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Biological Standards Commission - 2025

Prof Emmanuel Couacy-Hymann

92nd General Session



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Agenda

1. WOAH Standards Setting Process
2. Updates of the work of the BSC
3. Main changes emanating from the 2025 General Session
4. 2025-2026 Workprogramme





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1.WOAH Standards Setting Process





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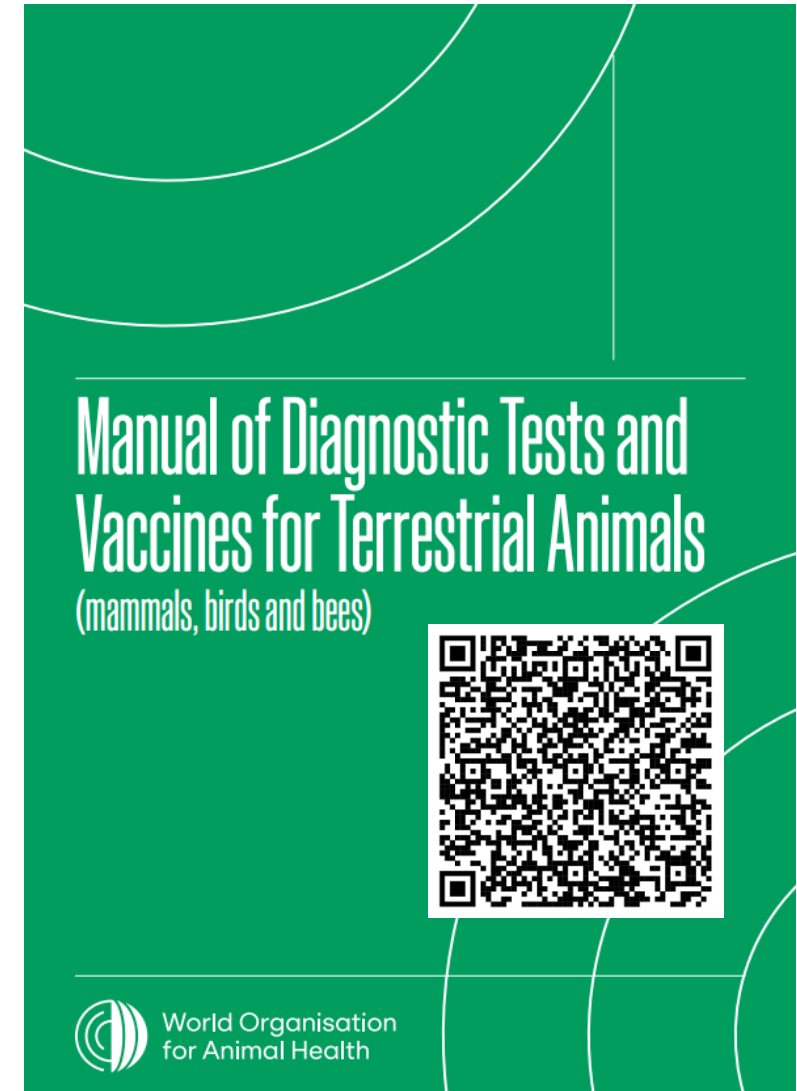


Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

Aims to **facilitate international trade** in animals and animal products and to **contribute to the improvement of animal health** services world-wide.

The principal **target** readership is **laboratories carrying out veterinary diagnostic tests and surveillance**, plus vaccine manufacturers and regulatory authorities in the WOA Member Countries.

The **objective** is to provide **internationally agreed diagnostic laboratory methods** and **requirements for the production and control of vaccines** and other **biological products**.





