WOAH International Standards and framework for quality control and evaluation - Vaccines and Diagnostics

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TAFS Conference: “Right Tools, Real Impact: Evaluation and Use of FMD Vaccines and Diagnostics in the Field”

4 – 5 November 2025, Bangkok, Thailand

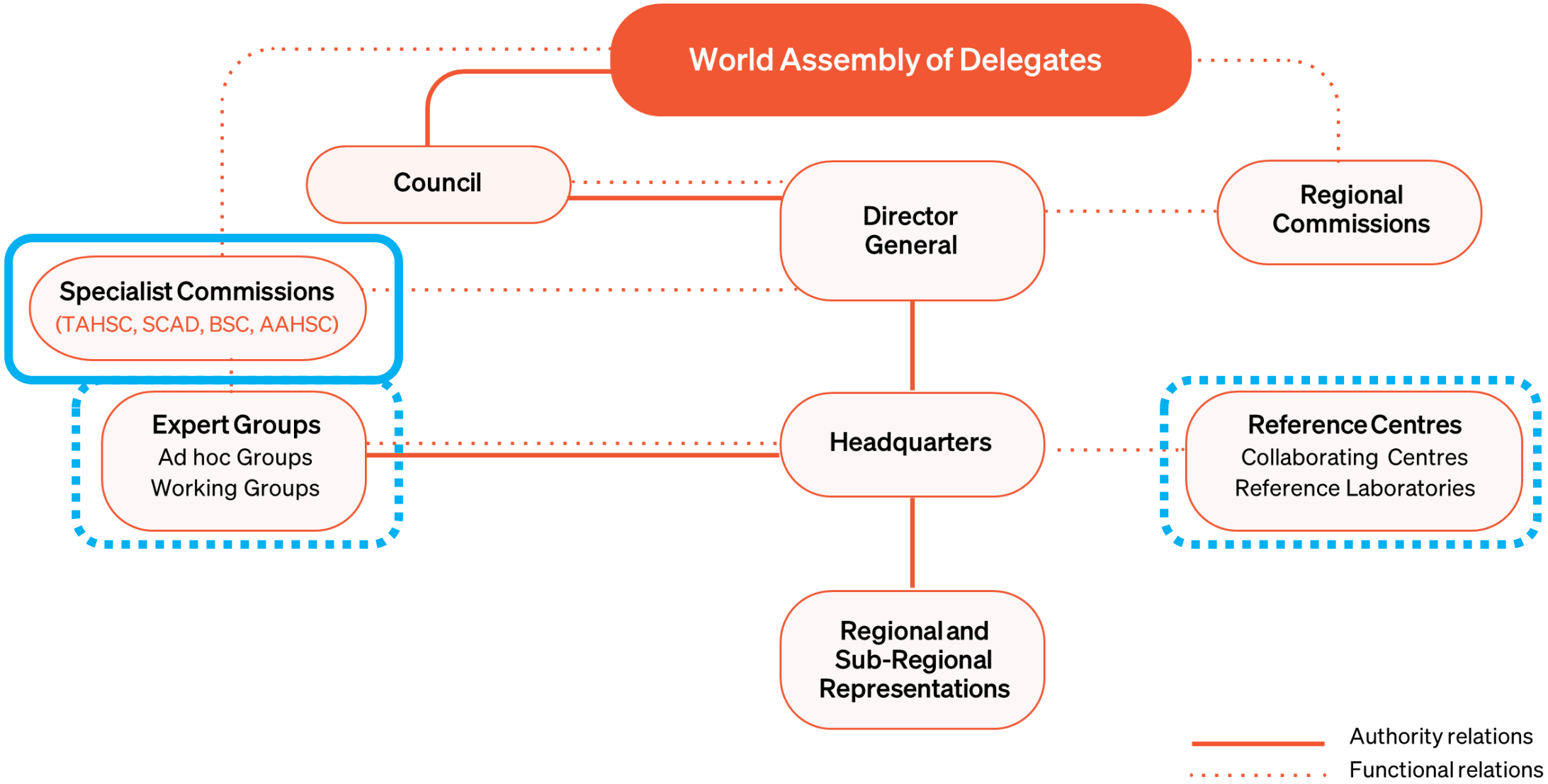
World Organisation for Animal Health
Founded as OIE

