Report of the Meeting of the WOAH Biological Standards Commission

Original: English (EN)

5 to 9 February 2024

Paris

Introduction and Member contribution

This report presents the work of the WOAH Biological Standards Commission (hereinafter called 'the Commission') who met in Paris, France from 5 to 9 February 2024.

During the meeting, 13 chapters from the WOAH *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*) were approved for circulation for second-round Member comment and proposal for adoption at the General Session in May 2024. The Commission wished to thank the following Members for providing comments on draft texts for the WOAH *Terrestrial Manual* circulated with the Commission's September 2023 report: Canada, China (People's Rep. of), Japan, New Zealand, Switzerland, the United Kingdom (UK), the United States of America (USA), and the Member States of the European Union (EU). The Commission also wished to acknowledge the valuable advice and contributions from numerous experts of the WOAH scientific network.

The Commission reviewed all comments that were submitted prior to the deadline and were supported by a rationale. Where amendments were of an editorial nature, no explanatory text has been provided. The Commission wished to note that when texts proposed by Members to improve clarity were not accepted, it considered the text was clear as currently written. The Commission made amendments to draft texts, where relevant, in the usual manner by 'double underline' and 'strikethrough'. In relevant annexes, amendments proposed at this meeting are highlighted in yellow to distinguish them from those made previously.

Your participation in the WOAH standard-setting process is valued. Thank you for your engagement in the process!

During the meeting, ten Reference Centre applications and ten nominations for replacement experts were also evaluated.

Annexes

Texts in Annexes 4 to 16 will be proposed for adoption at the 91st General Session in May 2024.

How to submit comments

The Biological Standards Commission strongly encourages WOAH Members and International Organisations with a WOAH Cooperation Agreement to participate in the development of WOAH International Standards by submitting comments on relevant annexes of this report.

Engagement of Members and International Organisations in the standard-setting process through the submission of comments is critical to ensure the Commission's work is science based and takes into consideration the different contexts among Members and stakeholders, and enables the implementation of standards. To ensure that comments are considered they should be submitted by the deadline and in the format described in the guidance and SOP documents available on the Delegate's website and the WOAH public website.

Comments that are not correctly formatted as described in the guidance, may not be considered by the Commission. Any questions on the requirements for formatting and submission of comments should be sent to BSC.Secretariat@woah.org

The Biological Standards Commission wished to highlight that when a Commission discussion is based on the input of an *ad hoc* Group, Members are encouraged to review the relevant *ad hoc* Group report together with the report of the Commission. *Ad hoc* Group reports are available on the dedicated webpages on the WOAH website at Ad hoc Groups - WOAH - World Organisation for Animal Health.

Deadline to comment

Comments on relevant texts in this report must reach the Headquarters by 30 April 2024 to be considered by the Biological Standards Commission.

Where to send comments

All comments should be sent to the Science Department at: BSC.Secretariat@woah.org

Date of the next meeting

The Biological Standards Commission noted the dates for its next meeting will be confirmed following the Commission election at the 91st General Session in May 2024.

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List of Annexes

1. Welcome from the Directors

1.1. Director General

Dr Monique Eloit, the WOAH Director General, met the Biological Standards Commission on 6 February and thanked its members for their support and commitment to achieving WOAH objectives.

Dr Eloit underlined that this meeting marked the conclusion of the current term of the Commission and expressed her gratitude to the members for their consistent efforts throughout their years of collaboration. With the term drawing to a close, a call for applications for members was issued last August. The list of candidates will be presented to the Council at their March meeting, followed by discussions and negotiations among the regions. The election for the four WOAH Commissions is scheduled to take place during the forthcoming General Session.

Dr Eloit informed the Commission about WOAH's ongoing consultancy project aimed at evaluating the organisation's *Basic Texts* from both a technical and legal perspective. This revision seeks to enhance WOAH's internal systems, reinforce its credibility, and strengthen its global standing. The consultancy focuses on three main pillars: institutional matters; the science system, which encompasses the ToR[1] for both the Commissions and Reference Centres; and the organisation's business model. The goal of analysing the *Basic Texts* is to facilitate a comprehensive review and to present the findings to the Assembly. Dr Eloit also noted that selected members from the four Commissions will play a significant role in the revision process of the *Basic Texts*.

In her closing remarks, Dr Eloit provided an update on the progress being made on the Pandemic Treaty with the WHO[2]. She highlighted that this treaty will formally recognise the importance of disease prevention, including animal health. Additionally, there will be an increased focus on research within the animal sector, emphasising the crucial role of vaccines. Dr Eloit also stressed the need to not only promote the use of existing vaccines but also to invest significantly in the development of new vaccines. This approach underscores a proactive strategy in disease management and prevention, particularly in the animal sector, aligning with the broader goals of global health and safety.

The Commission thanked Dr Eloit for these updates.

1.2. Deputy Director General, International Standards and Science

Dr Montserrat Arroyo, WOAH Deputy Director General, International Standards and Science, welcomed members of the Commission, expressing her gratitude for their sustained efforts and contributions over the past 3 years. She highlighted the significance of further elevating the Commission's impact and visibility.

Dr Arroyo updated the Commission on WOAH's standard-setting activities. She noted the harmonisation of processes across the four Commissions that include the new initiative to publish Member comments on draft standards from WOAH's *Manuals* and *Codes*. This initiative reflects WOAH's commitment to transparency and Member engagement. Dr Arroyo also informed the Commission of the schedule for this year's Bureau meetings, involving collaborations between the Aquatic Animal Health Standards and the Biological Standards Commissions, as well as between the Terrestrial Animal Health Standards Commission and Scientific Commission for Animal Diseases, highlighting the organisation's collaborative approach.

Dr Arroyo provided an update on the progress with the Standards Navigation tool, announcing that significant advancements have been made. The tool will be presented to the Assembly during the General Session and is expected to be operational by July 2024.

Turning to WOAH's upcoming events, Dr Arroyo announced that the Commission's pre-General Session webinar is scheduled for Tuesday, 16 April 2024 from 12.00 to 14.00 CET.

Concluding her address, Dr Arroyo expressed appreciation for the Commission's accomplishments during the 3-year term, which included the adoption of 68 chapters, with additional chapters expected to be adopted this year, the implementation of the justification tables for the scores of tests given in Table 1 *Test methods available and their purpose* of the disease-specific chapters, and a strategy to evaluate Reference Centres.

The members of the Commission thanked Dr Arroyo for the excellent support provided by the WOAH Secretariat.

1 ToR: Terms of Reference
2 WHO: World Health Organization

1.3. Updates from the WOAH Headquarters

1.3.1. Transparency of the WOAH process for the elaboration of Standards

The Secretariat updated the Commission on progress that had been made to improve the transparency of the WOAH process for the elaboration of Standards, in particular the publication of comments submitted by Members and partners.

The Secretariat informed the Commission that the Director General communicated this initiative to Members in December 2023 and that an SOPs[3] had been developed for the submission of comments during the process for the elaboration of WOAH international standards, as well as a guide on how to submit and present comments, and that these documents have been published on the WOAH website and on the Delegates' website.

The Secretariat reminded the Commission that this is a progressive process that will start in March/April 2024 with the publication on the Delegates' website of comments considered on new and revised standards during February 2024 Commission meetings, at the same time as the publication of the respective February 2024 Commission report. This process takes a step-wise approach and includes an evolution of the Commission reports towards transparency of comments considered and Commission responses, which will result in better documentation and traceability of the WOAH process for the elaboration of Standards.

2. Adoption of the agenda

The proposed agenda was presented and adopted. Dr Emmanuel Couacy-Hymann chaired the meeting and the WOAH Secretariat acted as rapporteur. The agenda and the list of participants can be found at Annexes 1 and 2 respectively.

3. Collaboration with other Specialist Commissions

3.1. Horizontal issues among the Specialist Commissions

3.1.1. Case definitions: tularemia, infection with avian metapneumovirus (turkey rhinotracheitis)

The Biological Standards Commission discussed the case definitions for tularemia and infection with avian metapneumovirus (turkey rhinotracheitis), and gave its recommendations to the Scientific Commission for Animal Diseases (see agenda item 8.3.2. of the report of the meeting of the Scientific Commission for Animal Diseases, 12–16 February 2024).

3.2. Scientific Commission for Animal Diseases

Nothing for this meeting.

3.3. Terrestrial Animal Health Standards Commission

Matters between the Terrestrial Animal Health Standards Commission and the Biological Standards Commission.

3.3.1. Updates from the September 2023 Code Commission meeting

The Biological Standards Commission was updated by the Secretariat of the Code Commission on the current topics under review by the Code Commission to ensure complementarity and alignment of the two Commission's respective work programmes.

In February 2021, the Code Commission agreed to develop a framework for Terrestrial Code Standards that would serve as a useful guide to ensure standardisation of Terrestrial Code content. Noting the differences in the objectives and structure of the chapters within Volume I and Volume II of the Terrestrial Code, and within the different sections of Volume I, the Commission requested the Secretariat to begin by working on the content of disease-specific chapters, i.e. Volume II.

Since then, Code Commission has worked closely with the Secretariat, in consultation with the Scientific Commission, and based on previous discussions and agreements between the Code Commission, the

3 SOPs: Standard Operating procedure

Scientific Commission and, where relevant with the Biological Standards Commission, to develop a document that provides a detailed description of the structure and content of a disease-specific chapter, including the key references to other parts of the *Terrestrial Code* and other WOAH Standards, and conventions regarding the use of terms, wording and structure.

The Code Commission acknowledged that the framework would be a living document and should be used as the reference for those undertaking work on the development of new or revised chapters. The Commission also agreed that the framework may help Members gain a better understanding of disease-specific chapters in the T*errestrial Code* and could eventually framework be made available to Members at a later stage.

In September 2023, the Code Commission reviewed the document and requested the Secretariat to finalise a first edition for its February 2024 meeting and requested that it be shared at the same time with the Scientific Commission and the Biological Standards Commission. Moreover, the Code Commission requested the Secretariat to use the Framework in upcoming disease-specific chapter revisions and provide feedback.

3.3.2. Biological Standards Commission's recommendations to the Terrestrial Animal Health Standards Commission

See agenda item 5.7. of this report

3.3.3. Update from the Biological Standards Commission on the request from the Code regarding Terrestrial Code Chapter 6.10 Responsible and prudent use of antimicrobial agents in veterinary medicine

See agenda item 5.8. of this report

3.3.4. Question on the chapter on bovine viral diarrhoea

The advice of the Biological Standards Commission was sought regarding the taxonomy of the causative agents of bovine viral diarrhoea. The Biological Standards Commission advised that the taxonomy had been updated and adopted by the International Committee on Taxonomy of Viruses (ICTV). The new nomenclature has been introduced in the *Terrestrial Manual* chapter (see agenda item 5.2) and should be applied to the *Terrestrial Code* chapter:

3.4. Aquatic Animal Health Standards Commission

Meeting of the Bureaus of the Commission (see item 3 of the Meeting of the Aquatic Animal Health Standards Commission, 14–21 February 2024.

4. Work Programme

The updated work programme was agreed and can be found at Annex 3.

5. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*

For this Agenda Item, the Commission was joined by Dr Steven Edwards, Consultant Editor of the WOAH *Terrestrial Manual*.

5.1. Report format and commenting system

In light of the implementation of the new system for submission and publication of Member comments, the Commission reviewed its reporting system. To better report amendments to the *Terrestrial Manual,* the Commission decided to adopt the table format currently used by the Aquatic Animals Commission. Members can more easily see and understand the Commission's decisions in response to comments.

5.2. Review of Member comments received on draft chapters and their endorsement for circulation for second-round comment and proposal for adoption in May 2024

The Commission reviewed 15 draft chapters and approved 13 for circulation, some subject to clarification of certain points by the experts, for second-round Member comment before presenting them for adoption by the Assembly in May 2024.

Chapter 1.1.5. 'Quality management in veterinary testing laboratories':

Section/paragraph	Comment	Decision
A.2. Standards, guides, and references, paragraph 3	Move the last sentence to Section A.7.3 *Validation of the test method*	Agree, text fits better in this Section
A.3. *Accreditation,* point iii)	Delete the requirement for equipment to be verified and managed in accordance with the relevant maintenance and calibration schedule as not all equipment will need to be verified	Disagree, equipment should be maintained and calibrated following a defined schedule
A.6. Quality assurance, quality control and proficiency testing, paragraph 2	Reinstate the word 'test' in the sentence: 'quality control test-oriented and ensures detection of any problems that arise'	Disagree, the amended sentence is correct: quality control is results-oriented
A.7.3.1 Activities that validation might include	Move steps i) and ii) to the end of the list as steps iii) to viii) would be done first as part of a validation process	Agree

The revised Chapter 1.1.5. 'Quality management in veterinary testing laboratories' is presented as Annex 4 and will be proposed for adoption at the 91st General Session in May 2024.

Chapter 1.1.9. 'Tests for sterility and freedom from contamination of biological materials intended for veterinary use':

Section/paragraph	Comment	Decision
General comment	Include a section for coccidiosis vaccines: the chapter has sections for living viral vaccines, inactivated viral and bacterial vaccines, and living bacterial vaccines, but not a section for live vaccines containing a preparation of sporulated oocysts of a suitable lines of species of coccidial parasites	Agree: this comment will be addressed in the next review cycle (2025/2025)
B. Living viral vaccines for administration by injection, or through drinking water, spray, or skin scarification, point 3	Add the Veterinary Drug Administration of China (People's Rep. of) to the list of acceptable published methods for testing vaccine batches for freedom from extraneous agents	Agree
C. Inactivated viral and bacterial vaccines, point 2	Add 'pre-' before 'inactivated in the sentence: 'If studies on representative extraneous agents are required, then spiking inactivated vaccine with live representative agents and following...' because representative agents should be added to the pre-inactivated vaccine to be inactivated for testing	Disagree: depending on the vaccine it may be safer to work with inactivated vaccine for this test rather than one containing live infectious pathogen
G. Protocol examples, Table 1	Members proposed some minor editorial changes	Agree
G.3.2 General testing for exclusion of Mycoplasma sp.	European Medicines Agency's link does not work	Updated the European Medicines Agency's link

Section/paragraph	Comment	Decision
H. Information to be submitted when applying for an import licence, paragraph 1	Reinstate the requirement that Veterinary Authorities should follow the *Terrestrial Manual* when undertaking risk analysis for biologicals	Agree but clarified that it is the *Terrestrial Code* that should be followed
H. Information to be submitted when applying for an import licence, paragraph 2	Add the Ministry of Agriculture and Rural Affairs of China (People's Rep. of) to the list of examples of a risk-based assessment of veterinary biologicals for import into a country	Agree

The revised Chapter 1.1.9. 'Tests for sterility and freedom from contamination of biological materials intended for veterinary use' is presented as Annex 5 and will be proposed for adoption at the 91st General Session in May 2024.