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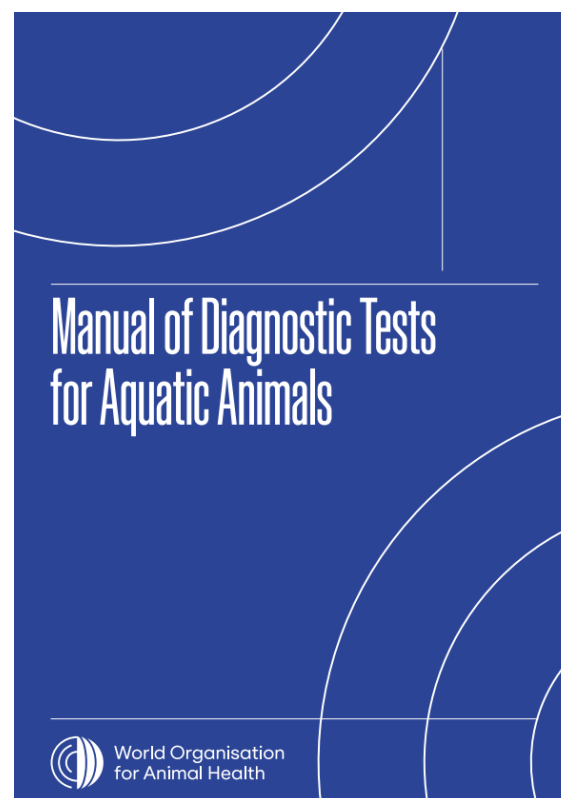
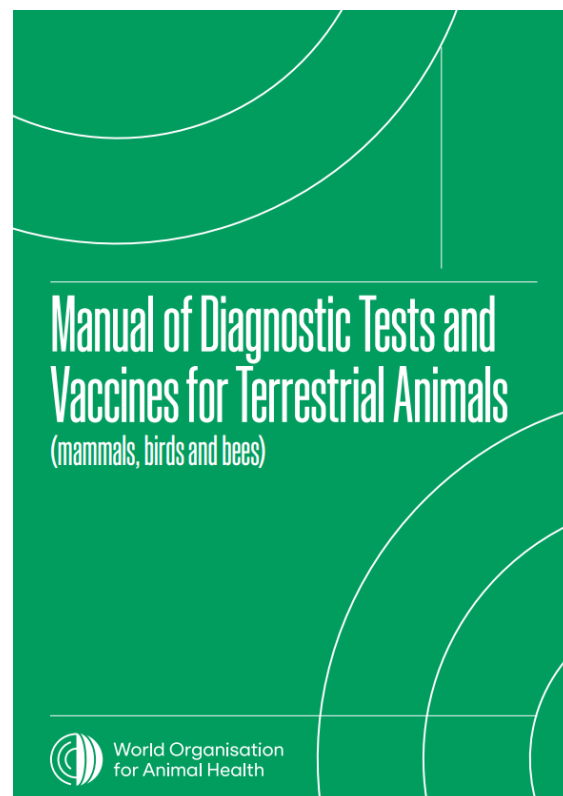