TAFS forum

INDEX

WOAH International Standards - video

WOAH structure



WOAH Specialist Commissions

→ *Elected by the World Assembly of Delegates*

Functions

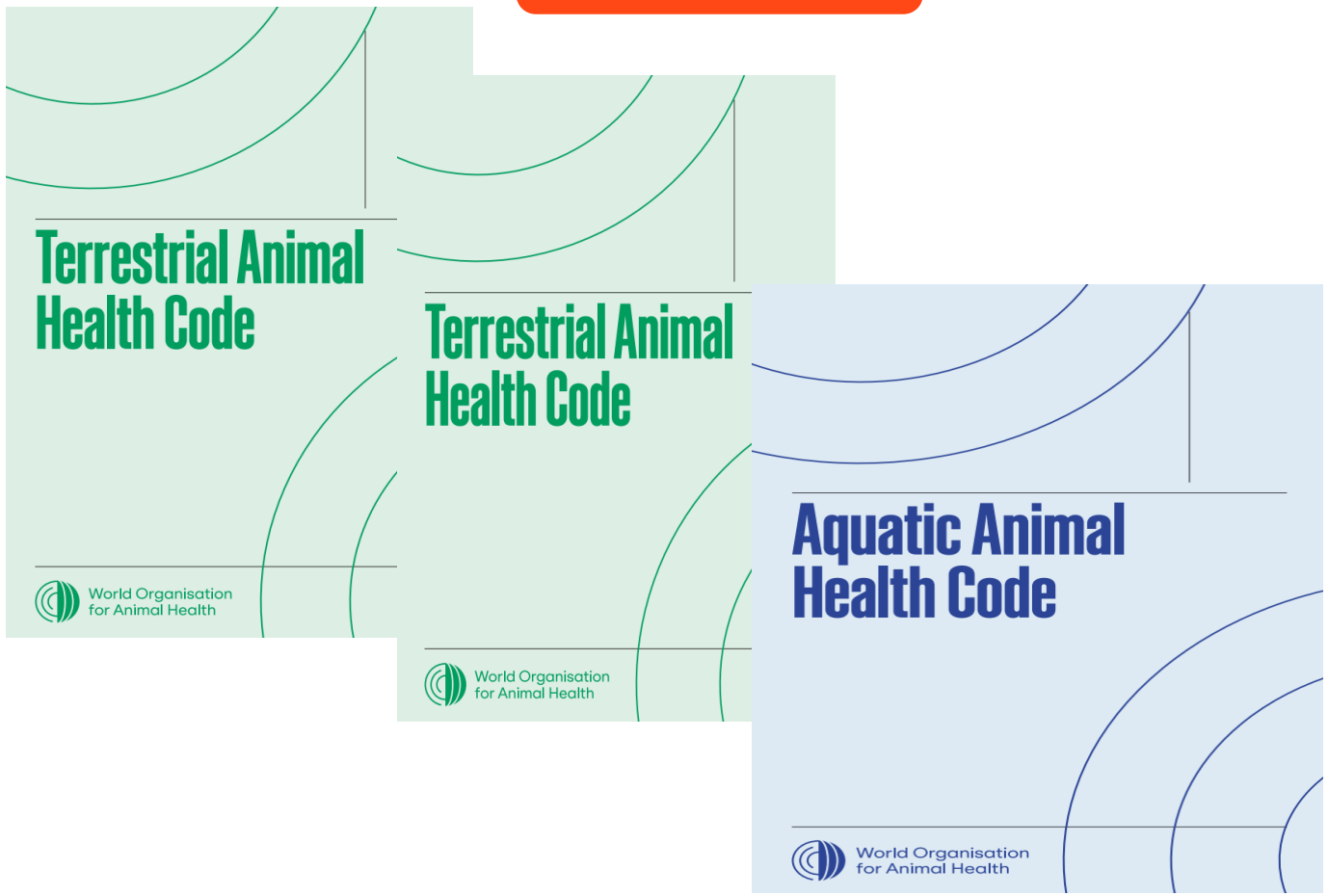
3-year Term

2024-2027

- Study **epidemiological** and **scientific** issues
  - Animal disease prevention and control methods
- Develop, update and propose international **standards** and **guidelines** for adoption by the World Assembly of Delegates
- Study **scientific** and **technical** issues raised by Members, excluding **trade** issues for which the Director General may propose mediation