Chapter 2.2.4. 'Measurement uncertainty'

Section/paragraph	Comment	Decision
Introduction, paragraph 2	For consistency, replace 'cut-off' with 'diagnostic threshold'	Agree
A. The necessity of determining MU, paragraph 1	Replace the term 'confidence interval' with 'reference interval' as it is the correct term used by ISO/IEC Guide 98-3	Agree and applied this amendment throughout the chapter
A. The necessity of determining MU, paragraph 1	Add a sentence clarifying that alternative methods are available that are less reliant on distributional assumptions, and better handle the presence of outliers	Agree
A.2.1 Method of expression of MU	Change the subscript from 'L' to 'W' as 'low' has been changed to 'weak' positive control	Agree and applied this amendment throughout the chapter
A.2.1 Method of expression of MU	Define 'X' in the equation and clarify what is meant by transformed result	Agree: added that X represents the set of replicates, and gave examples of a suitably transformed result
A.2.3 Calculating uncertainty		Added a statement on the need to transform not normally distributed data
A.2.4 Interpretation of the results	Replace the first sentence with a statement that a sample with a PI between 36% and 64% is within the MU surrounding the threshold value, and thus its diagnostic status is less certain than those of samples with results further from that threshold	Agree, the original interpretation was too precise given the multiple approximations made and the nuances of the interpretation of a reference interval
A.3.3 Interpretation of the results	Replace the sentence with a statement that a sample with a Ct between 36 and 37% is within the MU surrounding the threshold value, and thus its diagnostic status is less certain than those of	Partly agree, the original interpretation was too precise given the multiple approximations made and the nuances of the interpretation of a reference interval. However, the threshold is

Section/paragraph	Comment	Decision
	samples with results further from that threshold	37, the upper limit of the MU is 38 and the lower limit is 36; the values refer to Ct values and thus the percentage sign has been deleted

The revised Chapter 2.2.4. 'Measurement uncertainty' is presented as Annex 6 and will be proposed for adoption at the 91st General Session in May 2024.

Chapter 2.2.6. 'Selection and use of reference samples and panels'

Section/paragraph	Comment	Decision
Figure 2	Add 'Infection/disease outcome' and 'Time post-experimental infection' to Column 'Phase of infection data'. Infection/disease outcome is important: while an animal may (or may not) have evidence of infection or clinical signs of disease, the animal may recover. Even if the disease has a high mortality rate, some animals will recover with varying levels of infection or clinical signs, which can create a bias depending on what outcome is being looked for in the diagnostic assay. Time post-experimental infection: this is critical if using reference samples collected from experimental infection models as the analyte will likely change over time. It also allows recreation of samples if the experimental model is repeatable.	Agree
F.1 Animals of unknown status – diagnostic specificity and diagnostic sensitivity	Add 'analysis of' between 'Bayesian' and 'latent class models' because latent class is a model and Bayesian is an analysis approach	Agree

The revised Chapter 2.2.6. 'Selection and use of reference samples and panels' is presented as Annex 7 and will be proposed for adoption at the 91st General Session in May 2024.

Chapter 3.1.5 'Crimean–Congo haemorrhagic fever'

Section/paragraph	Comment	Decision
Table 1. Diagnostic test format for Crimean–Congo haemorrhagic fever virus infections in animals, Key	Delete the word 'very' from the key '+ = suitable in very limited circumstances'	Disagree: standard text Table 1 throughout the *Terrestrial Manual*
Table 1, real-time RT-PCR method, for the purpose of Individual animal freedom from infection prior to movement	Change the rating from '+++' to '++' due to the transient nature of viremia	Agree. Spengler *et al.* (2016) reviewed research into CCHV and confirms transient viremia

Section/paragraph	Comment	Decision
Table 1, all methods for the purpose of Confirmation of clinical cases in animals	Change the ratings of all the tests in this column to '–' because animals, including ruminants, are typically asymptomatic to infection, although could be transiently viraemic	Disagree: in cases of pyrexia these tests may detect viraemia
Table 1, IgM ELISA method, for the purpose of Prevalence of infection – surveillance	Change the rating from '–' to '++' due to the short persistence of IgM antibodies in response to acute infections, but the test has limitations as it may not be detected when IgM wanes	Disagree: the IgM response is weak, and the incidence of a detectable IgM response may be very low in a population given it does not last long. In addition, the IgM ELISA is not designed for use in animals and so has to be adapted prior to use (see Section 2 *Serological tests*)

The revised Chapter 3.1.5. 'Crimean–Congo haemorrhagic fever' is presented as Annex 8 and will be proposed for adoption at the 91st General Session in May 2024.

Chapter 3.3.6. '*Avian tuberculosis'*

Section/paragraph	Comment	Decision
General comments	Change the title of the chapter to avian mycobacteriosis as the disease is nontuberculous	Disagree: the chapter title is based on the pathogenesis of the disease in birds
Summary, paragraph 3	Add after 'pet birds owners' 'or caretakers of captive birds'	Agree
Summary, paragraph 4	Replace 'gene segments' with 'insertion sequences' as it is more correct, explains the naming convention, and also because some of the insertions are not gene 'segments' – they can contain whole genes, multiple genes, extra repetitive elements, no ORF at all, etc.	Agree
Summary, paragraph 4	Include a mention of matrix-assisted laser desorption ionisation-time of flight mass spectrometry (MALDI-TOF MS) as is also a valuable tool.	Agree
A. *Introduction*, paragraph 2	This seems confusing or possibly contains an error. Three species are set out in the initial sentence (*M. avium* subsp. *avium, M. avium* subsp. silvaticum and *M. avium* subsp. paratuberculosis,) and again later three species but not the same three: *M. avium* subsp. avium, *M. avium* subsp. paratuberculosis, and *M. avium* subsp. *Lepraemurium*; and then three sub-species of *M. avium* subspecies avium. In addition, the nomenclature used in the diagnostic section does not seem to include this approach in places, and also refers to additional classifications	Nomenclature of all bacteria is changing very fast. There is a consensus that many of these changes do not affect the treatment of the diseases. New names and classifications take a while to make it into the formal classifications according to the nomenclature standards. In this paragraph, formally approved species are mentioned along with results from recent research. Other sections have the traditional names most clinicians are familiar with and the limitations of typing in resource-limited areas

Section/paragraph	Comment	Decision
	not mentioned here such as serotypes 1,2, and 3 of *M. a. avium*	
Table 1. Test methods available for the diagnosis of avian tuberculosis and their purpose	The rating of Ziehl–Neelsen staining for the purpose Confirmation of clinical cases (++) is correct for organ material but not for faecal smears	The text does not refer to faecal smears but only to organs
B.1 Identification of the agent	Add a sentence and reference to MALDI-TOF MS as a valuable diagnostic tool	Agree
B.1 Identification of the agent	Clarify that though traditionally, M. a. avium is separated from common nonchromogenic slow-growing organisms by their ability to grow at 42°C, the method has limited value, as other species are able to grow at 42°C.	Agree
B.1.1 *Culture,* paragraph 1	Remove commercial names of products	Agree
B.1.1 *Culture,* paragraph 4	Replace the word 'pet' with 'captive' before 'birds'	Agree
B.1.2 Nucleic acid recognition methods, paragraph 1	Correct the presentation of the gene segments by using italics	Agree
B.2.1 *Tuberculin test,* paragraph 2	Add the scientific name '(*Phasianus colchicus*)' after 'common pheasant' to avoid confusion between the two different common names for the same species of bird	Agree
C.2.2.4, iii) *Safety,* paragraph 1	The study design in this paragraph is much less specific with regards to number of animals needed, minimum size of the animal and injection volume per animal in contrast to elsewhere in the text	Agee and deleted the last three sentences in the paragraph
C.2.2.4, iv) *Batch potency*	For clarity, add 'shaved (an area large enough' between 'flanks' and 'to provide space for three-to-four injections on each side).'	Agree

The revised Chapter 3.3.6. 'Avian tuberculosis' is presented as Annex 9 and will be proposed for adoption at the 91st General Session in May 2024.

Chapter 3.4.1. 'Bovine anaplasmosis'

Section/paragraph	Comment	Decision
General comment	Replace 'initial bodies' with 'inclusion bodies' throughout the chapter	Agree
B.1.1 *Microscopic examination*, paragraphs 1 and 8	Replace the word 'parasites' with 'bacteria'	Agree

Section/paragraph	Comment	Decision
Table 1. Test methods available for the diagnosis of bovine anaplasmosis and their purpose	Experts had prepared tables justifying the scores given in Table 1 for the various tests and purposes. Links to these justification tables had been embedded in the Table headings, but they were overlooked by Members during the first round of commenting.	These justification tables have been added as appendices to the chapter and cross referenced in Table 1.
Figure 1. Anaplasma marginale *inclusion bodies*	No comment, Commission decision	Request a clearer illustration of inclusion bodies
Table 2. Oligonucleotides used in PCR assays to detect A. marginale and A. centrale	Remove the hyphen from the oligonucleotide sequences	Disagree: this is the *Terrestrial Manual* style
B.2.2.3 *Data analysis*, last sentence	Replace the word 'reproducibility' with the word 'repeatability' because reproducibility typically refers to inter-laboratory precision.	Agree

The revised Chapter 3.4.1. 'Bovine anaplasmosis' is presented as Annex 10 and will be proposed for adoption at the 91st General Session in May 2024.

Chapter 3.4.7. 'Bovine viral diarrhoea'

Section/paragraph	Comment	Decision
General comment	The taxonomy of the pathogenic agent has been updated. The new taxonomy should be used and applied consistently throughout the chapter: *Pestivirus bovis* (commonly known as BVDV type 1), *Pestivirus tauri* (BVDV type 2), and *Pestivirus brazilense* (BVDV type 3 or Hobi-like pestiviruses)	Agree and implemented this change
Summary, paragraph 1	Clarify that bulls may have a prolonged and persistent testicular infection for prolonged periods as the length of the presence of the virus in the testicular tissue could vary significantly from 28 days post-acute infection to 5 years post-infection	Agree
Summary, paragraph 2	Add 'or pestivirus A, B, C, D or H', as appropriate, to the pathogenic agents	Disagree, the proposal is not in line with the adopted taxonomy
A.1 Impact of the disease, paragraph 2	Clarify that bulls may have a prolonged and persistent testicular infection and include a reference	Agree
Table 1. Test methods available for diagnosis of bovine viral diarrhoea and their purpose	Experts had prepared tables justifying the scores given in Table 1 for the various tests and purposes. Links to these justification tables had been embedded in the Table headings, but they were overlooked by Members during the first round of commenting.	These justification tables have been added as appendices to the chapter and cross referenced in Table 1.

Section/paragraph	Comment	Decision
B.1.1.1 Microplate immunoperoxidase method for mass screening for virus detection in serum samples, Acetone, d)	Add 'antiviral' before 'BVD antibody' to be consistent with the previous method discription	Agree

The revised Chapter 3.4.7. 'Bovine viral diarrhoea' is presented as Annex 11 and will be proposed for adoption at the 91st General Session in May 2024.

Chapter 3.4.12. 'Lumpy skin disease' (vaccine section only)

Section/paragraph	Comment	Decision
A. *Introduction*, paragraph 2	Replace the subfamily of the pathogenic agent from Chordopoxvirinae to Chordopoxviridae	Disagree, the adopted taxonomy is Chordopoxvirinae
B.1.3. Polymerase chain reaction (PCR)	Add two additional real-time PCRs and references	Disagree, only the vaccine section was sent for comment. These proposals can be addressed when the diagnostic test section is updated

The revised Chapter 3.4.12. 'Lumpy skin disease' (vaccine section only) is presented as Annex 12 and will be proposed for adoption at the 91st General Session in May 2024.