Participation of all the Members

Democratic

Flexible
and fast

Standard-
setting
procedure



Transparent

Science-based

Risk based

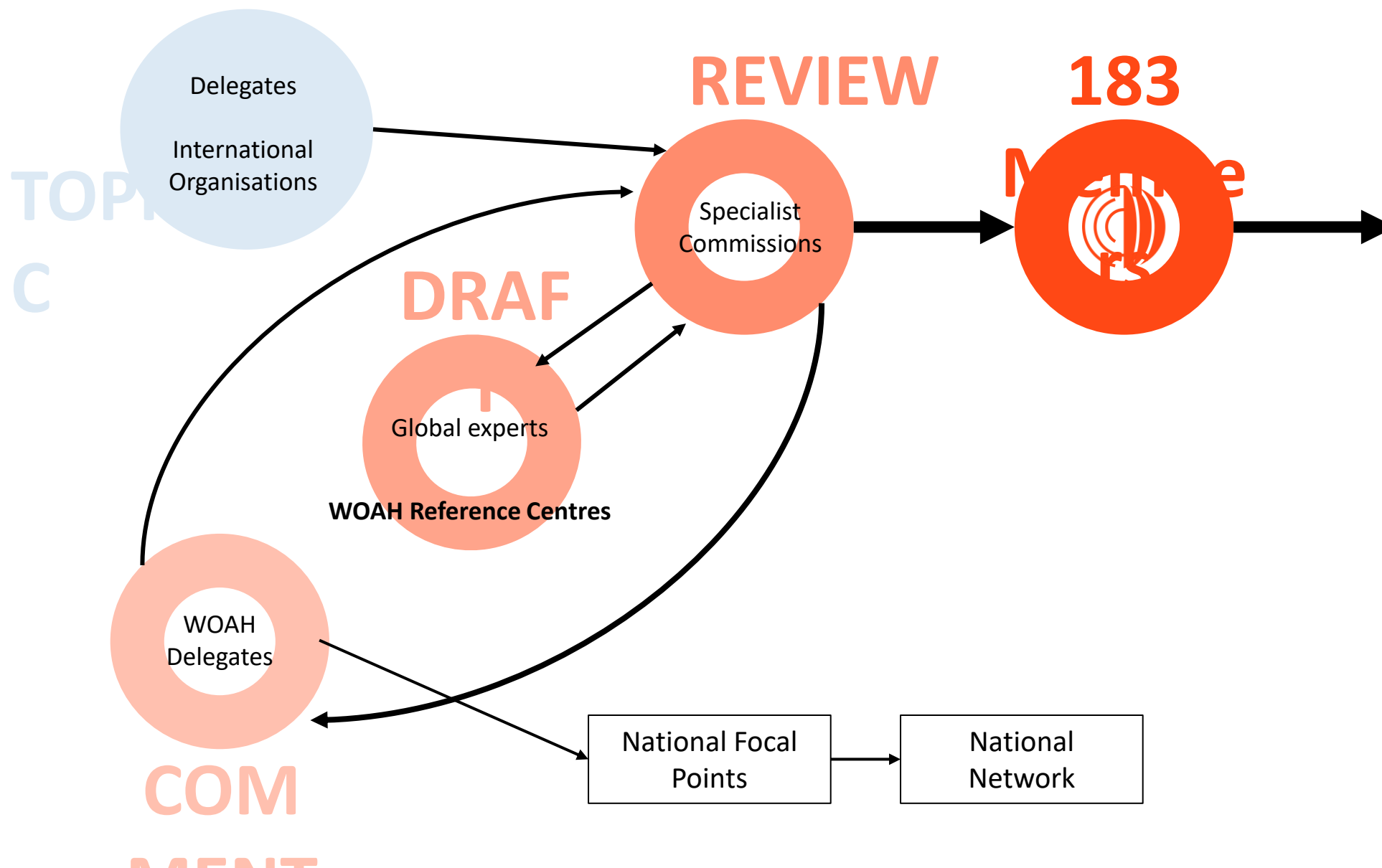
International
collaboration



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**WOAH
Internat
ional
Standard**