WOAH International Standards

Codes



Manuals

https://www.woah.org/en/what-we-do/standards/codes-and-manuals/

WOAH Standards setting process

TOPIC

Delegates

International Organisations

Phase 1 - New work identification

REVIEW

Specialist Commissions

DRAFT

Global experts

WOAH Reference Centres

Phase 2 – Development of standards

WOAH Delegates

Phase 3 - Commenting and review

COMMENTS

183 Members

Phase 4 - Adoption

WOAH International Standards

The principles of WOAH International Standards

Science-based

Specialist Commissions Working Groups, *ad-hoc* Groups and subject-matter experts

Consensus-based

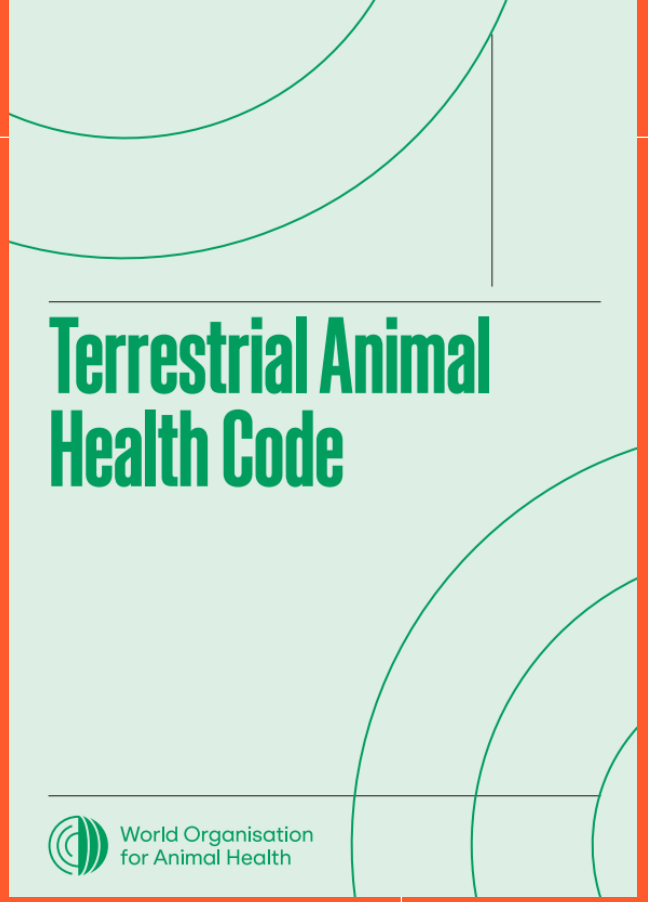
At least two cycles of comments by Members and partner organisations