Chapter 3.6.9. 'Equine rhinopneumonitis (infection with Varicellovirus equidalpha1)'

Section/paragraph	Comment	Decision
General comment	Update the taxonomy of the pathogenic agent. Clarify the deletion of EHV-4 from the title.	The nomenclature of the virus has changed from equid herpesvirus-1 (EHV-1) to Varicellovirus equidalpha1. The chapter title has been amended and the Code Commission advised of the change. A sentence has been added to stress that the chapter covers EHV-1 The second part of the title between brackets refers to the title of the corresponding *Terrestrial Code* chapter, as only EHV-1 is listed, that chapter only covers EHV-1
	Replace 'ml' with 'mL' as that is the correct SI symbol	Disagree, both 'mL' and 'ml' are acceptable, the latter is used throughout the *Terrestrial Manual*
Summary	Members proposed some minor editorial changes	Agree
A. *Introduction,* paragraph 1	The current taxonomic names of the viruses are: Varicellovirus equidalpha1 and Varicellovirus equidalpha4	Agree: for the purposes of the chapter, the acronyms EHV-1 and EHV-4 will continue to used

Section/paragraph	Comment	Decision
A. *Introduction,* paragraph 2	Remove references to EHV-4 throughout the chapter in line with the title	Disagree: it is an important differential, and the relative pathogenic potential of the two viruses is important for diagnosis
B. Diagnostic tests, paragraph	A Member proposed some minor editorial changes for clarity	Agree
Table 1. Test methods available for the diagnosis of infection with EHV-1 and their purpose	Remove 'equine rhinopneumonitis' from the title of the Table and replace with 'infection with EHV-1'	Agree
Table 1	Experts had prepared tables justifying the scores given in Table 1 for the various tests and purposes. Links to these justification tables had been embedded in the Table headings, but they were overlooked by Members during the first round of commenting	These justification tables have been added as appendices to the chapter and cross referenced in Table 1
Table 1	Amend the score for the ELISA: from '+' to '++' for Population freedom from infection; from '–' to '++' for Individual animal freedom from infection prior to movement; from '+' to '++' for Confirmation of clinical cases; from '++' to '+++' for Prevalence of infection – surveillance; from '+' to '++' for Immune status in individual animals or populations post-vaccination Amend the score for the CFT: from '+++' to '+' for Confirmation of clinical cases from '+++' to '++' for Immune status in individual animals or populations post-vaccination CFT is more complicated and difficult to maintain then and ELISA, so should not be considered a more suitable test: Hartley *et al.* (2005). Comparison of antibody detection assays for the diagnosis of equine herpesvirus 1 and 4 infections in horses. *Am. J. Vet. Res.*, **66**, 921–928.	Partly agree. The paper by Hartley *et al.* concerns a comparison of antibody detection assays using 33 acute and convalescent serum samples, i.e. it is not a seroprevalence study. The seroprevalence study by El Brini *et al.* (2021) suggests that the ELISA is less sensitive for EHV-1 antibody detection than the VNT. Members are invited to review the explanation for the test scoring in the tables appended to the chapter
Table 2,	Delete the first set of primers and probe because of problems with their specificity	Agree
B.1.2 Virus detection by polymerase chain reaction, Point of care (POC) molecular tests	Delete this paragraph as it is unusual to refer to methods not fully validated or included in Table 1	Disagree: the chapter is supposed to be an entry point to the literature, the assays have proven themselves useful, they are only

Section/paragraph	Comment	Decision
		mentioned briefly. The assays are not included in Table 1 because they are not fully validated
B.1.2 Virus detection by polymerase chain reaction, Molecular characterisation	Delete this paragraph: while correct the main point was made in the previous paragraph and the rest is generic. Molecular analysis can be used in every outbreak to support epidemiology	Disagree, it is important to make the point that sequencing cannot reliably predict neuropathogenic strains. The last sentence is provided in the context of the first two sentences, so is appropriate
B.2 *Serological tests*, paragraph 1	Replace 'however' with 'notwithstanding'	Disagree, the term 'notwithstanding' is not common usage and will be confusing to some readers; 'however' is clearer
B.2 *Serological tests*, paragraph 4	A modified live EHV-1 vaccine that lacks the glycoprotein E gene is licensed in Japan, and an ELISA using a synthetic peptide for glycoprotein E as an antigen (Andoh *et al.,* 2013) is used as DIVA[4] for horses vaccinated with this vaccine. Amend the text to take this fact into account	Agree, replaced the last sentence with new text and a reference reflecting the comment
C.2.1.3 Validation as a vaccine strain	Include a quantitative measure on the upper limit of VNT titre (serological status) of horses used to confirm immunogenicity of Master Seed Virus for vaccines. The rationale is that it will be very hard if not impossible to find immunologically naïve horses for this test	Agree and included a reference
C.2.3.4 *Duration of immunity*, paragraph 2	Acknowledging that EHV-1 and EHV-4 are cross reactive, but it is confusing to imply that there are two agents being discussed here called EHV-1 and EHV1/4. It would be clearer to either say 'EHV-1 or EHV-4' or to remove the mention of EHV-4 altogether	Agree to remove mention of EHV-4 here

The revised Chapter 3.6.9. 'Equine rhinopneumonitis (infection with Varicellovirus equidalpha1)' is presented as Annex 13 and will be proposed for adoption at the 91st General Session in May 2024.

Chapter 3.8.1. 'Border disease'

Section/paragraph	Comment	Decision
Summary, paragraph 3	Add mention of pestivirus A, B, C, D or H, as appropriate, to the pathogenic agents	Disagree, the proposal is not in line with the adopted taxonomy
A. *Introduction*, paragraph 1	Update the information on the genotypes and add more details and a reference	Agree, the detail is necessary as BDV requires differential diagnosis from CSFV

4 DIVA: differentiate infected from vaccinated animals

Section/paragraph	Comment	Decision
B.2.1.1 *Test procedure*, iii)	It is not clear why the acceptance limits were changed. They should be consistent with the BVD chapter re currently	Agree, the original range of 30–300 $TCID_{50}$ is reinstated: acceptable ranges are either calculated by the Reed and Muench or Spearman and Kärber methods
C.1.1 Characteristics of a target product profile, paragraph 1	Replace 'afford' with 'provide' and 'fetal infection' with 'fetal protection'	Agree

The revised Chapter 3.8.1. 'Border disease' is presented as Annex 14 and will be proposed for adoption at the 91st General Session in May 2024.

Chapter 3.8.12. 'Sheep pox and goat pox':

Section/paragraph	Comment	Decision
A. *Introduction*, paragraph 1	Replace 'fully susceptible' with 'naïve'	Agree
A. *Introduction*, paragraph 7	Add a sentence that there is no evidence of persistently infected animals, and more details on characteristics of the virus, i.e. resistance to physical and chemical actions	Agree
B.1.1 Specimen collection and submission, paragraphs 1 and 3	Delete antigen detection for consistency with Table 1	Agree
B.1.1 Specimen collection and submission, paragraph 1	Add a sentence stating that nasal and buccal swabs can also be collected because the virus will be present in nasal and saliva discharges	Agree
B.1.1 Specimen collection and submission, paragraph 2	Delete the statement that tissues in formalin have no special transportation requirements as it is vague and misleading. Sample submission should be described in the introductory chapter	Agree
B.1.2 Virus isolation	Replace 'antigen detection' with 'genome detection'	Agree
B.1.4 Histopathology	Delete 'and mounting of the formalin-fixed biopsy material' from the second sentence: the sequence is incorrect, incomplete, and unnecessary as this is a routine procedure and not specific to sheep pox. The previous sentence is sufficient	Agree
B.1.6 Nucleic acid recognition methods, paragraph 1	Add blood and semen a sample types	Agree and added a sentence to clarify that nucleic acid extraction and PCR amplification methods must be validated for the sample matrix being tested
B.1.6.2 *Real-time PCR methods*, paragraph 1	Add a reference to the list of pan-capripox virus real-time PCR assays:	Agree

Section/paragraph	Comment	Decision
	the test is used by the EURL for capripox viruses and several other national reference laboratories from Europe, and all the validation information on this test can be found in the publication	
B.1.6.2 *Real-time PCR methods*, paragraph 2	Clarify that the method is for the detection of genomic DNA	Agree
B.1.6.2 *Real-time PCR methods*, DNA extraction from blood and tissue	Clarify that commercially available kits are for the extraction not isolation of DNA, and that the manufacturer's instructions should be followed	Agree
B.1.6.2 *Real-time PCR methods*, Real-time PCR, iii) and iv)	Clarify that any commercial real-time PCR kit of choice can be used	Disagree, does not add any value to the test description
B.1.6.3 Isothermal genome amplification	Clarify that LAMP assays were reported to differentiate GTPV from SPPV	Agree
B.2 Serological tests	Add a sentence that blood for antibody detection should be collected in tubes without anticoagulant	Disagree: self-evident
B.2 Serological tests	Add text that detectable levels of antibodies develop 1 week after the animal shows clinical signs. The highest antibody levels are detected within 1–2 months after infection is detected	Agree
C.1.1 Rationale and intended use of the product	Add information on live attenuated vaccines	Disagree, only the diagnostic tests section was sent for comment. This proposal can be addressed when the vaccine section is updated

The revised Chapter 3.8.12. 'Sheep pox and goat pox' is presented as Annex 15 and will be proposed for adoption at the 91st General Session in May 2024.

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

A large number of comments were received on the newly proposed vaccine section. Given that live modified vaccines are in use in some Members, the Commission believes it is important to have a minimum standard in the WOAH *Terrestrial Manual*, with the commitment to review it regularly as scientific evidence becomes available.

Section/paragraph	Comment	Decision
General comment	Some Members have reservations about including vaccine standards in the *Terrestrial Manual* because of safety issues in the field	The Commission is aware of these issues, and of the fact that vaccines are currently authorised by some national regulatory authorities and in use in the field. The proposed Section was drafted by experts in liaison with vaccine manufacturers and veterinary medicine regulatory experts. It addresses these issues as best it can based on current scientific evidence. The Commission has a

Section/paragraph	Comment	Decision
		strong position that it is better to offer to national authorities and vaccine manufacturers science-based recommendations on ASF vaccines in the chapter rather than none at all
Summary	Some Members had provided comments on the *Summary*	Only the vaccine section was sent for comment. These proposals can be addressed when the diagnostic test section is updated
A. Introduction	Some Members had provided comments on unmodified text in the *Introduction*	Only the vaccine section was sent for comment. These proposals can be addressed when the diagnostic test section is updated
A. *Introduction,* paragraph 9	Amend the modified text to include information on mutants and recombinants that have emerged with potentially increasing prevalence, along with two references	Agree, text added
A. *Introduction,* paragraph 9	Add a sentence stating that it is not always necessary to follow the principles given in the Chapter 1.1.8 *Principles of veterinary vaccine production* when there are scientifically justifiable reasons for using alternative approaches	Disagree, chapter 1.1.8 is an adopted Standard and not an example
A. *Introduction,* paragraph 9	Add a paragraph stating that it is crucial to confirm the absence of circulating strains of other ASFV genotypes before the use of the vaccine due to the characteristics of ASFV, where frequent recombination occurs between different strains. And add a statement that it is essential to establish a robust vigilance monitoring system to rapidly detect and notify unexpected events resulting from such recombinations	Agree that it is important to confirm what genotypes of ASFV are circulating in a population prior to vaccination: added a sentence to C.1. Background, paragraph 16. Also agree it is important to have a robust monitoring system. Text amended accordingly
A. *Introduction,* paragraph 9	Reword the sentence on the validation of modified live vaccines (MLV) to remove non-transmissibility as according to the minimum standard some virus vaccine transmission might be allowed	Agree
A. *Introduction,* paragraph 10	Include safety and efficacy in different age-groups of pigs, including breeding boars and pregnant sows	The Commission's position is that such tests are preferred but not required in the minimum standard. At present, no vaccine is used in pregnant sows
A. *Introduction,* paragraph 10	Include duration of immunity and onset of immunity in the minimum standard	Agree, a statement has been added that onset and duration of immunity are also required to meet minimum standards

Section/paragraph	Comment	Decision
C.1. *Background*, paragraph 1	Add a sentence on the prevalence of other genotypes and recombinants	Agree and amended the proposed text
C.1. *Background*, paragraph 3	Clarify that the appropriate biosecurity level should be based on the virulence and characteristics of the virus	Disagree, the concept is covered by the word 'appropriate'
C.1. *Background*, Safe	Add reference to the definition of fever	Agree
C.1. *Background*, Safe and Efficacious	Minimum requirements for MLV should include safety for pregnant sows, pigs at different growth stages (suckling piglets, nursery pigs, fattening pigs), breeding boars, and cross-protection against other strains currently circulating in the field.	The Commission reiterated that its position is that such tests are preferred but not required in the minimum standard. The test would be needed if the MLV is to be licensed for those subpopulations
C.1. *Background*, Efficacious	Add 'ASF-induced' before 'mortality'	Disagree, the meaning is implicit
C.1. *Background*, Quality – potent	Replace 'potent' with 'stability'	Agree
C.1. *Background*, Quality – Identity	Replace 'identity' with 'vaccine matching	Agree
C.1 *Background*, paragraph 9	Include a statement that more research is needed to determine whether these genotype 2-specific MLVs can effectively protect against newly circulating variants of genotype II and recombinant strains	Agree
C.1 *Background*, paragraph 10	Include the target species of the vaccines that have been authorised	Agree
C.1 *Background*, paragraph 11, fifth point	Add a reference to a new vaccine candidate strain that has been demonstrated to provide strong suppression of viremia, etc., thus is expected to have higher safety compared with the virus in previous studies	Agree
C.1 *Background*, paragraph 11 and all points	There is a possibility that an animal that inadvertently received two different vaccine strains (with different single gene deletions) could potentially regenerate a fully virulent ASFV by recombination. Consider requiring that all MLV ASFV vaccines have at least one attenuating deletion in common so that it is not possible for this to occur. Also consider combining these viruses: all were designed by homologous recombination and are deletion mutants with a different number of genes deleted	This is a possibility but the risk of reversion by recombination through co-infection with a vaccine and wild-type strain is significantly higher. Requiring vaccines to have a single gene in common would be technically challenging considering that biological basis for attenuation remains poorly understood
C.1 *Background*, paragraph 13	The text makes it sound like the next generation vaccines will be MLVs; it is	Disagree, the text existing is clear