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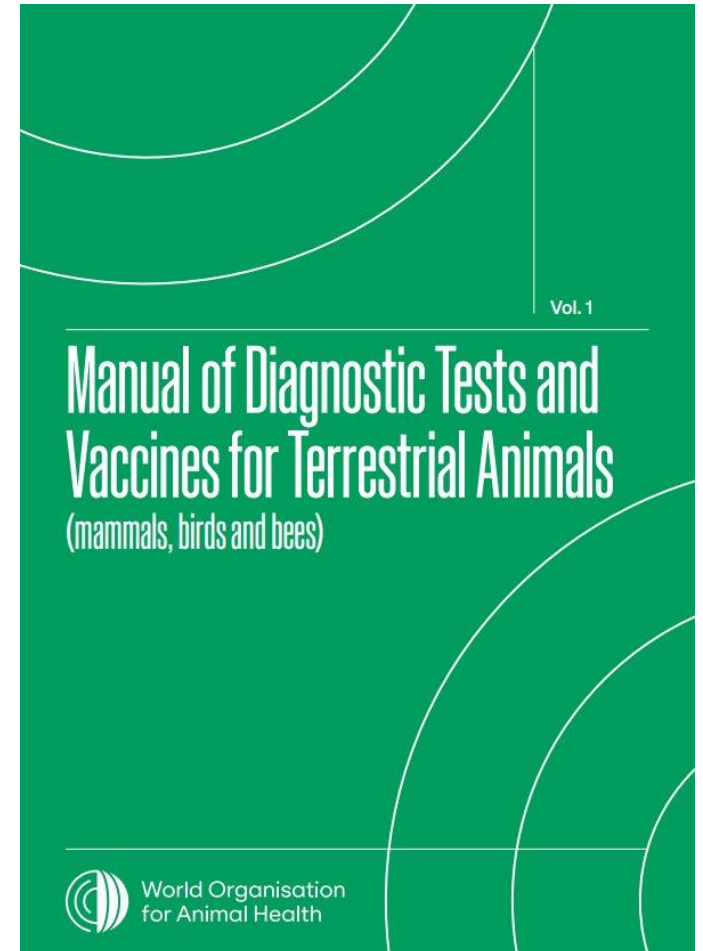


Review cycle

Review cycle (from the September meeting to the General Session)

Two rounds of commenting aimed at proposing updates for adoption within 1 year:

- **First-round** in October: Members submit their experts' in-depth reviews
- **Second-round** in March as the version to be presented for adoption: only essential amendments that are crucial to the update. All remaining comments will be filed and addressed when the chapter is next updated





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Structure of the Manual - 20245

- **General Standards** (10 Chapters)
- **Specific Recommendations**
 - Laboratory diagnostics (3 Chapters)
 - Validation of diagnostic tests (8 Chapters)
 - Veterinary vaccines (4 Chapters)
- **WOAH Listed Disease and other disease of importance**
 - Multiple species (26 Chapters)
 - Apinae (6 Chapters)
 - Aves (11 Chapters)
 - Bovidae (14 Chapters)
 - Camelidae (2 Chapters)

121 Chapters of diagnostic
procedures and source of
information for any veterinary
diagnostic laboratory

- Equidae (10 Chapters)
- Leporidae (2 Chapters)
- Caprinae (12 Chapters)
- Suidae (8 Chapters)
- Other disease (5 Chapters)



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2. Updates of the work of the Biological Standards Commission





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Activities

New term of the Biological Standards Commission

Since May 2024, the BSC met:

- 9 – 13 September 2024
- 3 – 7 February 2025

Electronic exchanges between meetings





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Chapters proposed for adoption

- A total of **28 chapters were proposed and adopted** at the 92nd General Session
- The chapters are available through a link in the BSC report, which is available on the Delegates website and in WOA's portal

WOAH Delegates Portal



BSC report



English



French



Spanish



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Update of the Terrestrial Manual

28 Chapters proposed for adoption

8 General chapters and 20 disease specific chapters

#	Chapter number	Chapter title	Level amendments
1	1.1.3.	Transport of biological materials	Minimal
2	1.1.7.	Standards for high throughput sequencing, bioinformatics and computational genomics	Moderate
3	1.1.9.	Tests for sterility and freedom from contamination of biological materials intended for veterinary use	Moderate
4	2.1.1.	Laboratory methodologies for bacterial antimicrobial susceptibility testing	Extensive
5	2.2.1.	Development and optimisation of antibody detection assays	Moderate
6	2.2.2.	Development and optimisation of antigen detection assays	Extensive
7	2.2.3.	Development and optimisation of nucleic acid detection assays	Extensive
8	2.2.5.	Statistical approaches to validation	Extensive
9	2.2.8.	Comparability of assays after minor changes in a validated test method	Extensive
10	3.1.2.	Aujeszky's disease (infection with Aujeszky's disease virus)	Moderate
11	3.1.8.	Foot and mouth disease (infection with foot and mouth disease virus)	Moderate
12	3.1.9	Heartwater	Minimal
13	3.1.21.	Rinderpest (infection with rinderpest virus)	Moderate
14	3.2.4.	Infestation of honey bees with Aethina tumida (small hive beetle)	Extensive