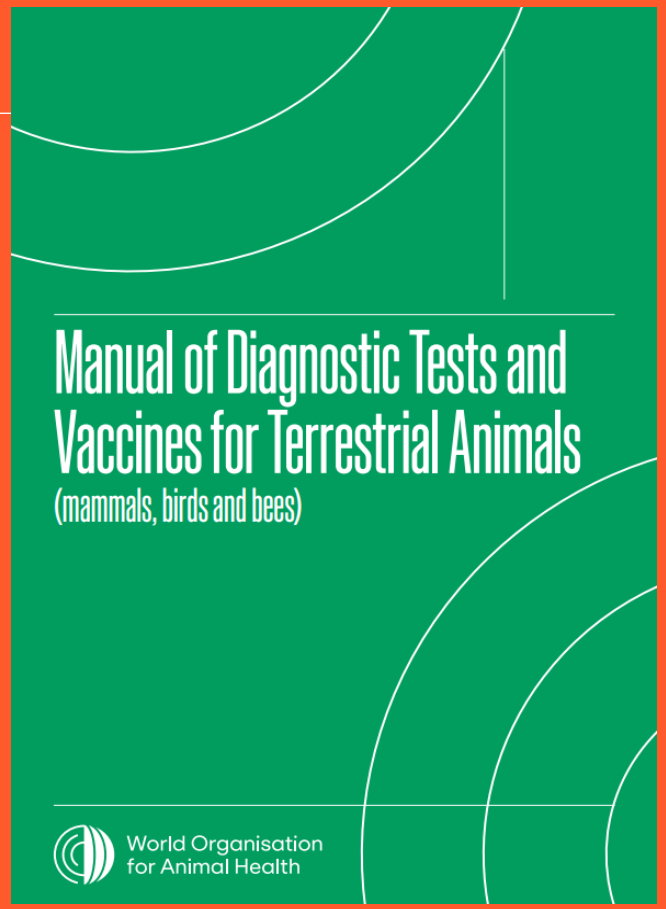
Inclusiveness

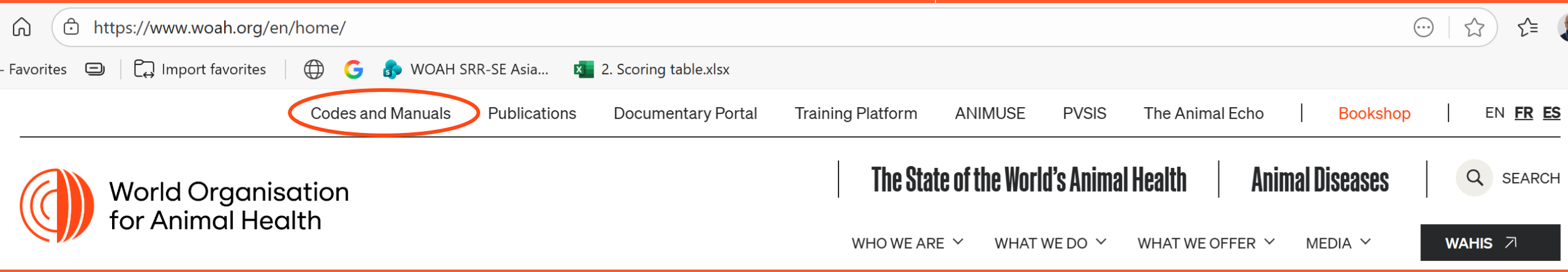
Members consult with national stakeholders

Adopted by resolution by the WOAH World Assembly (183 Members)

WOAH Standards on Foot and Mouth Disease







Terrestrial Animal Health Code

Horizontal Chapters

- Ch. 1.1. Notification of disease
- Ch. 1.4. Animal health surveillance
- Ch. 2.1. Import risk analysis
- Ch. 3.3. Evaluation of Veterinary Services
- Ch. 3.4. Veterinary legislation
- Ch. 4.4. Zoning and compartmentalisation
- Ch. 4.18. Vaccination
- Section 5 Import/export procedures and veterinary certification

https://sont.woah.org/portal/tool?le=en

FMD Chapter 8.8

Article	Topic/provision
8.8.1.	General provisions, including case definition
8.8.2	Safe commodities
8.8.3 to 8.8.11	Articles related to status: FMD-free country, zone compartment (without & with vaccination) Protection zone / Containment zone / Recovery of free status
8.8.12. to 8.8.33.	Recommendations for importation of commodities from - FMD-free countries, zones, or compartments - FMD-infected countries or zones
8.8.34 to 8.8.41.	FMD virus inactivation
8.8.42.	Requirements for endorsement of an official FMD control programme
8.8.43. to 8.8.45.	FMD surveillance: General principles, Methods, Use and interpretation of serological tests

WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals[11]

Part 1:

- Section 1.1. Introductory Chapters (Chapters 1.1.1 – 1.1.10)
- **Part 2: Specific recommendations**
  - Section 2.1. Laboratory diagnostics (Chapters 2.1.1 – 2.1.3)
  - Section 2.2: Validation of diagnostics (Chapters 2.2.1 – 2.2.8)
  - Section 2.3: Veterinary Vaccines (Chapters 2.3.1 – 2.3.5)
- **Part 3: WOAH Listed Diseases and Other Diseases of Importance**
  - Section 3.1: Multiple species (26 Chapters); 3.2: Apinae (6 Chapters); 3.3: Aves (11 Chapters); 3.4: Bovine; 3.5 (14 Chapters): Camelidae 3.6 (2 Chapters): Equidae; 3.7 (10 Chapters): Leporidae (2 Chapters); 3.8: Caprinae (12 Chapters); 3.9: Suidae (8 Chapters); 3.10: Other species (5 Chapters)

https://sont.woah.org/portal/tool?le=en

WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals[12]