Section/paragraph	Comment	Decision
	likely other technology will be better. This wording will create confusion through the vaccine section	
C.1 *Background*, paragraph 13	Add a statement that there is no inactivated vaccine with any level of protection that could be acceptable	Disagree, the existing text is clear
C.1 *Background*, paragraph 15	Delete MLV as this should apply to new vaccine technology developed	Agree
C.1 *Background*, paragraph 15	Add a description emphasising the importance of pharmacovigilance for ASF vaccine	Agree
C.1 *Background*, paragraph 16	Clarify the definition of 'exceptional circumstances'	Agree
C.2.1.2 Quality criteria (sterility, purity, freedom from extraneous agents) paragraph 1	Delete the last sentence as it is not in the appropriate place. The safety requirements are explained elsewhere.	Agree
C.2.1.2 Quality criteria (sterility, purity, freedom from extraneous agents) paragraph 3	Include a more detailed explanation of the reason why genetic stability to at least MSV+10 should be demonstrated when MSV+8 is the maximum passage for use in final product manufacturing	Agree, clarified that if final product yields are low, demonstration of stability is required for the maximum passage for use in the final product manufacturing as defined by the producer
C.2.2.4 Final product batch tests, ii) identity	Clarify the goal of the parenthetical (e.g. specific differential real-time PCR)	Agree, added that the detection methods should also differentiate the vaccine virus from the parent strain of the virus as a potential contaminant
C.2.2.4 *Final product batch tests,* vi) Residual humidity/residual moisture	Delete mention of the route of administration as the test will be required for any lyophilised or freeze-dried vaccine regardless of the route of administration	Agree
C.2.3.1 Manufacturing process	Amend the sentence as it is not necessary to provide information on consecutive vaccine batches and obtaining information from three or more batches is preferable	Agree, the text is deleted
C.2.3.2 Safety requirements	This Section is very detailed and prescriptive. Can it be shortened or added to another Annex? Suggest focus is on the principles rather than the exact nature on how to conduct the experiment	Disagree, general principles are given in chapter 1.1.8, the details given here are specific to ASF
C.2.3.2 Safety requirements	Additional demonstration of MLV safety in breeding age gilts and pregnant sows is preferred but not required as a minimum standard	Agree as before. Current vaccines are not licensed in breeding animals. Demonstration of safety in breeding age gilts and pregnant sows should be required if the vaccine is intended to be used in those subpopulations. This

Section/paragraph	Comment	Decision
		standard will be regularly reviewed as more data become available on the use of these vaccines
C.2.3.2 *Safety requirements,* i) Safety in young animals	Unless the most sensitive category for safety testing is considered to be pigs of 6–10 weeks of age, a more flexible wording would be preferable	Agree, amended to a minimum of 4 weeks and not older than 10 weeks in accordance with current evidence
C.2.3.2 *Safety requirements,* i) Safety in young animals, paragraph 5	The monitoring period proposed is far longer than that proposed in the VICH GL44 for target animal safety for veterinary live and inactivated vaccines. When injection site adverse reactions are present at the end of the 14 days observation, the observation period should be extended until clinically acceptable resolution of the lesion has occurred or, if appropriate, until the animal is euthanised, and histopathological examination is performed	Disagree, the period given here is to cover the chronic clinical signs that can appear many weeks after vaccination. This is not related to injection site adverse reactions
C.2.3.2 *Safety requirements,* i) Safety in young animals, paragraph 5	To detect any potential virus shedding, add checks for vaccine virus in oral, nasal and faecal secretions, every 7 days for at least 60 days and checks for vaccine virus in tissues at 28 days,	Disagree because there may be limited shedding associated with the use of MLV vaccines. Introducing a requirement for no shedding will preclude the use of vaccine. Despite being considered safe, a minimum level of horizontal transmission may be expected for MLV
C.2.3.2 *Safety requirements,* i) Safety in young animals, paragraph 7, first point	Clarify that no piglet shows notable signs of disease: current wording could be interpreted as if vaccinated piglets showing notable signs of disease but not reaching the pre-determined humane endpoint would comply with the test	Agree
C.2.3.2 *Safety requirements,* i) Safety in young animals, paragraph 7, second point	Clarify what is meant by 'average' body temperature increase	Agree, the point has been rewritten
C.2.3.2 *Safety requirements,* i) Safety test in pregnant sows and test for transplacental transmission, paragraph 1	As MLV itself can infect sows through horizontal transmission and can vertically transmit to fetal pigs, delete the current text and replace it with the requirement to test sows and the farrowings for virus shedding	Disagree: as above, the current text is correct; additional testing should only be required if the manufacturer recommends the use of the vaccine in breeding-age sows and pregnant sows
C.2.3.2 *Safety requirements,* ii) Safety test in pregnant sows and test for transplacental transmission, paragraph 1	Correct the first sentence as there have been experimental studies looking at the transmission of a genotype II ASFV from pregnant sows to the fetuses	Agree
C.2.3.2 *Safety requirements,* iii) Horizontal transmission, paragraph 1	Amend 'no fewer than 12 healthy piglets' to 'healthy piglets in sufficient number to confirm the presence or	Disagree, this text is consistent with CSF chapter and it is applicable to ASF

Section/paragraph	Comment	Decision
	absence of horizontal transmission between vaccinated animals and naïve animals' as there is no scientific basis for using 12 piglets.	
C.2.3.2 *Safety requirements,* iii) Horizontal transmission, paragraph 1	Consider not to co-mingle directly. If oral vaccines are considered, environmental contamination with vaccine virus could lead to 'vaccination' of naïve contacts	This point is valid and will be put forward for consideration when oral vaccines are ready for testing
C.2.3.2 *Safety requirements,* iii) Horizontal transmission, paragraph 4	No comment, arose from discussion with experts	Clarified what is meant by body temperature increase here and throughout the chapter, where appropriate
C.2.3.2 *Safety requirements,* iii) Horizontal transmission, paragraph 5	Delete the requirement to determine infectious virus titres by quantitative virus isolation	Disagree: virus genome persists for a much longer time than infectious virus so use of PCR alone can give misleading results. It is important to measure infectious virus (PCR may be used to identify samples that may potentially have infectious virus). PCR-positives should also be tested by qualitative/quantitative virus isolation
C.2.3.2 *Safety requirements,* iii) Horizontal transmission, paragraph 8, third point	Clarify the vaccine acceptance criteria	Agree and clarified the points: the Commission acknowledges that, according to current evidence, a minimum horizontal transmission could be expected for MLV yet the vaccine could be considered safe
C.2.3.2 *Safety requirements,* iv) Post-vaccination kinetics of viral replication (MLV blood and tissue dissemination) study, paragraph 8	Extend the days on which to euthanise piglets and determine virus titres to include Days 1, 3, and 5	Partly agree: will include day 5. Day 3 possible with highly virulent virus but if attenuated could be later; days 1 and 3 likely to be negative
C.2.3.2 *Safety requirements,* v) Reversion to virulence, First passage (p1), paragraph 1	Clarify the observation parameters	Agree, amended to be consistent with the agreed standard text here and throughout the chapter, where appropriate
C.2.3.2 *Safety requirements,* v) Reversion to virulence, First passage (p1), paragraph 3	Extend the days on which to euthanise piglets and determine virus titres to include Days 1, 3, and 5	As before, partly agree: will include day 5. Day 3 possible with highly virulent virus but if attenuated could be later; days 1 and 3 likely to be negative
C.2.3.2 *Safety requirements,* v) Reversion to virulence, second passage (p2), paragraph 2	For consistency, change 'intramuscular administration' to 'intended route'	Agree
C.2.3.2 *Safety requirements,* v) Reversion to virulence, Fifth passage (p5), paragraph 3, second point	Clarify what is meant by the term 'minimal chronic' clinical signs	Agree, amended the text to refer to mild clinical signs

Section/paragraph	Comment	Decision
C.2.3.2 *Safety requirements,* v) Reversion to virulence, Fifth passage (p5), paragraph 4	Delete paragraph, the requirements may not be feasible for countries where the disease is not endemic	Disagree, misunderstanding of the text. Field testing is very important and can be done in an endemic country. It need not necessarily be done in every country that wishes to use the vaccine as long as the relevant data is made available from the countries where the field testing has been carried out
C.2.3.3 *Efficacy requirements*, i) Protective dose, paragraph 3	Propose to replace the description, which is not in line with the VICH guidelines, with a more feasible description. There is no specification in the VICH guidelines regarding the test setting for protective dose such as number of pigs kept, age, consistency of origin, composition	Disagree: VICH does not provide a specific protocol for determining the minimal protective dose. However, the text is in line with general guidelines for safety testing as described in VICH GL 44 and other prescriptive documents. Protective dose is one of the defining characteristics of vaccines and will be required by most if not all Regulating Authorities
C.2.3.3 *Efficacy requirements*, i) Protective dose, paragraph 5	Amend the text so that the animal challenge tests are conducted using all the circulating strains present in the field	Disagree, not suitable for a minimal standard
C.2.3.3 *Efficacy requirements*, i) Protective dose, paragraph 5	Delete 'or non-HAD viruses' HAD_{50} or $TCID_{50}$ are indistinguishable	Disagree, maintain the original text
C.2.3.3 *Efficacy requirements*, i) Protective dose, paragraph 6	Add oral, nasal and anal to the samples to be collected from vaccinated challenged piglets and test every 7 days for 60 days	Partly agree: added the samples but limited the observation period to at least 45 days and preferably 60 days post-challenge
C.2.3.3 *Efficacy requirements*, i) Protective dose, paragraph 8	Add histopathology after gross pathology	Agree
C.2.3.3 *Efficacy requirements*, i) Protective dose, paragraph 9	100% mortality and morbidity may not be possible depending on the strain used for the experimental infection, i.e. not all strains will cause 100% mortality in control pigs. It is better to design the study to have some flexibility so: a) the experimental infection is repeatable and b) an appropriate number of animals are used to ensure statistically relevant findings are made regarding if the vaccine is providing protection	Agree, amended the text
C.2.3.3 *Efficacy requirements*, i) Protective dose, paragraph 10, second point	Clarify what is meant by average body temperature increase	Agree and amended here and throughout the chapter, where appropriate
C.2.3.3 *Efficacy requirements*, ii) Assessment for horizontal transmission (challenge virus shed and spread study), paragraph 10	Add days 7 and 14 to the days on which blood samples will be collected from naïve contact pigs and extend the observation period to 2 months due to	Partly agree, antibodies may not be present in the contact pigs on days 7 and14, post-contact, so better that blood samples are tested for antibodies on day 21 and 28 and at the end of the test

Section/paragraph	Comment	Decision
	the likely low dose of infection in the naïve contact pigs	period. Agreed to extend the observation period to at least 60 days, preferably 2 months
C.2.3.3 *Efficacy requirements*, ii) Assessment for horizontal transmission (challenge virus shed and spread study), paragraph 12	Add the requirement to make histopathological sections and check the cytopathic situation, and to undertake immunohistochemistry tests of ASFV to further trace its distribution in the organs	Disagree, the object is not to characterise the virus, PCR testing of the tissues is sufficient
C.2.3.4 Duration of immunity	Add a section on vaccine recombination: the MLV may have genetic recombination with the circulating strains in the field and other vaccine strains. It is thus recommended to carry out vaccine recombination experiments to evaluate the risk of vaccine recombination	Partly agree as it is documented that recombination can occur but, due to the difficulty in carrying out these types of 'recombination' studies in the laboratory, this should not be a minimum standard, but could be a recommendation. Added text to C. Background, paragraph 16

The newly drafted section of Chapter 3.9.1. 'African swine fever' (infection with African swine fever virus) (vaccine section only) is presented as Annex 16 and will be proposed for adoption at the 91st General Session in May 2024.

	Appendix	Chapter	
1.	4	1.1.5.	Quality management in veterinary testing laboratories
2.	5	1.1.9.	Tests for sterility and freedom from contamination of biological materials intended for veterinary use
3.	6	2.2.4.	Measurement uncertainty
4.	7	2.2.6.	Selection and use of reference samples and panels
5.	8	3.1.5.	Crimean–Congo haemorrhagic fever
6.	9	3.3.6.	Avian tuberculosis
7.	10	3.4.1.	Bovine anaplasmosis
8.	11	3.4.7.	Bovine viral diarrhoea
9.	12	3.4.12.	Lumpy skin disease (vaccine section only)
10.	13	3.6.9.	Equine rhinopneumonitis (infection with Varicellovirus equidalpha1)
11.	14	3.8.1.	Border disease
12.	15	3.8.12.	Sheep pox and goat pox
13.	16	3.9.1.	African swine fever (vaccine section only)

5.3. Fast-track revision of the chapter on avian influenza: follow-up from the Animal Health Forum and the adopted Resolution on avian influenza

At the meeting in September 2023, the Commission agreed on the need for a fast-track review of the *Terrestrial Manual* chapter on avian influenza to ensure the information is up to date with the latest science and fit for purpose. To this end, the WOAH Reference Laboratories were asked to update the chapter to include important amendments as needed on an immediate basis. The objective was to submit the chapter for one review round with the February 2024 report and propose it for adoption in May 2024.

The Commission noted that the update submitted by the Reference Laboratories had been extensively amended. The idea of the fast-track review was to include minimal essential revisions, such as primer and probe sequences, that are urgently required to keep the chapter valid in the current context of avian influenza situation and that could be proposed for adoption after just one commenting round. The Commission decided that for a chapter that had been substantially revised, more than one commenting round was required before submission to the Assembly and so

agreed to put the update in the 2024/2025 review cycle where it would follow the normal review procedure (two rounds of commenting in October and March before being proposed for adoption in May 2025). The Reference Laboratories would have the opportunity to further amend it before re-submission to WOAH in July 2024.

In the meantime, the Commission was made aware of a booklet entitled 'Protocols and guidelines for ASF', which had been developed by the ASF network and would be made available on the WOAH website in the near future. The Commission agreed that it is an excellent method of publishing essential updates to protocols, including primer and probe sequences, rapidly with widespread dissemination of vital information. The OFFLU network would be asked if they could develop a similar publication for avian influenza.

5.4. Update on Chapter 2.3.1 The application of biotechnology to the development of vaccines for veterinary use

The Commission identified a Collaborating Centre and expert that could assist with the revision of this chapter. The Commission would like to include future research approaches in vaccine development while retaining information on classical vaccine developments. Their proposal is that the chapter should focus on vaccines against the WOAH listed diseases including:

1. Classical vaccines

2. New generation vaccines

3. Future research approaches in vaccine development.

5.5. Update on draft chapter on diagnostic validation of point-of-care tests for WOAH-listed viral diseases using field samples

Since the last meeting, the ASF, rabies and peste des petits ruminants (PPR) Reference Laboratory networks have been asked to comment on the draft of a new chapter on the diagnostic validation of point-of-care tests (POCTs) for WOAH-listed viral diseases using field samples. The networks agree with the principle of publishing information on validation of POCTs, whether as a stand-alone chapter or part of Chapter 1.1.6 or disease-specific chapters, but felt the text needed further development to improve its practicality and applicability. The comments would be submitted to the Collaborating Centre expert who had drafted the text to decide on the best way forward.