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Update of the Terrestrial Manual

28 Chapters proposed for adoption

#	Chapter number	Chapter title	Level amendments
15	3.2.5.	Infestation of honey bees with <i>Tropilaelaps</i> spp.	Extensive
16	3.3.1.	Avian chlamydiosis	Moderate
17	3.3.2.	Avian infectious bronchitis	Moderate
18	3.3.4.	Avian influenza (including infection with high pathogenicity avian influenza viruses)	Extensive
19	3.4.9.	Enzootic bovine leukosis	Moderate
20	3.4.13.	Theileriosis in cattle (infection with <i>Theileria annulata</i> , <i>T. orientalis</i> and <i>T. parva</i>)	Minimal
21	3.4.14.	Trichomonosis	Extensive
22	3.6.1.	African horse sickness (infection with African horse sickness virus)	Extensive
23	3.6.5.	Equine infectious anaemia	Extensive
24	3.8.2.	Caprine arthritis/encephalitis and Maedi-visna	Moderate
25	3.8.5.	Enzootic abortion of ewes (ovine chlamydiosis) (infection with <i>Chlamydia abortus</i>)	Moderate
26	3.9.2.	Classical swine fever (infection with classical swine fever virus)	Moderate
27	3.9.7.	Swine vesicular disease	Moderate
28	3.9.1.	African swine fever (vaccine section only)	Extensive



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Chapter 3.9.1. 'African swine fever (infection with African swine fever virus)' (vaccine section only) (2021)

- **Thoroughly updated Section C 'Requirements for vaccines'** of the African swine fever (ASF) chapter, covering the manufacture of pure, potent, safe, and efficacious vaccines for ASF, including key vaccine performance and quality criteria
- **Presented the newly drafted section** for four rounds of comment
- **Acknowledged that live modified vaccines** are already in use in some Members highlighting the Commission's decision to establish a minimum standard in the WOAHP *Terrestrial Manual*, with a commitment to reviewing it regularly as new scientific evidence becomes available
- **Main focus on Safety and Reversion-to-virulence of the vaccine strain:**
 - **Review to Introduce mock-vaccinated control groups** in the piglet and sow safety studies
 - **Clarified the reversion-to-virulence experiment**, specifying that: The same quantity and viral titre of the master seed vaccine virus used in the first passage (P1) must be used : An equal quantity and viral titre (diluted if necessary) of the positive material used for the final passage (P5) should be used to inoculate the two groups of pigs



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Chapter 3.9.1. 'African swine fever (infection with African swine fever virus)' (vaccine section only) (2021)

Following second-round Member comments, the Commission proposes:

- In Section C.1. 'Background', **add** a new paragraph mentioning that: "There is evidence that first generation MLV vaccines may revert to virulence and negatively affect the reproductive performance of pregnant sows (Nguyen *et al.*, 2025; Van den Born *et al.*, 2025). Additionally, as first generation MLV vaccines are unlikely to cause sterile immunity, immunised pigs are likely to shed the vaccine viruses, which may result in horizontal transmission of the vaccine viruses. This could affect reproductive performance of pregnant sows and may also increase the risk of recombination of the vaccine virus with circulating strains." And add the references.



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Deletion of Chapter 2.3.2. *'The role of official bodies in the international regulation of veterinary biologicals'*

→ Commission agreed to remove it from the *Terrestrial Manual* as the chapter is not fit for purpose. The role of the *Terrestrial Manual* in providing a standard on regulation of biologicals should be further discussed

CHAPTER 2.3.2.