Horizontal Chapters

- Ch. 1.1.5. Quality management in veterinary testing laboratory
- Ch.1.1.6. Validation of diagnostic assays for infectious diseases of terrestrial animals
- Ch. 2.2.1. Development and optimisation of antibody detection assays
- Chapter 2.2.2. Development and optimisation of antigen detection assays
- Chapter 2.2.3. Development and optimisation of nucleic acid detection assays
- Chapter 2.2.4. Measurement uncertainty

https://sont.woah.org/portal/tool?le=en

FMD Chapter 3.1.8.

Section A.	Introduction
Section B.	Diagnostic tests
Section B.1.	Detection and identification of the agent
Section B.1.1.	Virus isolation
Section B.1.2	Antigen detection ELISA
Section B.1.3	LFD
Section B.1.4	Real-time RT-PCR
Section B.1.5	Conventional RT-PCR
Section B.2.	Serological tests
B.2.1.	Virus Neutralisation Test
B.2.2.	NSP Antibody ELISA
B2.2.3.	SP Antibody ELISA

WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals[13]

Horizontal Chapters

- Ch. 1.1.8. Principles of veterinary vaccine production
- Ch.1.1.9. Tests for sterility and freedom from contamination of biological materials
- Ch. 2.3.3. Minimum requirements for the organisation and management of a vaccine manufacturing facility
- Ch. 2.3.4. Minimum requirements for the production and quality control of vaccine
- Ch. 2.3.5. Minimum requirements for aseptic production in vaccine manufacture

FMD Chapter 3.1.8.

Section A.	Introduction
Section C.	Requirement for Vaccines
Section C.1.	Seed virus management and selection of vaccine strain
Section C.2.	Method of manufacture (
Section C.3.	In-process control (inactivation kinetics and inactivation control)
Section C.4.	Final product batch tests (Innocuity, sterility, Identity, Purity, Safety, Potency Testing)
Section C.5.	Requirement for registration of vaccine (manufacturing process, Safety, efficacy, Purity, Duration of immunity, Stability)
Section C.6.	Storage and monitoring of concentrated antigens
Section C.7.	Emergency release of vaccines

https://sont.woah.org/portal/tool?le=en

WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals[14]

Horizontal Chapters

- Ch. 1.1.8. Principles of veterinary vaccine production
- Ch.1.1.9. Tests for sterility and freedom from contamination of biological materials
- Ch. 2.3.3. Minimum requirements for the organisation and management of a vaccine manufacturing facility
- Ch. 2.3.4. Minimum requirements for the production and quality control of vaccine
- Ch. 2.3.5. Minimum requirements for aseptic production in vaccine manufacture

FMD Chapter 3.1.8.

Section A.	Introduction
Section B.	Diagnostic tests
Section C.	Requirement for Vaccines
Section D	Vaccine Matching Tests
Section D.1.	Introduction
Section D.2.	Selection of field virus for vaccine matching
Section D.3.	Selection of vaccine strains to be matched
Section D.4.	Tests – Vaccine Matching
Section D.4.1.	Relationship between field isolate and vaccine strain (VNT, ELISA?)
Section D.4.2	Testing for fitness of purpose of a vaccine