5.6. Progress on development of a validation report form for tests recommended in the *Terrestrial Manual*

The validation report template has now been finalised and is available on the Commission's web page for contributors to the *Terrestrial Manual* to provide data regarding the tests they recommend.

5.7. Application of the criteria for keeping chapters in the *Terrestrial Manual* on non-listed diseases

There are currently 26 chapters in the *Terrestrial Manual* for non-listed diseases. Some of these chapters are for delisted diseases that no longer fulfil the listing criteria (e.g. leptospirosis), and others are for diseases, often zoonoses, that were never listed but for which it was deemed important to provide Members with diagnostic information (e.g. toxoplasmosis) The Commission is aware that maintaining these chapters may not be the best use of resources, and noted that for some there are no designated Reference Laboratories, which poses problems for maintaining the chapters up to date. The Commission agreed the following evidence-based criteria be applied when deciding to maintain a chapter in the *Terrestrial Manual* on non-listed diseases:

1. An important differential diagnosis for a listed disease
2. A Reference Laboratory for the disease exists and is able to provide scientific support
3. A *Terrestrial Code* chapter exists

The Commission applied these criteria to the current 26 non-listed disease chapters in the *Terrestrial Manual.*

The following chapters were retained:

1.	Leptospirosis	2.	Hendra virus disease
3.	Vesicular stomatitis	4.	Marek's disease
5.	Border disease	5.	Melioidosis
7.	Influenza A viruses of swine	8.	Swine vesicular disease
9.	Verocytotoxigenic *Escherichia coli*	10.	Bunyaviral diseases of animals (excluding Rift Valley fever and Crimean-Congo haemorrhagic fever)
11.	Zoonoses transmissible from non-human primates		

The following chapters will be removed from the next edition after the General Session in May 2024. These chapters will still be available from the BSC secretariat (BSC.Secretariat@woah.org) upon request:

1.	Nosemosis of honey bees	2.	Avian tuberculosis*
3.	Duck virus enteritis	4.	Fowl cholera
5.	Fowl pox	6.	Malignant catarrhal fever
7.	Epizootic lymphangitis	8.	Ovine pulmonary adenocarcinoma (adenomatosis)
9.	Atrophic rhinitis of swine	10.	Teschovirus encephalomyelitis
11.	Cryptosporidiosis	12.	Infection with *Campylobacter jejuni* and *C. coli*
13.	*Listeria monocytogenes*	14.	Mange
15.	Toxoplasmosis		

*once the chapter is adopted in May 2024, information on avian tuberculin will be moved to the mammalian tuberculosis chapter and this chapter will be removed

The Commission also agreed that once these chapters have been removed from the *Terrestrial Manual* in May, it would no longer accept applications for Reference Laboratories for non-listed diseases.

5.8. Review of advice submitted by experts of seven *Terrestrial Manual* chapters updated and circulated in October 2023 on whether the update had an impact on the corresponding chapter in the *Terrestrial Code*

At the September 2022 meeting of the Bureaus of the Code and Biological Standards Commissions, it was agreed that the experts who reviewed a *Terrestrial Manual* chapter be requested to advise the Biological Standards Commission as to whether the proposed revision could have an impact on the corresponding *Terrestrial Code* chapter. Six *Terrestrial Manual* chapters in the current review cycle were identified as having a potential impact on the *Terrestrial Code*. The Biological Standards Commissions reviewed the advice received from experts who had undertaken the updates and agreed to submit the following recommendations to the Code Commission:

Code chapter	Recommendations from Biological Standards Commission to the Code Commission
Chapter 11.1. Bovine anaplasmosis	The Commission agrees that Article 11.1.2 of the *Terrestrial Code* chapter could be updated to take account of improved diagnostic test methods and knowledge of the effective treatment methods
Chapter 11.X. Bovine viral diarrhoea	The Commission agrees that the taxonomy of the agent in the *Terrestrial Code* should be updated to align with the *Terrestrial Manual*
Chapter 11.9. Lumpy skin disease	The Commission agrees the *Terrestrial Manual* update has no impact on the *Terrestrial Code* chapter

Code chapter	Recommendations from Biological Standards Commission to the Code Commission
Chapter 12.8. Equine rhinopneumonitis	The Commission agrees that the taxonomy of the agent in the *Terrestrial Code* should be updated to align with the *Terrestrial Manual.* It would also be useful to add a case definition to the *Terrestrial Code*
Chapter 14.9. Sheep pox and goat pox	The Commission agrees the *Terrestrial Manual* update has no impact on the *Terrestrial Code* chapter
Chapter 15.1. Infection with African swine fever virus	The Commission agrees that the *Terrestrial Code* chapter should be updated due to the inclusion of vaccination in the *Terrestrial Manual*

5.9. Update on the request from the Code Commission regarding Chapter 2.1.1 Laboratory methodologies for bacterial antimicrobial susceptibility testing

The Commission was updated on progress since the September 2023 meeting on the request from the Code Commission to review *Terrestrial Manual* Chapter 2.1.1. *Laboratory methodologies for bacterial antimicrobial susceptibility testing* to determine if the chapter provides sufficient and up-to-date information on the establishment of clinical breakpoints or whether it needs to be revised.

To address this request, the Biological Standards Commission consulted the WOAH Working Group on Antimicrobial Resistance (AMR). The Group advised that the expertise on current and upcoming laboratory methodologies for AMR, including the establishment of clinical breakpoints, sits with WOAH's Collaborating Centres. In October 2023, three relevant WOAH Collaborating Centres were asked to review the current chapter and submit a detailed outline of what needs to be done to update it and address the Member concerns.

The Commission reviewed the 'map' submitted by the Centres and agreed the planned outline for the chapter's revision. The Centres would be asked to implement their plan and submit the updated chapter for review at the September 2024 meeting. The aim is to propose the chapter for adoption in May 2025.

5.10. Request to reconsider inclusion of foot and mouth disease virus-like particles in the WOAH *Terrestrial Manual*

A group of researchers that had developed a novel foot and mouth disease (FMD) vaccine based on recombinantly expressed virus-like particles (VLP) requested that the Commission reconsider its decision not to include VLP vaccines in the *Terrestrial Manual* until they have received market authorisation (cf: Report of the Meeting of the Biological Standards Commission/September 2022). The Commission again consulted the WOAH Reference Laboratories for FMD, and again concluded that it is too early for such an addition to the *Terrestrial Manual*, which does not include vaccines not yet in use. Given the significance of such vaccines, including their impact on the *Terrestrial Code*, the Commission would welcome reports from the developers on progress with the registration process, and any peer-reviewed information on their use. Once the vaccines are available and in use, the Commission could implement the fast-track procedure to include them in the *Terrestrial Manual* should the Reference Laboratory network of experts deem it appropriate.

5.11. Follow-up from the General Session: proposal to include a vaccine in the chapter on American foulbrood

At the General Session, a Member had informed the Assembly that a new vaccine for *Paenibacillus larvae* had been authorised for use in the country and requested that the vaccine be included in Chapter 3.2.2. '*American foulbrood of honey bees* (*infection of honey bees with* Paenibacillus larvae)'. The WOAH Reference Laboratories advised the Commission that the vaccine remains under study and thus, does not yet have the necessary scientific support to warrant a recommendation for its inclusion in the *Terrestrial Manual*. The Commission will request the experts to monitor the field trials and inform the Commission if the vaccine can be included in the future.

5.12. Terrestrial *Manual* status: update on chapters selected for the 2024/2025 review cycle

The Commission encouraged those Reference Laboratories with outstanding chapters to deliver by the deadline. The following chapters have been identified for update in 2024/2025 (year last adopted in brackets after the title).

1.1.2. Collection, submission and storage of diagnostic specimens (2013)

1.1.3. Transport of biological materials (2018)

1.1.4. Biosafety and biosecurity: Standard for managing biological risk in the veterinary laboratory and animal facilities (2015)

1.1.7. Standards for high throughput sequencing, bioinformatics and computational genomics (2016)

2.1.3. Managing biorisk: examples of aligning risk management strategies with assessed biorisks (2014)

2.1.1. Laboratory methodologies for bacterial antimicrobial susceptibility testing (2019)

2.2.1 Development and optimisation of antibody detection assays (2014)

2.2.2 Development and optimisation of antigen detection assays (2014)

2.2.3 Development and optimisation of nucleic acid detection assays (2014)

2.2.5 Statistical approaches to validation (2014)

2.2.7 Principles and methods for the validation of diagnostic tests for infectious diseases applicable to wildlife (2014)

2.2.8. Comparability of assays after minor changes in a validated test method (2016)

2.3.2. The role of official bodies in the international regulation of veterinary biologicals (2018)

2.3.3. Minimum requirements for the organisation and management of a vaccine manufacturing facility (2016)

2.3.5. Minimum requirements for aseptic production in vaccine manufacture (2016)

3.1.2. Aujeszky's disease (infection with Aujeszky's disease virus) (2018)

3.1.8. Foot and mouth disease (infection with foot and mouth disease virus) (2021)

3.1.9. Heartwater (2018)

3.1.14. New World screwworm (*Cochliomyia hominivorax*) and Old World screwworm (*Chrysomya bezziana)* (2019)

3.1.17. Q fever (2018)

3.1.20. Rinderpest (infection with rinderpest virus) (2018)

3.1.25. West Nile fever (2018)

Introductory note on bee diseases (2013)

3.2.5. Infestation of honey bees with *Aethina tumida* (small hive beetle) (2018)

3.2.6. Infestation of honey bees with *Tropilaelaps* spp. (2018)

3.3.1. Avian chlamydiosis (2018)

3.3.2. Avian infectious bronchitis (2018)

3.3.4. Avian influenza (including infection with high pathogenicity avian influenza viruses) (2021)

3.3.8. Duck virus hepatitis (2017)

3.3.11. Fowl typhoid and Pullorum disease (2018)

3.3.12. Infectious bursal disease (Gumboro disease) (2016)

3.4.9. Enzootic bovine leukosis (2018)

3.4.11. Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (2017)

3.4.15. Theileriosis in cattle (infection with *Theileria annulata, T. orientalis* and *T. parva*) (2018)

3.4.16. Trichomonosis (2018)

3.6.1. African horse sickness (infection with African horse sickness virus) (2019)

3.6.6. Equine infectious anaemia (2019)

3.6.7. Equine influenza (infection with equine influenza virus) (2019)

3.6.10. Equine viral arteritis (2013)

3.6.11. Glanders and melioidosis (2018)

3.8.2. Caprine arthritis/encephalitis and Maedi-visna (2017)

3.8.3. Contagious agalactia (2018)

3.8.5. Enzootic abortion of ewes (ovine chlamydiosis) (infection with *Chlamydia abortus*) (2018)

3.8.7. Ovine epididymitis (*Brucella ovis*) (2015)

3.8.11. Scrapie (2022)

3.8.12. Sheep pox and goat pox (2017) (vaccine section)

3.9.3. Classical swine fever (infection with classical swine fever virus) (2022: diagnostic tests section)

3.9.8. Swine vesicular disease (2018)

3.9.10. Transmissible gastroenteritis (2008)

3.10.9. Verocytotoxogenic *Escherichia coli* (2008)

5.13. Update on WOAH Standards Online Navigation Tool Project

The Commission was updated on the WOAH Standards Online Navigation Tool, which is an innovated project aimed at providing users with streamlined access and navigation of WOAH Standards.

The project will deliver three user interfaces on the WOAH Website:

- Navigation and search tool: this interface will provide a guided navigation experience that will allow users to navigate through the WOAH Codes and Manuals.

- Recommendations for safe international trade by commodity: this interface will enable users to easily visualise recommendations for safe international trade by commodity through a comprehensive filtering system.

- Management of Standards; this interface will enable WOAH staff to efficiently manage and update WOAH International Standards, following adoption of new or revised text at the WOAH General Assembly.

The tool will be demonstrated at a kiosk at the 91st General Session in May 2024 and is projected to go 'live' in July 2024.

This project represents a significant milestone in WOAH's commitment to enhance access and utilisation of WOAH standards and contributes to the objectives of the 7th Strategic Plan to implement digital transformation, respond to Members' needs and improve WOAHs efficiency and agility.

6. WOAH Reference Centres

6.1. Update on the system for evaluating the annual reports

During the last meeting of the Commission in September 2023, a risk-based approach was introduced to the system for evaluating the annual reports to increase its efficiency while reducing workload for the Commission. This system is a semi-automated method aimed at creating an effective means of performance assessment, capable of detecting underperforming Reference Laboratories (RL) with high sensitivity. The goal was to create a system that can digitally and automatically evaluate reports.

The system employs a risk-based methodology for the initial analysis of annual reports, categorising RL as either low risk or high risk for underperformance. This categorisation is based on risk criteria identified during the Commission's September 2023 meeting, such as negative responses to identified 'Essential' questions (questions 1, 18, 19, 20, and 27 of the report template), being a new RL, scoring below 50% on average across all questions. This strategy guarantees uniform screening of all reports, flagging those requiring more thorough individual assessment by Commission members, with a focus on potential underperformers. This reduces the number of reports each BSC member needs to evaluate, thereby optimising their efforts.

Regarding questions 25 and 27, the Commission agreed that the requirement to organise or participate in inter-laboratory proficiency tests could be satisfied if the reply to either question is yes, i.e. if the proficiency tests are either with WOAH Reference Laboratories or with non-WOAH laboratories.

The Commission agreed to implement this system for the first time in the review of the 2022 reports. The Secretariat distributed the reports by identified the system equally among Commission members, reducing the number from approximatively 40 annual reports per BSC member to between 20 and 23 reports, approximately half of the previous

number. An extraordinary meeting was convened in November 2023 to finalise the evaluations of the 2022 annual reports, assess the performance of the new system, and communicate the findings within the network.