THE ROLE OF OFFICIAL BODIES IN THE INTERNATIONAL REGULATION OF VETERINARY BIOLOGICALS



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Changes to the Glossary of the WOAH Terrestrial Manual

~~• Biosafety~~

~~Laboratory biosafety describes the principles and practices for the prevention of unintentional exposure to biological materials, or their accidental release.~~

~~• Biosecurity~~

~~Laboratory biosecurity describes the controls on biological materials within laboratories, in order to prevent their loss, theft, misuse, unauthorised access, or intentional unauthorised release.~~

• Laboratory biosafety

See Biosafety Laboratory biosafety describes the principles and practices for the prevention of unintentional exposure to biological materials, or their accidental release.

• Laboratory biosecurity

See Biosecurity Laboratory biosecurity describes the controls on biological materials within laboratories, in order to prevent their loss, theft, misuse, unauthorised access, or intentional unauthorised release.



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3. Main changes from the 2025 General Session





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Reference Centres

FIGURES FROM END OF MAY 2025

	Reference Laboratories	Collaborating Centres	Total
Number	270	80	350
Countries	39	33	48
Diseases/Topics	109	All 6 main focus areas: 36 specialities	–
Experts	206	–	–

FIGURES FROM END OF MAY 2025

Region	Reference Laboratories	Collaborating Centres	Total
Africa	14	7	21
Americas	49	23	72
Asia-Pacific	64	16	80
Europe	138	27	165
Middle East	7	5	12

3 New Reference Laboratories:

- Equine piroplasmosis – INDIA
- Equine rhinopneumonitis – JAPAN
- African swine fever – SPAIN

5 New Collaborating Centres:

- Wildlife Trade and Wildlife Health – SINGAPORE
- Wildlife Health Surveillance and Epidemiology – THAILAND
- One Health – KENYA
- Advanced Training in Livestock Health – CANADA
- Research, Diagnosis and Surveillance of Wildlife Pathogens – USA



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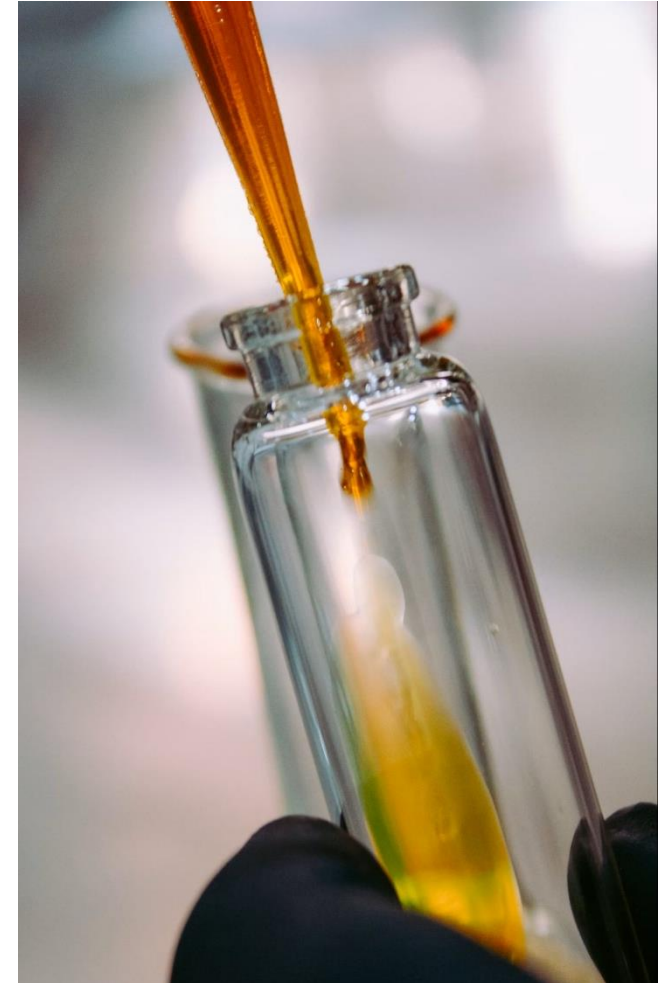
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Reference Centre activities

- Performance review of annual reports submitted by Reference Centres
- Amendments to the annual report template to improve the quality of data collected
- Review of new applications for Reference Centre status
- Review of nominations for changes of experts at Reference Laboratories
- Review of new applications for laboratory twinning projects
- Monitoring the functioning of Reference Centre networks for ASF, PPR, FMD, Rabies, welfare and wildlife.