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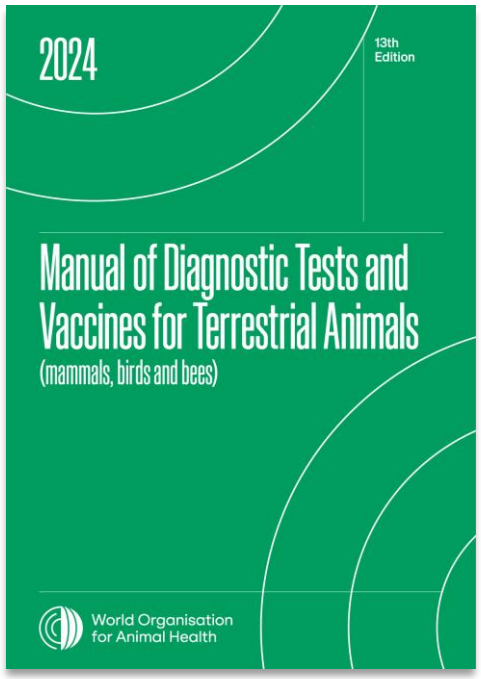
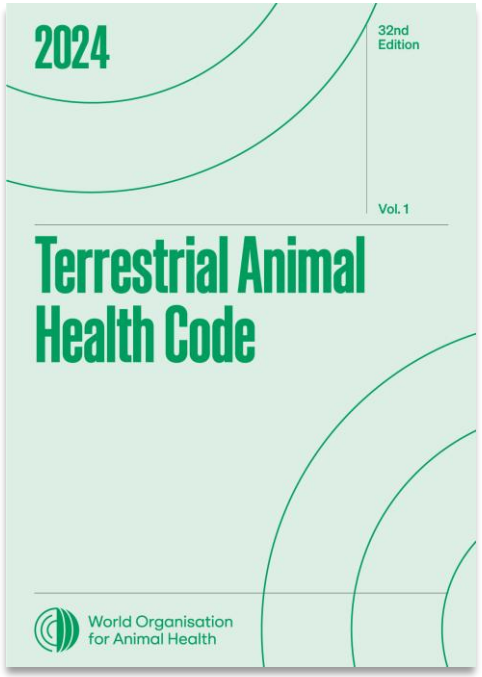
WOAH International Standards on FMD