After this initial application of the system, 130 annual reports were flagged based on various risk criteria: 90 for essential issues, 12 for underperformance, eight as new laboratories, and 13 were randomly selected. A detailed evaluation of these reports revealed that 49 out of the 90 Laboratories with an essential issue were confirmed as problematic and received notification letters. Of the 12 labs scoring below 50% on average across all questions, four were contacted.

The Commission agreed that the system effectively minimised its workload and strategically targeted its efforts towards the RL that most require attention. The Commission also agreed that the system demonstrated a high sensitivity in identifying annual reports with significant risks of underperformance. However, there was a discussion regarding specific situations where laboratories are engaged with diseases having low epidemiological incidence, work with eradicated diseases, or unique disease-specific laboratories. In such cases, these laboratories may struggle to fulfil all the terms of reference and hence should be accorded special consideration. Moreover, the Commission recognises the need to standardise the criteria for issuing underperformance notification letters. Moving forward, the Commission is committed to continually testing and improving the system.

6.2. Applications for WOAH Reference Centre status

The Commission recommended acceptance of the following applications for WOAH Reference Centre status:

WOAH *Reference Laboratory for sheep pox and goat pox*
Sciensano, Groeselenberg, 99 1180 Uccle
BELGIUM
Tel.: + 32-2 379.05.14 / 379.06.27
E mail: nick.deregge@sciensano.be
Website: https://www.sciensano.be/en https://www.eurl-capripox.be/homepage
Designated expert: Dr Nick De Regge

WOAH *Reference Laboratory for rabies*
Veterinary Research Institute, Ministry of Agriculture
No.376, Zhongzheng Rd., Tamsui Dist., New Taipei City 251018
CHINESE TAIPEI
Tel.: +886-2 26.21.21.11 Annex 602
E-mail: aphsu@mail.nvri.gov.tw
Website: https://eng.nvri.gov.tw
Designated expert: Dr Ai-Ping Hsu

WOAH *Reference Laboratory for leptospirosis*
ICAR-National Institute of Veterinary Epidemiology and Disease Informatics (ICAR-NIVEDI),
Post Box No. 6450, Yelahanka, Bengaluru 560064, Karnataka
INDIA
Tel.: +91-80 23.09.31.36 / 31.00
E mail: b.vinayagamurthy@icar.gov.in; director.nivedi@icar.gov.in;
Website: https://www.nivedi.res.in/
Designated expert: Dr Vinayagamurthy Balamurugan

WOAH *Reference Laboratory for peste des petits ruminants*
ICAR-National Institute of Veterinary Epidemiology and Disease Informatics (ICAR-NIVEDI),
Post Box No. 6450, Yelahanka, Bengaluru- 560064, Karnataka
INDIA
Tel.: +91-80 23.09.31.36 /31.00
E mail: b.vinayagamurthy@icar.gov.in; director.nivedi@icar.gov.in;
Website: https://www.nivedi.res.in
Designated expert: Dr Vinayagamurthy Balamurugan

WOAH *Reference Laboratory for salmonellosis*
Central Veterinary Laboratory,
Ministry of Agriculture, Water and Land Reform
24 Goethe Street, P-Bag 13187, Windhoek
NAMIBIA
Tel.: +264-61 23.76.84
E-mail: Siegfried.Khaiseb@mawlr.gov.na

Designated expert: Dr Siegfried Khaiseb

WOAH *Collaborating Centre* for *Field Epidemiology*
Centre National de Veille Zoosanitaire (CNVZ)
38, Avenue Charles Nicolle, Cite Mahrajène, 1082 Tunis
TUNISIA
Tel.: (+216) 71849790 - (+216) 71849812
E-mail: kalthoum802008@yahoo.fr; baccar.vet@gmail.com;
Website: www.cnvz.agrinet.tn
Contact point: Dr Sana Kalthoum

An application had been received from a county in Africa for a Reference Laboratory for avian Influenza. The Commission was fully satisfied with the quality and capacity of the applicant institution and the services it could provide to WOAH Members. However, the Commission questioned the choice of designated expert. The Commission would seek clarification of the nominee's experience in diagnosis and research, and role in the laboratory. The applicant will be asked to provide more detailed information on their experience in standardisation and validation of diagnostic tests, as well as peer-reviewed publications on avian influenza. Although the laboratory clearly had a great deal of experience with the disease, the proposed expert did not fulfil the expectations of a WOAH Expert. The Commission therefore did not accept the application at this time.

Another application had been received from a country in the Asia-Pacific region for a Reference Laboratory for FMD. Some years ago, the Commission was made aware of a number of quality and safety issues in this laboratory. Three areas of concern were identified: the level of expertise of the designated expert; lack of trust in the choice and efficacy of the tests undertaken by the laboratory and in the safety of the reagents it produces and supplies to other laboratories; and concern about the inadequate biosafety level. The laboratory withdrew from the list of WOAH Reference Laboratories while it underwent a performance monitoring scheme (PMS) with other independent WOAH Reference Laboratories to address these issues. The Commission questioned the timing of the application as the PMS is not complete and the laboratory remains under construction. The Commission also had questions about the biosafety level at which the laboratory is currently operating, given the nature of the work being undertaken there. The Commission noted gaps in the information provided. On a positive note, the proposed designated expert submitted an excellent curriculum vitae and meets the expectations of a WOAH expert. Overall, however, the Commission found that it is premature to apply for Reference Laboratory status and did not accept the application.

Another application had been received from a country in the Asia-Pacific region for a Reference Laboratory for equine piroplasmosis. The Commission was fully satisfied with the excellence of the centre for equine diseases, notably acknowledging the applicant institution's scientific excellence and its potential to significantly contribute to WOAH as well as the expertise of the designated expert. Despite these strengths, the Commission has two major concerns: the limited range of diagnostic methods routinely employed and the laboratory's international outreach, for example the organisation and participation in international proficiency tests. The Commission did not accept the application at this time, but would encourage the applicant to address these important issues. The Commission will closely evaluate any supplementary information submitted.

Finally, an application had been received for a Collaborating Centre for Reference Materials for Molecular Diagnostic Techniques in Aquatic and Terrestrial Animal Diseases. The Commission was satisfied with the scientific excellence of the expert and believed the Centre would be a useful addition to the WOAH network. As the application was more focused on aquatic animal diseases, the Biological Standards Commission agreed that responsibility for the final decision on endorsing the application lies with the Commission on Aquatic Animals (see item 13.1 of the report of the meeting of February 2024 meeting of the Aquatic Animals Commission.

6.3. Changes of experts at WOAH Reference Centres

The Delegates of the Members concerned had submitted to WOAH the following nominations for changes of expert at WOAH Reference Laboratories. The Commission recommended their acceptance:

Brucellosis (*Brucella abortus, B. melitensis, B. suis*):
Dr Liangquan Zhu to replace Prof. Jiabo Ding at the China Institute of Veterinary Drug Control (IVDC), CHINA (PEOPLE'S REP. OF)

Infectious bursal disease (*Gumboro disease*):
Dr Yulong Gao to replace Dr Xiaomei Wang at the Division of Avian Immunosuppressive Disease, Harbin Veterinary Research Institute (HVRI), Chinese Academy of Agricultural Sciences (CAAS), CHINA (PEOPLE'S REP. OF)

Sheep pox and goat pox:
Dr Mohammand Hassan Ebrahimi-jam to replace Dr Hamid Reza Varshovi at the RAZI Vaccine & Serum Research Institute, IRAN

Swine influenza:
Dr Junki Mine to replace Dr Takehiko Saito at the Viral Disease and Epidemiology Research Division, National Institute of Animal Health, National Agriculture and Food Research Organization, JAPAN

Avian influenza:
Dr Eun Kyoung Lee to replace Dr Youn-Jeong Lee at the Animal and Plant Quarantine Agency Ministry of Agriculture, Forest and Rural Affairs, KOREA (REP. OF)

Rabies:
Dr Juan Antonio Montaño Hirose to replace Dr José Álvaro Aguilar Setién at the National Centre for Animal Health Diagnostic Services, MEXICO

Leptospirosis:
Dr Paula Ristow to replace Dr Marga Goris at the Academic Medical Centre, Department of Medical Microbiology and Infection Prevention University of Amsterdam, NETHERLANDS

Q fever:
Dr Agnieszka Jodelko to replace Dr Krzysztof Niemczuk at the National Veterinary Research Institute, Department of Cattle and Sheep Diseases, POLAND

Lumpy skin disease:
Dr Antoinette Van Schalkwyk to replace Dr David Wallace at the Onderstepoort Veterinary Institute, SOUTH AFRICA

The Commission reviewed one additional nomination for change of expert and based on the information provided found that the nominee did not fulfil the expectations of a WOAH Expert. The Member would be asked to either resubmit a strengthened curriculum vitae or to propose a different expert.

6.4. Review of new and pending applications for laboratory twinning

As of February 2024, 90 projects have been completed and 16 projects are underway. Of the completed projects, 15 Reference Laboratories and four Collaborating Centres have achieved WOAH designation status.

Six Laboratory Twinning project proposals were presented for the Commission's review:

1. **Jordan – United Kingdom** for foot and mouth disease: the Commission supported the technical contents of this project proposal.
2. **South Africa – Türkiye** for Rift Valley fever: the Commission supported the technical contents of this project proposal.
3. **United States of America – Romania** for Biorisk management: the Commission supported the technical contents of this proposal.
4. **Germany and Cameroon** for Newcastle disease: the Commission supported the technical contents of this proposal.
5. **United States of America – Vietnam** for rabies: the Commission supported the technical contents of this proposal.
6. **South Africa – Tanzania** for capacity development for standard diagnostic methods for small ruminant diseased: the Commission supported the technical contents of this proposal with some amendments.

6.5. Feedback from Laboratories that are not complying with the key ToR

The Commission reviewed the feedback received from 28 Reference Laboratories that were not complying with key performance criteria according to their 2022 annual reports. The majority of these RLs responded with acceptable justifications for their non-compliance with the ToR, and the Commission accepted their explanations. However, while the responses were accepted, all the RL will be placed on a watch list. This implies that their annual report will undergo a more thorough review during the next round of assessments to ensure compliance and progress.

Some RLs reported that they did not receive any requests for diagnostic testing because they are located in regions free from the disease. The Commission will consider how to evaluate laboratories in situations where the disease is well controlled or not widely distributed. Similarly, being the only RL for a specific disease meant that certain laboratories were unable to join or form networks, which was noted by the Commission. However, in these cases, the ToR indicate that networks can also be formed with institutions that are not WOAH RLs, and the Commission encourages RLs to establish such networks.

6.6. Review the template for the curriculum vitae for nominations of replacement experts

While reviewing nominations for replacement experts, the Commission identified a recurring issue with the information provided, which often is incomplete or fails to meet the required evaluation standards. To promote consistency in nominations and prevent delays caused by inadequate curriculum vitae (CV) details, the Commission agreed to review the CV template for new applicants and nominations of replacement experts at Reference Centres.

First, the Commission added more mandatory fields for basic information such as an email address and the name of the disease. To better assess their suitability, nominees, would be asked to provide a more comprehensive list of academic and professional qualifications, including the year each degree was obtained. In a separate section, experts are asked to provide information on past roles, durations, and responsibilities.

Given the need to determine the level of their expertise, nominees are now prompted to provide details of their international recognition and standing, including appointments, awards, memberships, participation in working groups and relevant activities. Finally, the section on peer-reviewed publications has been amended to ensure relevance to the field, requiring the experts to highlight their name in bold in the title of the publication, along with the disease or pathogen in question. Publications should be listed chronologically and should demonstrate the expert's ongoing contribution and current standing in their field of expertise.

The template was also approved by the Aquatic Animals Commission (see item 3.1 of the report of the February 2024 meeting of the Aquatic Animals Commission.

The amended template can be found at Annex 17 for information.

6.7. Feedback from Centres that are not complying with the key ToR

The Commission reviewed feedback from seven Collaborating Centres that were not meeting key performance criteria according to their 2022 annual reports. Two reasons for not complying with the key ToR were commonly cited. 1) Collaboration or activities with other Centres does not usually occur annually. The Commission understands and accepts that efforts and resources might be directed towards these activities biennially. 2) The impact of SARS-CoV-2: the Commission accepted this response for the 2022 reports, but emphasised that it does not expect the Covid-19 pandemic to be among the reasons for not complying the ToR in the 2023 annual reports.

The Commission accepted the proposals offered by the seven Centres for improving performance and placed them on a watch list for a follow-up review during the next annual report review cycle.

6.8. Review the proposed procedure on how to evaluate Centres at the end of their 5-year mandate

Collaborating Centres are designated for a period of 5 years, during which they adhere to a 5-year work plan, which was submitted at the beginning of the designation period. At the end of this period, the Director General sends a letter requesting a report of the achievements of the 5 years as outlined in the work plan. The Commission evaluates this report and decides if the Collaborating Centre's designation should be renewed or not based on their performance and the need to maintain a Centre for the specific topic.

This system of designating Collaborating Centres for a 5-year period was introduced in 2020 with the adoption of the SOPs (Collaborating Centre - Procedures for Designation). The first Centres to reach the end of their 5-year designation will do so at the end of 2024.

At its September 2023 meeting, the Commission agreed that a letter requesting a final report of their activities over the past 5 years in relation to the 5-year work plan originally submitted should be sent at the end of the second quarter of the fifth year of the designation. The Centres will also be requested to submit the regular annual report, and both will be assessed by the Commission.

The Commission reviewed and updated the template for this final report, including specific performance criteria. The template is designed to capture comprehensive evidence of the Centre's impacts and achievements over the 5-year period, as well as the benefits provided to the territory, region or even globally. The revised template is tailored to

gather the necessary information to assess the Centre's adherence to their planned 5-year work plan. It includes sections for detailing the goals and objectives from the original submission, indicating their current status as 'achieved', 'in progress', 'modified', or 'not started', always providing reasons for each response. Additionally, the template includes a table for summarising completed activities, with a focus on the expected and achieved benefits. To conclude, a 'Renewal' section has been added, where Collaborating Centres can express their interest in being considered for renewal. The Centre will be asked to outline their strategy for contributing to the WOAH mandate and enhancing the visibility of the Centres. They are also be asked to describe in bullet points how they can assist WOAH Members. Finally, the Commission will evaluate the relevance of the domain of activity of each Collaborating Centre in line with the WOAH Strategic Plan.

