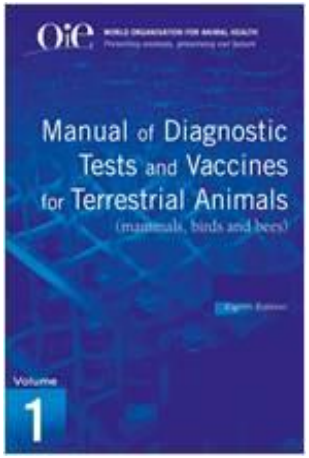
- Terrestrial
- Aquatic

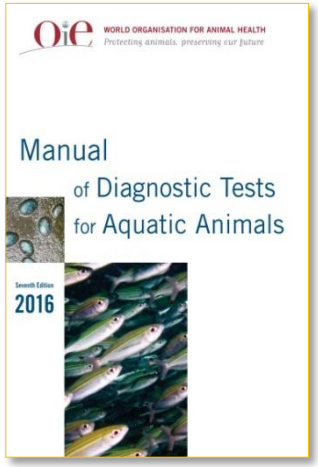




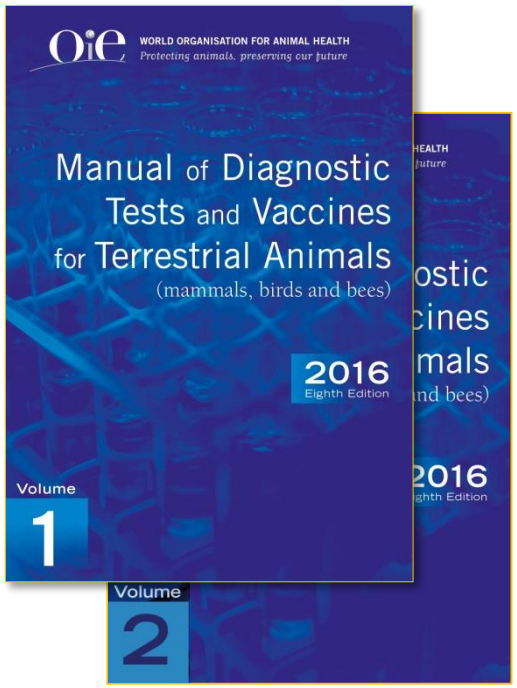
MANUALS

- Terrestrial
- Aquatic





Terrestrial Manual – present



3.7 Recommendations for the Manufacture of Vaccines (new)

Now available online, and the printed version is scheduled for release late 2018

can be purchased directly at pub.sales@oie.int,

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

84th General Session in May 2016

- **Resolution No. 13** **Amendments to the *Manual of Diagnostic Test and Vaccines for Terrestrial Animals* (*Terrestrial Manual*):**

3.7.Recommendations for the manufacture of vaccines

- 3.7.1. Minimum requirements for the organisation and management of a vaccine manufacturing facility (new)
- 3.7.2. Minimum requirements for the production and quality control of vaccines (new)
- 3.7.3. Minimum requirements for aseptic production in vaccine manufacture (new)

Terrestrial Manual - Relevant standards

Provides <u>generic</u> and <u>specific guidance</u> on vaccine production and testing:

- Chapter 1.1.8 Principles of veterinary vaccine production (including diagnostic biologicals) (New version adopted in 2015, to be updated in 2018)
- Chapter 1.1.9 Tests of biological materials for sterility and freedom from contamination. Developed in consultation with VICH counterparts. The revised chapter incorporating Member Countries' comments ADOPTED in 2017)

Terrestrial Manual: Chapter 1.1.8 (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 1.1.8 (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/1.01.08_VACCINE_PRODUCTION.pdf

Terrestrial Manual: Chapter 1.1.8 (3)

Summary of the contents (cont'd)

7.1. SAFETY TEST

7.1.1. Target animal safety tests
7.1.2. Increase in virulence tests
7.1.3. Assessing risk to the environment

7.2. EFFICACY TEST

7.2.1. Laboratory efficacy
7.2.2. Interference test
7.2.3. Field (safety and efficacy)
7.2.3.2. Additional requirement for live rDNA products

8. Updating the Production Outline (materials and methods)

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.08_VACCINE_PRODUCTION.pdf

Terrestrial Manual: Chapter 1.1.8 (4)

Summary of the contents (cont'd)

Quality Controls (QC) in vaccine production :

- **Principle** (The independence of quality control from production is considered fundamental to the satisfactory operation)
- **Batch/serial release for distribution**
  - Batch/serial purity test
  - Batch/Serial safety test
  - Batch/Serial potency test
- **Other certification and tests**
  - Tests or certification on starting materials or finished products:
    - Purity
    - Freedom from extraneous agents
    - TSE certification for material of animal origin

Terrestrial Manual: Chapter 1.1.8 (4)

Summary of the contents (continued)

Quality Controls (QC) in vaccine production :

- **Inspection** of Production Facilities: The onsite inspections should be carried out on a regular basis.
- Monitor the manufacturing and quality control procedures.
- Assess conformance to current good manufacturing practices standards (e.g., EU GMP, United States Code of Federal Regulations, PIC/S)
- PIC/S :The Pharmaceutical Inspection Cooperation Scheme

Terrestrial Manual: Chapter 1.1.8 (5)

Summary of the contents (cont'd)

Two Appendices:

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

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

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.08_VACCINE_PRODUCTION.pdf

85th General Session in May 2017
Terrestrial Manual: Chapter 1.1.9

Tests for sterility and freedom from contamination of biological materials intended for veterinary use

Approved by the **Biological Standards Commission** sent to Member Countries for second-round comment and proposal for adoption in May 2017. **Adopted during the 85th General Assembly.**

VICH Biologicals Quality Monitoring Expert Working Group (BQM-EWG) provided inputs-to be harmonized as much as possible in the future with VICH extraneous agents guidelines.