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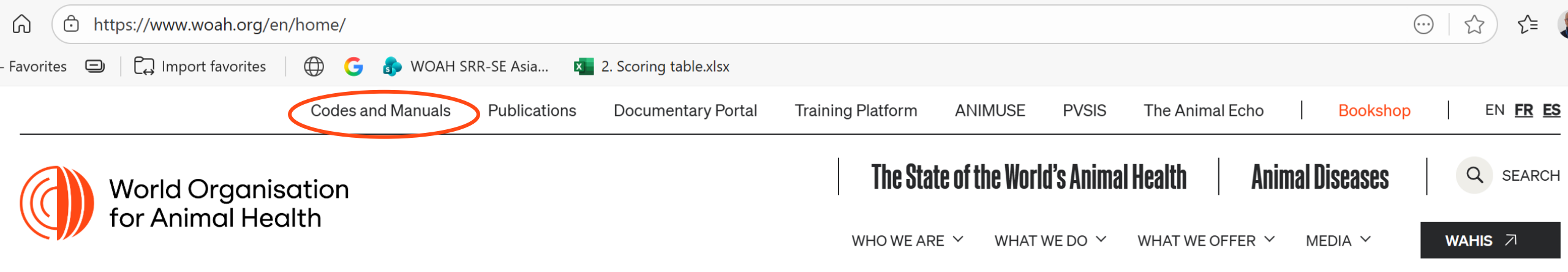
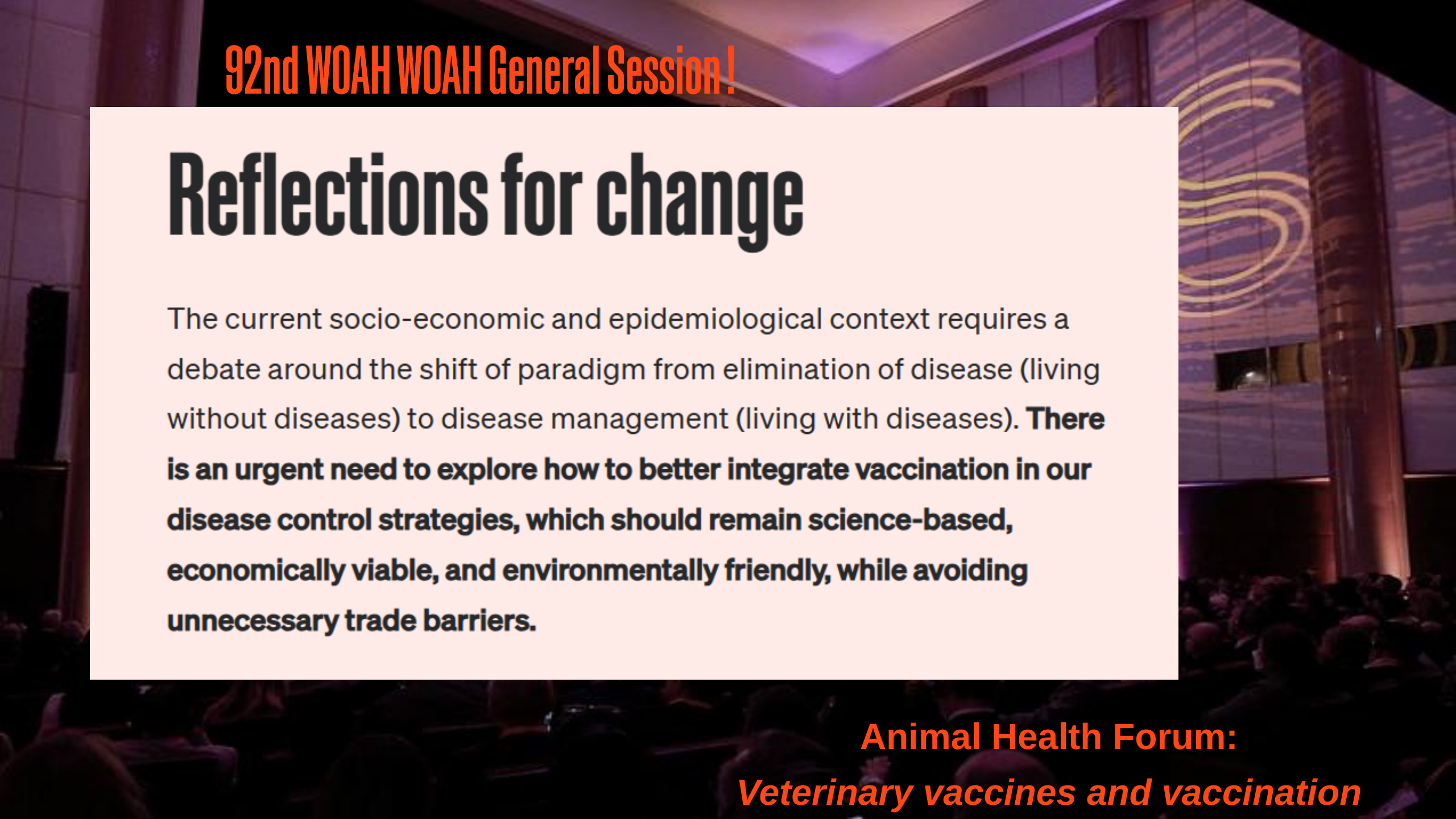
Terrestrial Code – *Chapter 8.8.*

- Significant revisions adopted in 2024

Terrestrial Manual – Chapter 3.1.8

- Changes adopted in 2025 at the WOAH 92nd General Session
  - 'Diagnostic techniques' – composition of transport medium, use of the probang cup
  - Update protocols for virus isolation, ELISA, LFD, VNT
  - Deletion of CFT
  - Differential dx for Senecavirus A





92nd WOAH WOAH General Session !

Reflections for change

The current socio-economic and epidemiological context requires a debate around the shift of paradigm from elimination of disease (living without diseases) to disease management (living with diseases). **There is an urgent need to explore how to better integrate vaccination in our disease control strategies, which should remain science-based, economically viable, and environmentally friendly, while avoiding unnecessary trade barriers.**

Animal Health Forum:

Veterinary vaccines and vaccination

WOAH Animal Health Forum: Veterinary vaccines and vaccination – 92nd GS

- ✓ The discussions and recommendations of the Animal Health Forum, held during the 92nd General Session and focused on the topic of ***"Veterinary Vaccines and Vaccination: From Science to Action – Reflections for Change"***, highlighted the need to strengthen the availability, access to, regulation of, and integration of vaccines into disease prevention strategies;
- ✓ The Forum's recommendations included fostering **public-private partnerships,** harmonising **regulatory frameworks**, improving **sustainable financing**, and enhancing **communication** and **monitoring** to build **trust** in vaccination;
- ✓ Veterinary vaccines, along with other preventive measures, can significantly r**educe the need for antimicrobials in animals**, thereby playing a critical role in the containment of AMR in line with the 79th UN General Assembly Political Declaration on AMR

Effective disease control requires a combination of measures, including biosecurity, movement control, zoning and compartmentalisation, surveillance, and effective communication strategies.

