



OIE STANDARDS AND GUIDELINES FOR VETERINARY MEDICINAL PRODUCTS

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Outline

Terrestrial Code Chapter 3.4 Veterinary legislation

- ➔ Update on OIE standards and guidelines related to vaccines
- ➔ Update on OIE standards and guidelines related to antimicrobial resistance (AMR)
- ➔ Currently no OIE standards or guidelines related to antiparasitic products



WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

Terrestrial Animal Health Code



2019
28th
Edition

Volume I



Update on OIE standards and guidelines related to vaccines

Update on OIE standards and guidelines related to vaccines

OIE Technical standards for manufacturing and quality control of veterinary vaccines.

- Compilation of seven vaccine-related chapters from the *Terrestrial Code* and *Terrestrial Manual*. Published in 2019.
- Handbook intended to serve as a readily accessible technical resource for vaccine manufacturers and regulatory officials to
 - Advance global awareness and implementation of the established science-based standards for the quality, safety, and efficacy of veterinary vaccines
 - Maximize the quality and availability of veterinary vaccines that are required for prevention and control of animal diseases.

Available for purchase from OIE online bookshop as a paperback book or downloadable pdf file at

<http://web.oie.int/boutique/index.php>

<http://web.oie.int/boutique/index.php>



Update on OIE standards and guidelines related to vaccines

Glossary of Terms

Chapter 1.1.8 Principles of Veterinary Vaccine Production (2018)

Chapter 1.1.9 Tests for Sterility and Freedom from Contamination of Biological Materials Intended for Veterinary Use (2017)

Chapter 1.1.10 Vaccine Banks (2016)

Section 2.3 Recommendations for the Manufacture of Vaccines (2016)

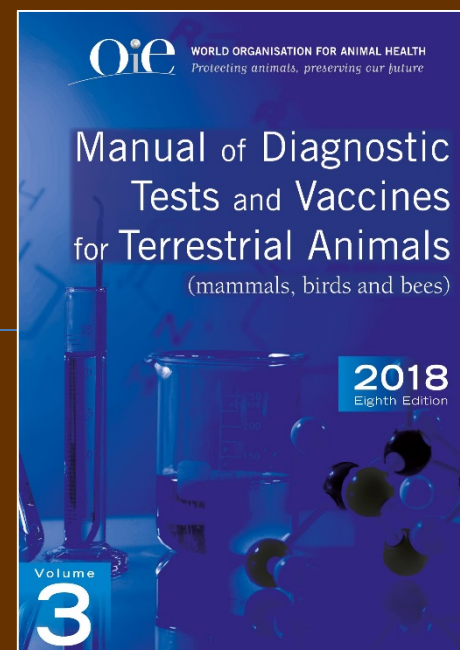
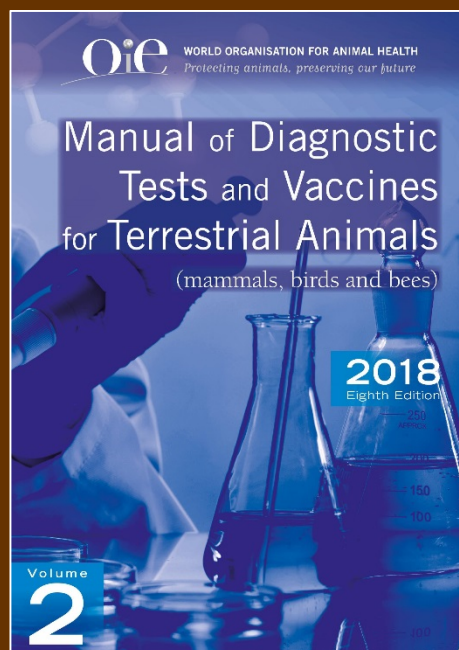
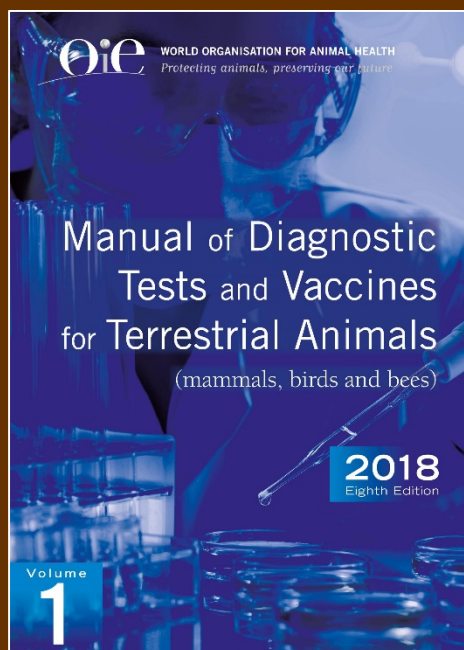
Chapter 2.3.3 Minimum Requirements for the Organisation and Management of a Vaccine Manufacturing Facility (2016)