Outline of vaccine section of the disease chapters(1)

1. Background

2. Outline of production and minimum requirements for vaccines

2.1. Characteristics of the seed

- Biological characteristics
- Quality criteria (*sterility, purity, freedom from extraneous agent*)
- Validation of the vaccine strain
- 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 disease 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 (DIVA vaccines permit differentiation of infected versus vaccinated animals)

2.3.5. Duration of immunity

2.3.6. Stability

Terrestrial Manual – Part 3 related to veterinary medicinal products

Specific Recommendations

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- *under revision- for adoption in May 2018*

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

Recent Updates (1)

Waiving or not waiving Target Animal Batch Safety Tests (TABST)?

- **The OIE Biological Standard Commission,** concluded that, rather than completely eliminating all references to the TABST, references to the TABST in the *Terrestrial Manual* should be revised to include a note that the prescribed TABST could be eliminated in situations where other quality control measures are in place.

- BSC implemented its decision regarding TABST by modifying chapters 1.1.8 and 3.7.2 and amending to all relevant disease chapters when they are updated.

Recent Updates (2)

Reasons

- Potential variability of quality assurance systems employed by manufacturers in OIE Member Countries

- Potential for residual toxicity of some vaccines

It would be inappropriate to completely eliminate all references to the TABST in OIE guidelines such as the *Terrestrial Manual*

Recent Updates (3)

Request for an refined OIE definition of thermostable or thermoresistant vaccines

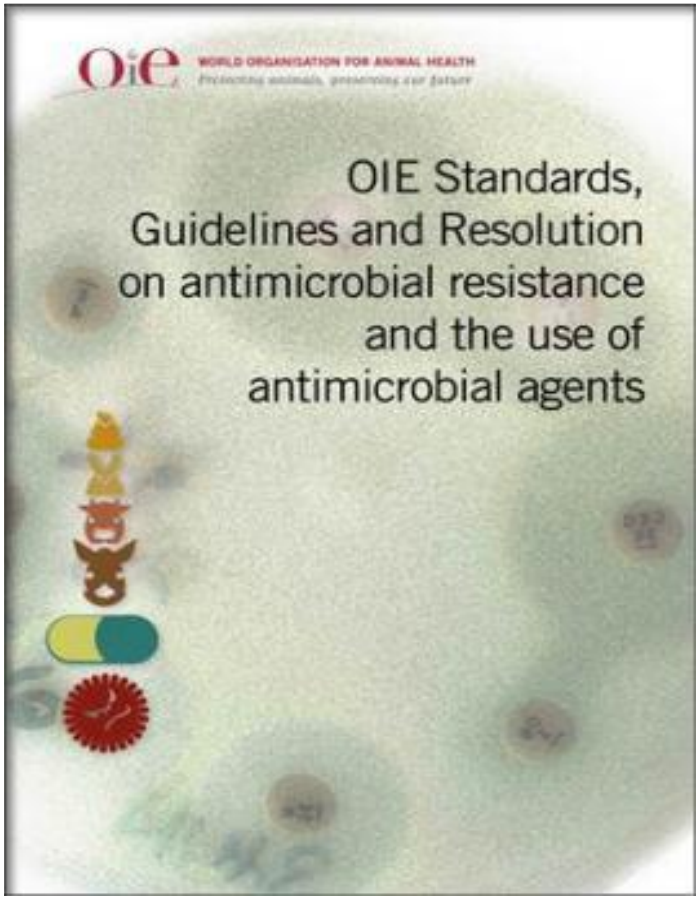
- Benefit of access to: science–based, pragmatic standards to objectively characterise the thermotolerant properties of vaccines
- There is much interest in characterising the thermotolerant properties of existing vaccines and developing new formulations
- Need revised pertinent definition(s) for thermotolerant vaccines to revise or expand the *OIE Manual's* definition on thermotolerance
- Need to define relevant parameters of thermotolerance for label claims for various types of veterinary vaccines (e.g conventional live or killed vaccine or a new generation thermotolerant vaccine)

Recent Updates (3)

Biological Standards Commission :

Developed a revised draft glossary definition and expanded guidance for characterizing thermotolerant vaccine in the Terrestrial Manual.

Standards and guideline related to antimicrobial resistance



http://www.oie.int/fileadmin/home/eng/Media_Center/docs/pdf/PortailAMR/EN-book-AMR.PDF

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 feedback of previous Focal Point training seminars: work on guidelines for prudent use of antiparasitic products, subject to future direction from OIE Delegates (and Focal Points) from Member Countries.**

Conclusion

- We need to continue to work together to have **high quality, practical global standards and guidelines** for **v**eterinary medicinal products

- We need to build the capacity to respond to the new challenges, for example by potentially developing an OIE guideline on prudent and responsible use of antiparasitics

Conclusion

- We need to build the capacity to respond to the new challenges, like how we respond to emerging diseases ?

- How can the OIE **contribute** in helping you to implement the standards and guidelines ?

Thank you for your attention!

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