Technical Item 1: Animal Vaccines and Vaccination – WOAH 34th RC Conference

TECHNICAL ITEM I

Animal Vaccines and Vaccination: Development, Registration, Use, Surveillance, and Impact on Trade

- ✓ The Regional Commission emphasized the vital role of veterinary vaccines in preventing and controlling transboundary and zoonotic diseases, supporting One Health, food security, and reducing AMR
- ✓ Members to strengthen collaboration with **WOAH Reference Centres** through sample sharing to improve surveillance, diagnosis, and vaccine development
- ✓ WOAH to update the list of priority diseases where vaccination can reduce AMR and to support Members in developing national vaccination plans
- ✓ Enhance **regional coordination, information sharing, and vaccine research** to ensure quality vaccines and prevent substandard products
- ✓ Improve **vaccine access** through better procurement systems, mutual recognition of registration, and stronger supply chains.
- ✓ Maintain **safe trade and effective disease control** by adhering to WOAH standards on vaccination and animal health.

Report

Recommendations

Pool 1: Status in 2025

Characterisation of different FMD virus lineages

Based on data from WRLFMD, RRLSEA, the WOAH/FAO Lab Network, publications* and reported @SEACFMD

Country	O					A		Asia-1
	ME-SA/Ind-2001e	SEA / Mya-98	CATHAY	ME-SA / PanAsia	ME-SA/ PanAsia-2	ASIA / Sea-97	ASIA/Ind	
Cambodia	2024	2016		2024		2016		
Laos	2024	2017		2024		2018		
Malaysia	2024	2016	2005	2023	2009	2023		
Myanmar	2022	2021				2021	2010	2017
Thailand	2024	2018	2012	2019		2022		
Vietnam	2023	2024	2018	2024		2017		2007
PR China	2025	2020	2024	2019		2019		2009
Indonesia	2025							
Mongolia	2022	2018		2017		2016		

*Recent papers: Khanh et al., (2025)

SEACFMD Roadmap 2026 – 2030

World Organisation for Animal Health

GOAL 🎯

To achieve regional control and eradication of FMD through strengthened veterinary services and regional collaboration

OUTCOME 1 🏅

🧬 FMD control enhanced through risk-based strategies, supporting PCP-FMD progress and maintaining FMD-free zones

OUTPUTS

- 🧬 Fit for purpose FMD Surveillance
- 🔬 Veterinary Laboratory diagnostic system
- 🚚 Movement control, quarantine and biosecurity
- 💉 FMD vaccination and access to quality vaccines
- 🚨 Emergency preparedness and contingency planning

OUTCOME 2 🏅

📜 Improved ownership and enabling environment (policy, legislation, advocacy, workforce) at national level

OUTPUTS

- ⚖️ Policies and legislations
- 📢 Communication, Advocacy and stakeholder engagement
- 💰 Cost efficient synergies with other TADs control

OUTCOME 3 🏅

🤝 Enhanced partnerships and regional collaboration for effective FMD and TADs control.

OUTPUTS

- 👷 Enhanced engagement and multi-disciplinary partnerships with key stakeholders
- 🌉 Cross border collaboration and partnerships among key stakeholders
- 🏛️ Efficient and effective SEACFMD coordination platforms
- 🌏 Sustained collaboration with key partners in the region

Some takeaway points…

- ✓**Vaccine is one of the most cost-effective and impactful tools** for the prevention, control, elimination and eradication of animal diseases.
- ✓The minimum requirements for veterinary vaccines are well-defined in horizontal chapters and disease specific chapters of the WOAH Terrestrial Manual;
- ✓ **“Vaccines don’t protect—vaccination does”**, - success depends on coverage, compliance, and policy (risk-based vaccination policies)
- ✓**Vaccination along is not enough!**

- Animal movement control
- Biosecurity
- Early detection and response

} are key to success

World Organisation for Animal Health

SEACFMD

TAFS forum

Thank You