Chapter 2.3.4 Minimum Requirements for the Production and Quality Control of Vaccines (2018)

Chapter 2.3.5 Minimum Requirements for Aseptic Production in Vaccine Manufacture (2016)

Terrestrial Manual is available online at

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



TERRESTRIAL MANUAL

Eighth Edition published in 2018 in three volumes

Part 1 • General Standards chapters available online in English, French and Spanish

Part 2 • Specific Recommendations chapters available online in English, French and Spanish

Resolution No. 14

Amendment to the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*

Chapter 1.1.8

Principles of veterinary vaccine production

(VICH guidelines 50 and 55 referenced in Chapter 2.2, criteria to characterize thermotolerance claims)

Chapter 2.3.2

The role of official bodies in the international regulation of veterinary biologicals

(EU, Japan USA and VICH texts updated)

Chapter 2.3.4

Minimum requirements for the production and quality control of vaccines

(Adopted by the World Assembly of OIE Delegates during their 86th General Session May 2018)

Recent update on OIE standards and guidelines on vaccines

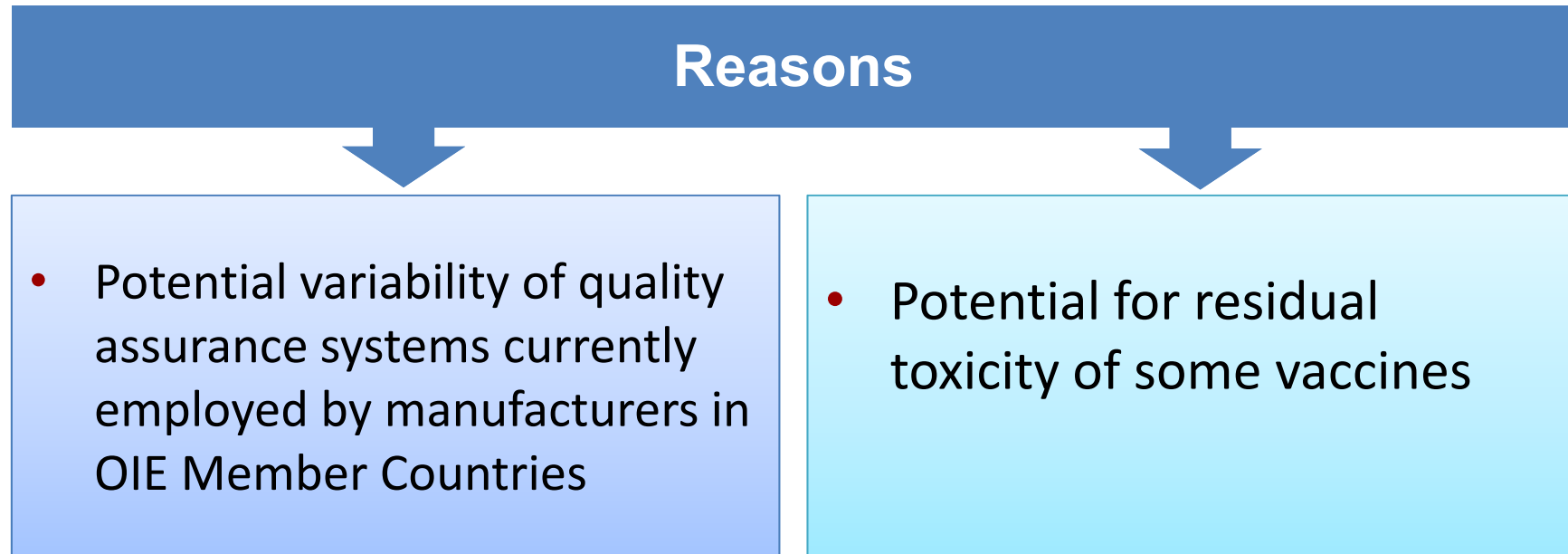


Waiving or not waiving Target Animal Batch Safety Tests (TABST)?