The Commission will conduct a preliminary review of these final reports, with initial results to be announced at the subsequent February meeting. Centres with approved final reports and with a clear vision to contribute to WOAH's Strategic Plan will be informed following the February meetings of the Commission of their eligibility for renewal and will be invited to present a new 5-year plan. Centres whose performance is deemed unsatisfactory or those that do not submit a report will be granted a 6-month appeal period, leading up to the next Commission meeting in September. During this meeting, their designation status will be re-evaluated, which may result in their removal from the list.

6.9. Review ways to improve the output of Collaborating Centres for the benefit of WOAH and Members

The Commission discussed ways of enhancing the outputs of Collaborating Centres for the benefit of the Centres themselves, WOAH and its Members. One possibility considered was to review the ToR to ensure they remain relevant and effective. Recognising the broad scope of topics covered by the Centres as a valuable resource, the Commission wondered if the current network adequately covers all the needs of Members and WOAH. The Commission agreed to focus on evaluating potential gaps between the existing areas of expertise, particularly in relation to maintaining expertise amid ever evolving technology. A significant point of discussion was how to enable Members to better leverage this resource, which might be achieved by increasing communication with Members and facilitating more effective use of the Centres. To increase their visibility, the Commission proposed to ask the Centres to submit three to five bullet points on the services they offer, which will be added to the Centre's entry on the WOAH website through a link entitled 'How can we help you'. Finally, the Commission pointed out that an important criterion for support involves maintaining contact with Reference Laboratories, ensuring a collaborative and informed network.

6.10. Update on the three Reference Laboratory network (ASF, PPR[5] and rabies)

African swine fever

The WOAH ASF Reference Laboratory network held regular virtual meetings to exchange scientific and technical expertise, including recent developments on ASF vaccines, and discussed activities in developing training programmes to assist at-risk countries, including the organisation of proficiency tests.

The network is finalising a laboratory manual, including diagnostic algorithms to detect low virulent and novel emergent ASFV variants, to explore user requirements on an open-access information sharing platform for ASF virus genome sequence data and detecting circulant recombinant virus.

Peste des petits ruminants

The WOAH PPR Reference Laboratory network continues to regularly update its website and organise activities in support of its members. In November 2023, the PPR Global Research and Expert Network's sixth meeting was held in Bengaluru, India, focusing on PRR research innovations to support the PPR Blueprint's second and third eradication phases. Also in November 2023 in the African region, a key cross-border harmonisation workshop and Regional Advisory Group meeting for PPR eradication took place in Grand Bassam, Cote d'Ivoire. This workshop focused on collaborative strategies for PPR risk management and eradication efforts. In December 2023, the WOAH PPR Reference Laboratory network conducted a workshop focusing on critical aspects of PPR management.

The ongoing development of the PPR Monitoring and Assessment Tool (PMAT) training e-modules is being managed by the FAO[6] Virtual Learning Centre. In parallel, the digitalisation of PMAT is progressing, marking significant strides in modernising these tools. The newly developed PPR Episystem Guidelines were presented during a virtual stakeholder meeting. Final approval is expected shortly. Finally, a revised template for developing National Strategic Plans (NSP) for PPR was crafted and presented to countries and stakeholders for adoption. This updated template is now set to be used by countries to align their NSPs with the PPR blueprints, ensuring a more cohesive and effective approach to PPR management and eradication efforts.

5 PPR: Peste des petits ruminants
6 FAO: Food and Agriculture Organization of the United Nations

Rabies

The WOAH Reference Laboratory Network for Rabies (RABLAB) continued to meet bimonthly to share information and align activities to improve global support for rabies diagnostics, surveillance, capacity building and implementation of rabies control activities. A second in-person meeting of the network was held 8 November 2023, in Rome, Italy, to review progress and identify key priorities for 2024.

Efforts continue to improve promotion and transparency of RABLAB activities, including an upcoming annual newsletter showing key outputs and updates from the network. BSC noted again the need to better highlight RABLAB activities on the WOAH website.

RABLAB continues to support WOAH Members through several Twinning projects to build laboratory capacity for rabies diagnosis and will support the United Against Rabies Forum in implementing the initial three pilots of the Country Partnership Programme, which aims to provide broader, One Health support for rabies-endemic countries. RABLAB experts have also contributed to the development of the 'Oral vaccination of dogs against rabies: Recommendations for field application and integration into dog rabies control programmes'.

RABLAB are continuing discussions with relevant manufacturers to explore how protocols for lateral flow devices (LFDs) can be improved to support rabies surveillance. At present, the RABLAB statement on the use of LFDs remains unchanged.

In 2024 RABLAB will continue to provide direct support rabies-endemic countries in the drafting and implementation of their National Strategic Plans, and, when appropriate, help them apply for WOAH endorsement; support WOAH in monitoring international standards to ensure these remain fit for purpose; enhance collaboration among RABLAB members; and disseminate scientific information among WOAH Members and the wider rabies community.

6.11. Annual reporting system for WOAH Collaborating Centres and Reference Laboratories

In December 2022, an electronic system was launched to collect annual reports from WOAH Reference Centres. Regrettably, several Reference Centres encountered difficulties in completing and submitting their reports due to bugs in the system.

To address the identified issues and enhance user-friendliness, a service provider was hired by WOAH in November 2023 to upgrade and evolve the current system based on the problems identified during its initial use. This system renovation aims to enhance and develop additional functionalities for the existing WOAH Reference Laboratories and Collaborating Centres (RL&CC) information system. The RL&CC information system must effectively collect, store, process, and submit reports of WOAH RL and CC activities, supporting decision-making, coordination, control, analysis, and visualisation of the final reports. It is designed to automate and streamline business processes, thereby reducing manual effort, mitigating potential risks, and improving operational efficiency for both WOAH and the network of CC and RL.

The system evolution will implement the use of one email address for access to both CC and RL templates facilitating those involved with both. This enhancement will allow RL and CC users to access multiple reports without the need to manually log in and out when switching reports. Furthermore, it will enable RL and CC to add multiple users to fill out and edit reports simultaneously. Additionally, the system will improve existing functionalities such as User Experience (UX) design, modify existing form templates for both RL and CC, and fix existing bugs within the system.

The current project plan envisages launching the new system in March 2023. The Commission emphasised that should the system not meet the requisite high standards in the projected timeline, its deployment will have to be postponed until it fully satisfies all the necessary quality criteria.

The Commission expressed concern about ensuring the system reaches the Organisation's level of excellence and that the Reference Centres can use a system that meets their needs. The Commission thanked the Reference Centres for their understanding regarding the postponement of annual report submissions and emphasised that their annual reports would be evaluated in September 2024.

6.12. Fraudulent use of the WOAH emblem/logo

The Commission was made aware of a WOAH Reference Laboratory that is using the WOAH emblem on vaccines that it is selling to Members. This is fraudulent use of the WOAH emblem/logo, which is clearly described as such in the Guidelines on the Use of the WOAH Reference Centre Emblem. The WOAH is pursuing this issue with the institution involved, which has withdrawn the products from the market. Reference Centres are reminded that to follow the Guidelines or to ask WOAH Headquarters if they have a question about how they can use the WOAH Emblem.

7. *Ad hoc* Groups: Update on activities of past *ad hoc* Groups

7.1. *Ad hoc* Group on Replacement of the International Standard Bovine Tuberculin (ISBT) and Avian Tuberculin (ISAT)

The Commission was informed that the third trial has been completed in October 2023 and based on the results, the *ad hoc* Group recommended to continue performing one last set of trials on candidate B by fine-tuning the parameters of the experiment. The *ad hoc* Group also discussed the results of all the sets of trials, which had indicated that two of the four assays were invalid. One assay however, had approached acceptability based on EU Pharmacopoeia criteria suggesting potency between 50% and 200%, and the inhouse standard provided by the manufacturer was close to the acceptable range of potency of 30,000 units. The *ad hoc* Group recommended to review the original data from the manufacturer to better understand the factors contributing to lower potency estimates. In the last set of trials, the duration of infection and the inoculation dose was increased sequentially to minimise any variables. This fourth and final trial is currently ongoing, and results are anticipated in mid-March 2024.

If the trials are favourable, the Commission will consult remotely to decide whether to identify candidate B as a replacement for ISBT at the next General Session. Furthermore, the Commission recommended that in case the trials are unfavourable, WOAH should continue to identify a new candidate and restart the trials. The Commission recommends that WOAH continue to mobilise resources to identify funding to sustain the project, as without a universally accepted standard, Members would have to rely on the manufacturer's standard, which may lead to variability in the results.

Regarding avian tuberculin, the Commission was informed of a call for donations of a candidate avian tuberculin was launched in December 2023. The last date for receiving applications from the manufacturers was 16 February 2024.the Commission recommended that the *ad hoc* Group review and recommend the shortlisted candidates to the Commission.

7.2. *Ad hoc* Group to Review *Terrestrial Code* Chapter 4.7. 'Collection and processing of bovine, small ruminant and porcine semen'

The Commission was informed that an expert consultation would be held virtually to develop an action plan for the work of this *ad hoc* Group. A member of the Biological Standards Commission was identified to participate in meetings of the Group.

7.3. *Ad hoc* Group on Emerging Diseases (including Re-Emerging Diseases) and Drivers of Disease Emergence in Animals

The Commission was informed of the activities of this Group and noted the relevant recommendations.

8. International Standardisation/Harmonisation

8.1. WOAH Register of diagnostic kits – update and review of new or renewed applications

The Secretariat for Registration of Diagnostic Kits (SRDK) informed the Commission of the status of ongoing applications. At present, there are 16 diagnostic test kits in the WOAH Register of Diagnostic Kits.

8.1.1. Addition of a new diagnostic kit to WOAH's register: Genelix™ ASFV Real-time PCR Detection kit

The assessment of the application for GenelixTM ASFV real-time PCR detection kit (Sanigen) is under evaluation. The review and endorsement of conclusions, recommendations in the Review Panel Final Report and Validation Studies Abstract (VAS) will be processed by written procedure. Depending on the endorsement, a Resolution is planned: to add a new diagnostic kit to WOAH's register for adoption during the 91st General Session in 2024.

The intended purpose of the kit: the Genelix™ ASFV Real-time PCR Detection kit is a product that qualitatively detects and confirms the diagnosis of ASFV using a real-time PCR detection system in the whole blood, serum, and tissues of swine suspected of being infected with the ASFV.

The Validation Studies Abstract – Supplementary Data, drafted by the manufacturer and approved by the Expert Review Panel, was endorsed by the Commission (see Annex 18).

8.1.2. Addition of a new diagnostic kit to WOAH's register: Sentinel® ASFV Antibody Rapid Test

The Commission was informed that the evaluation of the dossier on Sentinel® ASFV Antibody Rapid Test (Manufacturer: Excelsior Bio-System Incorporation) has been completed. Based on the final report from the Expert Review Panel, the Commission endorsed the Panel's recommendation to approve the kit's 'fitness for purpose' as described in the Validation Studies Abstract and User's Manual (Instructions for Users).

The Sentinel® ASFV Antibody Rapid Test is an immuno-chromatographic lateral flow assay (LFA) intended for the detection of ASFV antibodies in porcine serum samples. The test is designed to be used for the diagnosis of ASFV infection, in conjunction with other tests or diagnostic procedures, and the evaluation of antibody response to infection.

The Validation Studies Abstract drafted by the manufacturer and approved by the Expert Review Panel was endorsed by the Commission (see Annex 19).

A Resolution will be prepared accordingly to add a new diagnostic kit to WOAH's register for adoption during the 91st General Session in 2024.

8.1.3. Decision of the 5 year-Renewal and a Resolution's: Avian Influenza Antibody test kit (registration number 20080203) BioChek (UK) Ltd

The Commission endorsed the recommendation for the 5-year renewal with a Resolution for the Avian Influenza Antibody test kit (registration number 20080203) BioChek (UK) Ltd, based on the provided information and in accordance with the agreed procedure.

8.1.4. Decision of the 5 year-Renewal and a Resolution's: Newcastle Disease Antibody test kit (CK116; registration number 20140109) BioChek (UK) Ltd

The Commission endorsed the recommendation for the 5-year renewal with a Resolution for Newcastle Disease Antibody test kit (registration number 20140109) BioChek (UK) Ltd based on the provided information and in accordance with the agreed procedure.

8.1.5. Update on the WOAH Register of diagnostic kits

Following the information given to the Commission in February 2023 (agenda item **8.1.7.**) about the Future Secretariat for Registration of Diagnostics Kits (SRDK), the Commission was informed that, in agreement with the Director General and Deputy Director General, International Standards and Science, SRDK will proceed with the complete freeze of the Diagnostic Kits Register's activities and all related procedures starting after the 91st General Session, for a renewed period of 24 more months, thus, until May 2026. This will mean:

- Validated and approved kits will maintain their certification;
- No renewal processing, even if they arrive to the 5-year due date;
- Withdrawal of all incomplete applications, with return of fees to applicants;
- No review of any potential appeal procedure;
- No review or validation of new applications;
- Consideration of exceptional cases, linked to an emergency animal health situation, upon Members request.

8.2. Standardisation programme

8.2.1. Project to extend the list of WOAH-approved reference reagents: review of guidelines

At the last meeting in September 2023, the Commission decided to send the current guidelines (for antibody standards[7], antigen standards[8] and PCR assays[9]) to the disease-specific networks, namely ASF, FMD, rabies and PPR, with the request that they establish minimum criteria for the development of reference reagents so that the guidelines could be made more achievable while maintaining the quality of the reagents

7 https://www.woah.org/app/uploads/2021/03/a-guideline-antibody-standards.pdf
8 https://www.woah.org/app/uploads/2021/03/a-guideline-antiegen-standards.pdf
9 https://www.woah.org/app/uploads/2021/03/a-guideline-pcr-standards.pdf

produced.