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**Important
change to the
requirement
regarding
accreditation
to ISO 17025
or equivalent
quality
management
system**

As Reference Laboratories are designated for a specific disease, they **must hold accreditation for the disease's frontline diagnostic test**

Recognising that some laboratories would not currently meet that criterion, the Biological Standards and Aquatic Animals Commissions agreed to give a 3-year deadline before introducing the new requirement.

The new criterion will be as follows:

“Provide documented proof (certificates) of accreditation to the ISO 17025 or equivalent quality management system, ideally with relevant tests (at least one test described in the corresponding Manual chapter) included in the scope of the accreditation.”



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WOAH- approved International Standard reagents

Reactivate the project to extend the list of WOAH-approved reference reagents, which is part of an initiative to strengthen the WOAH Standard Reagents Programme

WOAH aims to **reinforce the availability of high-quality diagnostic reagents for its Members**, providing them with a trusted global repository while also offering Reference Laboratories an opportunity to showcase their validated reagents

WOAH supports international collaboration and strengthen laboratory capacities worldwide



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6 new lab twinning projects approved:

1. Australia – Indonesia (avian influenza)
2. Canada – Nigeria (Anthrax)
3. China – Kazakhstan (equine infectious anaemia)
4. Italy – Saudi Arabia (aquatic diseases)
5. Italy – Uzbekistan (quality management, biosafety and biosecurity)
6. Italy – Algeria (quality management, biosafety and biosecurity)