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 2.3.4, and amending the relevant disease chapters when they are updated.

Update on OIE standards and guidelines related to vaccines



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

Update on OIE standards and guidelines related to vaccines

Biological Standards Commission

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



***“Thermotolerant:** For vaccines, the term is used to describe the ability to retain protective immunogenicity after exposure to temperatures above the storage temperature required according to the manufacturer’s recommendations. Claims of thermotolerance must be supported by data.”*

Further information is provided in Chapter 1.1.8 Principles of Veterinary Vaccine Production. Stability Tests.

Update on OIE standards and guidelines related vaccines

To determine **the minimum standards** for **thermotolerant vaccines**, participants at the Peste des petits ruminants (PPR) - Global Eradication Programme Thermotolerant PPR Vaccines Workshop Rome, December 2017, agreed that minimum requirements should be set for manufacturers to be able to use the term “thermotolerant vaccine”.

AU-PANVAC was asked to develop a draft Standard Operating Procedure to describe the process for testing thermotolerance of PPR vaccines.

Update on OIE standards and guidelines related to vaccines

Thermotolerance Test for PPR Vaccines


Purpose: This procedure describes the process for the titration of PPR vaccine for thermotolerance testing of veterinary vaccines.

Performance of the test:

- Vaccines should be placed at any of the three temperature conditions for the determination of thermotolerance, i.e. 2-8°C, 25°C or 40°C.
- Rapid evaluation of vaccines by AU-PANVAC to be carried out at 40°C.
 - Conduct virus titrations at day 0,1, 2, 3, 4 and 5.
 - Titrations should be carried out at approximately same time each day.
 - Testing period can be extended if there is a need for further information.

Storage	Standard Cold Chain	Room	Field
Temperature	2 - 8° C	25° C	40° C
Period	2 years	10 days	5 days

Draft for consultation



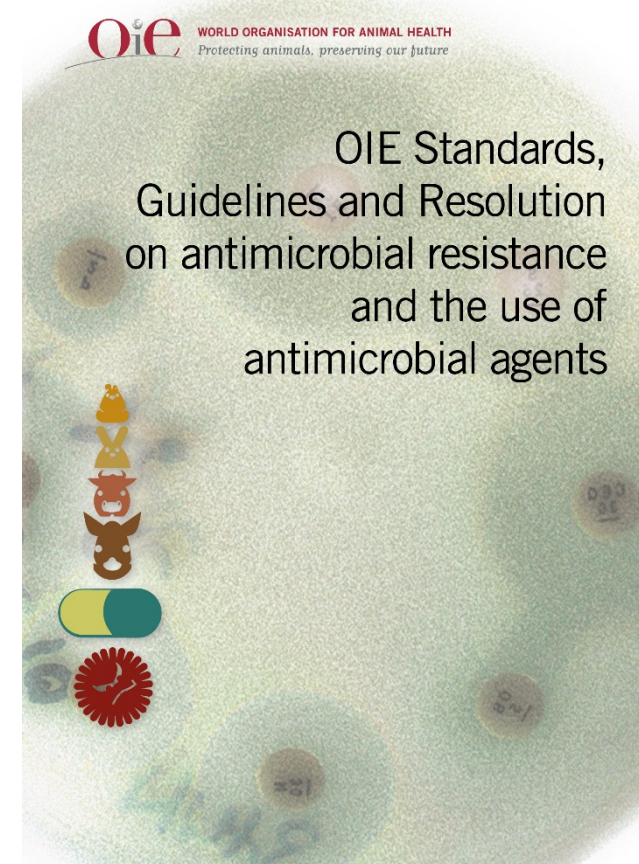
African Union
Pan African Veterinary Vaccine Centre
(AU-PANVAC)

Recommended procedure for
Peste des Petits Ruminants (PPR) Vaccine
THERMOTOLERANCE TEST
As part of the PPR Global Eradication
Program



Update on standards and guidelines related to antimicrobial resistance (AMR)