Projects initiated
since 2008
117

Completed
97

Underway
17

New RLs/CCs **23**



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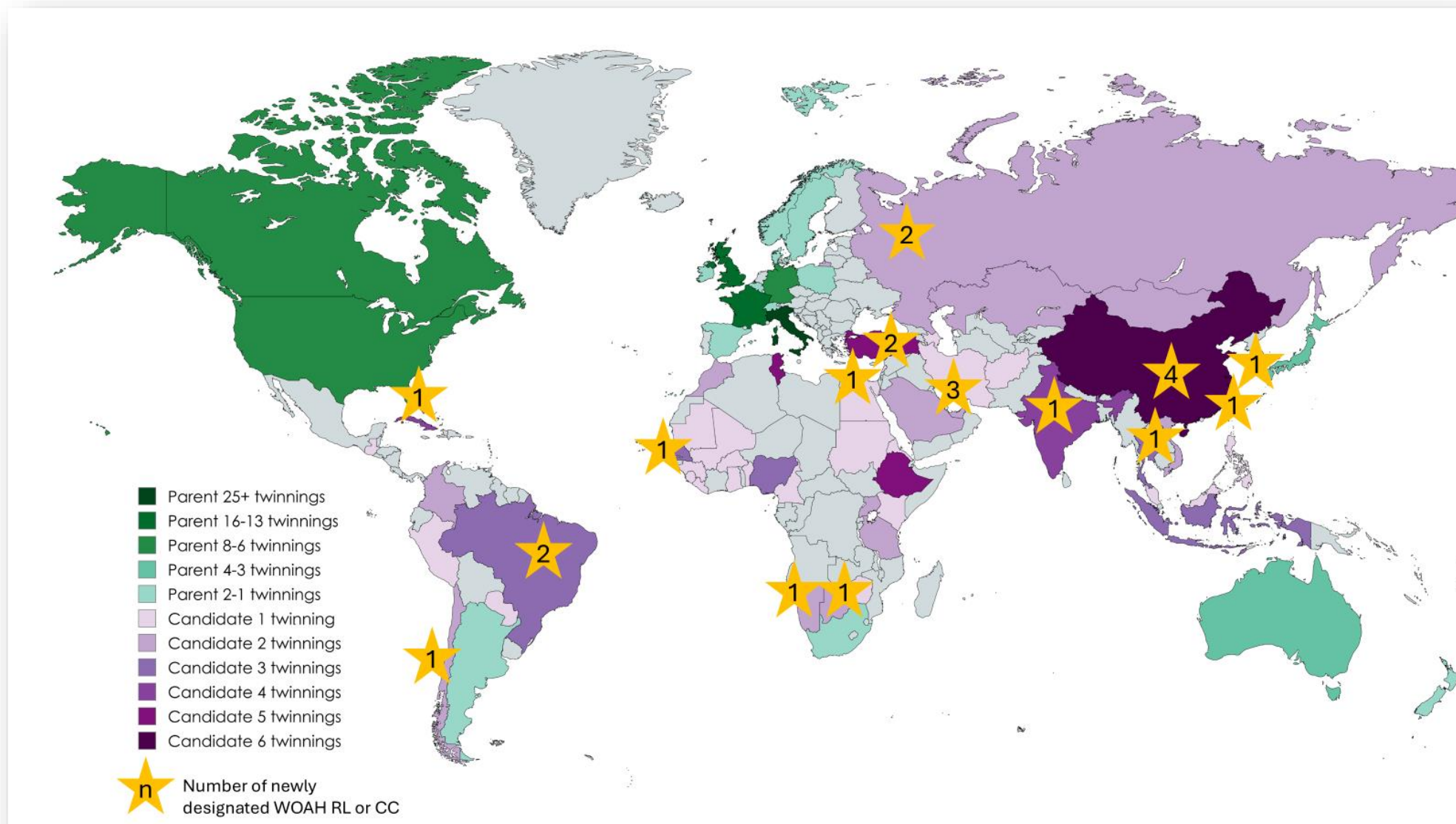
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Laboratory Twinning Programme

Implementation 2024-2025





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Opportunities and needs

Identified opportunities and needs of WOAH Reference Centres

Type of Centre	Disease/ Area	Region
Reference Laboratory	Equine encephalitides	All
Reference Laboratory	PPR	Africa
Reference Laboratory	Nagana	Africa
Reference Laboratory	Rabies	Africa
Reference Laboratory	Glanders	Americas & Asia and the Pacific
Reference Laboratory	West Nile fever	Americas
Reference Laboratory	Caprine arthritis/encephalitis and maedi Visna	All
Reference Laboratory	Lumpy skin disease	All
Reference Laboratory	Mammalian tuberculosis	Africa
Collaborating Centre	Artificial Intelligence	All



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Coordination with other Specialist Commissions

Scientific Commission for Animal Disease (SCAD)

- Case definitions: Paratuberculosis and caprine arthritis/encephalitis and maedi visna
- Listing assessment: Nairobi sheep disease

Terrestrial Animal Health Standards Commission

- Provided advice on a number of topics requested by the Code Commission
- Ensure that relevant amendments in the corresponding chapters of the *Terrestrial Code* and the *Terrestrial Manual* are well coordinated

Aquatic Animals Commission

- Discussion of management of the Reference Centres and other transversal topics



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4. 2025-2026

Work programme





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Work programme

Terrestrial Manual

- Updating the chapters of the *Terrestrial Manual*
- Report format and publishing of comments

Reference Centres

- Enhance annual performance review
- Evaluate Annual Reports
- Increase the visibility and accessibility of current Centres
- Explore mechanisms to improve collaboration by bringing together the Centres with the same main focus area

Case definitions

- Follow up the implementation of the SOPs for case definitions

Standardisation/Harmonisation

- Project to extend the list of WOAH-approved reference reagents
- Project to develop replacement International Standard Bovine and Avian Tuberculin

Projects

- Virtual Biobanks



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Thank you