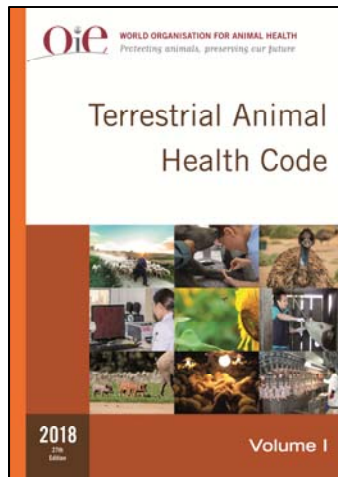
Update on OIE standards and guideline related to antimicrobial resistance (AMR)



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

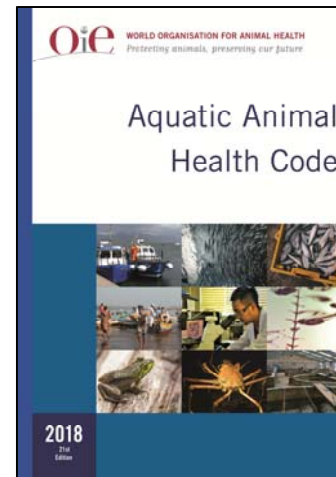
Update on OIE standards and guidelines related to AMR

Terrestrial Animal Health Code



- Ch.6.7. **Introduction** to the recommendations for controlling antimicrobial resistance
- Ch.6.8. Harmonisation of national AMR **surveillance and monitoring** programmes (updated in May 2018)
- Ch.6.9. **Monitoring of the quantities and usage patterns** of antimicrobial agents used in food-producing animals (Agreement on definitions)
- Ch.6.10. **Responsible and prudent use** of antimicrobial agents in veterinary medicine
- Ch.6.11. **Risk analysis** for AMR arising from the use of antimicrobial agents in animals

Aquatic Animal Health Code



- Ch.6.2. Principles for **responsible and prudent use** of antimicrobial agents in aquatic animals
- Ch.6.3. **Monitoring of the quantities and usage patterns** of antimicrobial agents used in aquatic animals
- Ch.6.4. Development and harmonisation of national AMR **surveillance and monitoring** programmes for aquatic animals
- Ch.6.5. **Risk analysis** for AMR arising from the use of antimicrobial agents in aquatic animals

Update on OIE standards and guidelines related to AMR

Definitions adopted in May 2018

Veterinary medical use of antimicrobial agents: means the administration of an [antimicrobial agent](#) to an individual or a group of [animals](#) to treat, control or prevent infectious disease:

01

To treat: means to administer an antimicrobial agent to an individual or a group of animals showing clinical signs of an infectious disease

02

To control: means to administer an antimicrobial agent to a group of animals containing sick animals and healthy animals (presumed to be infected), to minimize or resolve clinical signs and to prevent further spread of the disease

03

To prevent: means to administer an antimicrobial agent to an individual or a group of animals at risk of acquiring a specific infection or in a specific situation where infectious disease is likely to occur if the drug is not administered.

Terrestrial Code
Chapter 6.9

Update on OIE standards and guidelines related to AMR

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. **WHO list of critically important antimicrobials** took into consideration

OIE List of Antimicrobial Agents of Veterinary Importance: Recommendations (additional adopted in May 2018 updated May 2019)

[List of antimicrobial agents of veterinary importance](#)

Update on OIE standards and guidelines related to AMR

OIE List of Antimicrobial Agents of Veterinary Importance (May 2018)

Among the Veterinary Critically Important Antimicrobial Agents, some are also of critical importance for human health (third and fourth generation *Cephalosporins*, and *Fluoroquinolones*).

Colistin has been moved in 2016 to the WHO category of Highest Priority Critically Important Antimicrobials.

Therefore these two classes and *Colistin* should:

- ▶ **Not to be used** as preventive treatment in feed or water or in absence of clinical signs
- ▶ **Not to be used** as first line treatment, unless justified and bacteriological test
- ▶ **Extra label/off label limited** and reserved for instances no alternatives are available
- ▶ Urgently prohibit their use as **growth promoters**

Conclusion

1 We made a **significant progress** since December 2017, (Regional Seminar for OIE National Focal Points for Veterinary Products (Cycle V) Ezulwini, Swaziland, 6 - 8 December 2017)

2 OIE staff and Focal Points for Veterinary Products need to continue to **work together with partners and stakeholders** to have **high quality, practical global standards and guidelines** for veterinary medicinal products (VMPs)

3 How can the OIE **contribute** to support Member Countries to implement the standards and guidelines for VMPs?

4 Do we need **new** or **updated** OIE standards and guidelines for VMPs?

Thank you for your attention!



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