The PPR network had replied to the request and submitted minimum guidelines for the preparation and validation of reference materials for PPR diagnostic methods. The Commission reviewed the guidelines, made amendments to make them generic, and proposed that they be provided to the other networks for comment and approval before they are made available on the WOAH website. It is hoped that these guidelines will encourage more laboratories to apply to have their reagents approved by WOAH as reference reagents.

8.2.2. Association française de normalisation: follow-up from September 2023

Following the September 2023 meeting, the Commission deliberated on the current status of AFNOR, noting that they have an Agreement of Liaison with WOAH. The Commission noted that the current status does not clarify if AFNOR has the jurisdiction to independently comment on WOAH Standards. The established agreement allows WOAH to act as a liaison organisation, participating in the CEN/TC's activities. The Commission noted that receiving feedback under these terms might inadvertently set a precedent, allowing multiple organisations to offer comments on the Standards, potentially leading to an unsustainable situation.

In light of this, the Commission decided that a thorough examination of the liaison agreement by WOAH's Legal Affairs Unit is necessary to clarify the scope of the agreement.

Finally, the Commission reiterated its recommendation that AFNOR send its feedback through a Member, using the representation of a designated official Delegate.

9. Resolutions for the General Session

The Commission noted that the following resolutions would be proposed for adoption at the General Session in May 2024:

- A resolution proposing the adoption of 13 draft chapters for the *Terrestrial Manual*;
- A resolution proposing the new WOAH Collaborating Centres.

The following resolutions would be proposed for adoption by the alternative procedure developed in May 2020 in response to the Covid-19 pandemic, where Delegates submit their votes through an online mechanism available before the General Session in May 2024:

- A resolution proposing the new WOAH Reference Laboratories for terrestrial animal diseases;
- A resolution on the WOAH Register of Diagnostic Kits.

10. Conferences, Workshops, Meetings

10.1. Update on the WOAH seminar to be held during the WAVLD Symposium in Calgary, Canada in 2025

The World Association of Veterinary Laboratory Diagnosticians has a mission to improve animal health, human health, and One Health by facilitating the availability of quality laboratory testing provided by veterinary diagnostic laboratories around the world. As part of their mission, they hold an international symposium every two year. This symposium brings together veterinary diagnosticians and others involved in veterinary laboratory diagnostics. The next ISWAVLD will be held in Calgary, Canada from 12 to 14 June 2025 and will adopt the One Health theme of 'Partnerships in Health: from Disease Detection to Prevention' with a focus on one health, antimicrobial resistance, disease detection, and outbreak response bringing veterinary medicine, human medicine, and industry together.

Traditionally, the Biological Standards Commission organises in parallel a 1-day seminar during the Symposium that will be held on 13 June 2025. The Commission discussed various topics that could be of interest for the next Seminar and suggested to invite presentations from WOAH disease-specific networks on ASF, PPR, Rabies, FMD and Avian influenza on the latest technologies for disease diagnosis, case studies of recent communicable disease such as Japanese encephalitis spread in Australia, the emergence of Western equine encephalitis in South America, a summary on the pros and cons of POCTs and how to integrate them in field diagnosis, information on validation techniques, whole genome sequencing and metagenomics, artificial intelligence, bioinformatics, impact of the Nagoya Protocol in animal health, etc. The Secretariat will contact various speakers on the suggested topics to draft a provisional agenda for discussion in the September meeting.

10.2. Vaccination and Surveillance for HPAI in poultry: Current situation and future perspectives

A workshop entitled 'Vaccination and Surveillance for HPAI in poultry: Current situation and perspectives' organised by IABS (International Alliance for Biological Standardization) in partnership with WOAH will be held at WOAH Headquarters from 22 to 23 October 2024. The aim of the workshop is to discuss how to implement surveillance in vaccinated poultry populations along with other aspects of HPAI vaccination. Participation is expected by a wide variety of stakeholders including Delegates, scientists, international organisations, poultry breeding and biological companies, animal welfare organisations, human health. Recommendations will be prepared and presented by a designated panel.

The organisation will waive the registration fees to WOAH Delegates and designated WOAH reference laboratory experts.

11. Matters of interest for consideration or information

11.1. Update on OFFLU[10]

The Commission was briefed on OFFLU and WOAH activities on avian influenza. During the reporting period, the avian influenza epidemic continued with high numbers of detections reported globally in poultry and non-poultry including wild birds and the first incursion of the HPAI H5 virus in the Sub-Antarctic region was detected in October 2023 in South Georgia Island. OFFLU experts point out that the negative impact of HPAI H5 on Antarctic wildlife could be immense and can result in high mortality.

In December 2023, WOAH published a policy brief on the use of avian influenza vaccination: 'Avian influenza vaccination: Why it should not be a barrier to safe trade'. The purpose of this document is to remind national authorities that vaccination, when used in accordance with WOAH international standards, is compatible with safe trade in domestic birds and their products.

For the September 2023 WHO vaccine composition meeting, data for 1368 HPAI H5 and 117 H9 avian influenza genetic sequences were contributed by animal health laboratories in countries representing Africa, the Americas, Asia, Europe and Oceania. Additionally, data for 191 swine H1 sequences and 49 swine H3 sequences were analysed and submitted. Antigenic characterisations were undertaken by OFFLU contributing laboratories and subsequently there were updates to the WHO recommendations for the development of new candidate vaccine viruses for pandemic preparedness purposes.

OFFLU embarked on a project called avian influenza matching (AIM) to provide real time antigenic characteristics of circulating avian influenza viruses in different regions to support poultry vaccination. A preliminary pilot project has been taking place involving selected Reference Centres and OFFLU experts. In October 2023, the report was released presenting the results of this project to support stakeholders and countries in their decisions regarding vaccine selection and vaccine match.

The Biological Standards Commission, with the support of WOAH Reference Laboratories avian influenza experts, are reviewing the current *Terrestrial Manual* chapter on avian influenza for an in-depth revision with the aim for adoption in May 2025.

The implementation of the resolution framework on avian influenza (June 2023–May 2025) is progressing through a dedicated monitoring & evolution tool that collects, tracks, and evaluates the execution of activities on a quarterly basis aligned with the mandate outlined in Resolution No. 28 to combat avian influenza.

The development of the new GF-TADs HPAI strategy for 2024–2033 is ongoing and the draft strategy is set to undergo consultations and commenting process with different stakeholders including Members in March 2024 aiming for a launch in May 2024.

11.2. Update on rinderpest

The Commission was updated on the rinderpest post-eradication activities. WOAH continues to work in partnership with FAO to reduce the RVCM[11] holdings around the world, with the exception of diagnostic materials and vaccines as part of the 'second phase' of the post-eradication era. This effort will lead to a reduction in the number of FAO-WOAH designated RHFs[12] Category A, in addition to the reduction of RVCM held by WOAH Members in unauthorised institutes.

10 OFFLU: Joint WOAH-FAO Network of Expertise on Animal Influenza
11 RVCM: Rinderpest virus-containing materials
12 RHF: Rinderpest holding facilities

Unfortunately, there has not been any progress in the sequestration or destruction of RVCM in the five Members that hold these materials outside of FAO-WOAH designated RHFs, despite several in-person and virtual discussions having been held. With regards to preparedness, the Ethiopia National Veterinary Institute has been given exceptional permission to produce two million doses of RBOK vaccine to replenish the reserve at AU-PANVAC[13] after a thorough inspection and review of procedures. WOAH hosted a meeting on 25 October 2023 to review repository inspection SOPs together with representatives of the smallpox and polio secretariats and the EuFMD[14]. The outcome of the assessments from the 2022 RHF inspections were considered, and the recommendations from the meeting will be applied in the 2024 inspections.

The biennial meeting of the FAO-WOAH designated RHF Network took place in Paris 6–7 December 2023. The members of the network updated their terms of reference and drafted a work plan for the term 2024–2026. The members of the network highlighted the need for more frequent simulation exercises to test the Global Rinderpest Action Plan and the vaccine deployment mechanism. The RHFs also encouraged FAO and WOAH to foster closer cooperation with the PPR GREN[15].

The new members of the FAO-WOAH Joint Advisory Committee (JAC) for Rinderpest were invited in January 2024. The next meeting of the JAC will be held virtually in the second quarter of 2024 and be focused on the global reduction of RVCM, advocacy with outstanding countries, and emergency preparedness.

11.3. Update on Global Burden of Animal Diseases programme

2024 is a transition year for WOAH's role within the GBADs Programme. The programme continues to be in a scientific discovery phase and more time is needed to establish robust and systematic analytical methods. The expertise required at this stage is being filled by academic and research institutions of the GBADs consortium. Thus, WOAH has decided to reposition the organisation's involvement in GBADs and step back from its co-leadership and lead-grantee role. WOAH should continue assuming an advisory and steering role to contribute to evaluating GBADs' scientific robustness from a fit-for-purpose for WOAH Members perspective, and advise on the programme direction to ensure consistency and usefulness for WOAH Members policy needs. This change is not immediate, as WOAH would honour its role as lead grantee to active grants for their respective lifespan until the last grant closes (in 2025). Notwithstanding, as of May 2024, WOAH would withdraw from its role as co-leader of the GBADs consortium. Once the research-centred phases are complete and the methodologies have proven utility to WOAH Memberships and national Veterinary Services, WOAH may reconsider its engagement in GBADs: This may include facilitating GBADs sustainable rollout or institutionalisation by using GBADs methodologies to inform WOAH guidelines on animal health economics, potential WOAH standards, and training materials for Members.

11.4. Update on DIVA vaccines for peste des petits ruminants

The current PPR live-attenuated vaccines are safe, inexpensive and effective and provide long-lasting immunity following a single immunisation. However, these vaccines have drawbacks: first, they are thermolabile and thus expensive to deliver due to the cold chain requirement, secondly, the immune response is identical to natural infection, therefore it is not possible to differentiate infected from vaccinated animals. This is an important issue because serological surveys would lead to confusion in determining whether the virus has been eliminated by vaccination.

There are several technologies developed to achieve DIVA goals noting that recombinant and vector-based vaccines expressing viral subunits can provide an alternative to conventional vaccines, as they can easily be paired with DIVA diagnostic tools. This will be useful during the eradication phase of PPR to prove that previously PPR-free, but DIVA-vaccinated susceptible animal population is free from infection by employing DIVA tests.

Poxvirus vectored vaccines

Capripoxvirus-vectored vaccines have also been developed against PPR that act as dual vaccine to protect against both PPR and sheep and goat pox.

The capripox vectored vaccine has been described by Fakri *et al*. (2018), has been taken up by a commercial company in Africa and was identified as a candidate for production under the market name 'Combivax POX-PPR'. The vaccine was found to be relatively thermo-stable, though it did not elicit optimum antibody response probably because of the pre-existing immunity against vector.

The progress in the registration and production of the vaccine is not available yet.

13 AU-PANVAC: African Union Panafrican Veterinary Vaccine Centre
14 EuFMD: European Commission for the Control of Foot-and-Mouth Disease
15 PPR GREN: PPR Global Research and Expertise Network

Adenovirus vectored vaccine

Replication-deficient adenovirus 5 (Ad5) is considered a good recombinant vector for use in small ruminants because they lack any pre-existing immunity to this vector (Thacker *et al.,* 2009). Immunisation of goats with PPR Ad-H alone or Ad-F has been found to induce potent antibody and cell-mediated immune response though the combination of Ad-H and Ad-F induced better protection. Several reports have described Ad5 vectored PPR recombinant technology and the possibility of DIVA capabilities.

A commercial company in Africa has also identified the Adenovirus vectored PPR vaccine as a candidate for production under the market name 'Adeno-PPRH'. However, progress in registration and production is not available.

Newcastle disease virus vectored vaccine

Newcastle disease virus (NDV) vectored vaccine has been shown to protect against PPR and has DIVA-applicability and a high thermal tolerance.

A commercial company in Africa has also identified the Adenovirus vectored PPR vaccine as a candidate for production under the market name 'Combivax ND-PPR'. However, progress in registration and production is not available.

Bovine herpes vectored vaccines

Bovine herpesvirus-vectored vaccine delivering PPR virus haemagglutinin has been shown to induce both neutralising antibodies and cell-mediated responses16. The vaccine is reported as a DIVA candidate to protect against PPRV herd infection and is potentially applicable to eradication programmes.

There is no information on field trials, registration and production.

11.5. Update on VICH[16] activities: the 42th VICH Steering Committee and 16th Forum meeting took in Tokyo 13–16 November 2023

The Commission was informed about the 42nd VICH Steering Committee and 16th Forum meeting, which took place in Tokyo from 13 to 16 November 2023. It was highlighted that the VICH Steering Committee (SC) agreed to criteria for countries to progress along VICH membership categories as a consequence of restructuring of VICH. This effort was a continuation of work to modernise the organisation's structure and better align the VICH Forum with members' diverse expectations. In addition, Switzerland became a new observer member to VICH.

The Steering Committee also initiated two new activities related to:

(1) Global Regulatory Dossier Framework for Veterinary Medicinal Products; and
(2) Principles for technical guidance for the transition to in-vitro methods for batch potency tests of veterinary immunologicals.

The Biological Expert Working Group made progress regarding the 'Test on the Presence of Extraneous Viruses in veterinary vaccines'. The first draft of the Guideline has been prepared. The Guideline will be shared during the consultation phase with the Commission and WOAH Delegates and their respective Focal Points of Veterinary Products. The subgroup has finalised its tasks as three Guidelines (GL 50, 55 and 59) Harmonization of Criteria to Waive Animal Batch Safety Testing for implementation phase.

Training material was developed by JMAFF (Ministry of Agriculture, Forestry and Fisheries of Japan) and is available on the VICH website: https://www.vichsec.org/en/training.html on GL 50, 55 and 59).

GL 50: Harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use.
GL 55: Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use.
GL 59: Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use
https://www.vichsec.org/en/guidelines/biologicals/bio-safety/target-animal-batch-safety.html

11.6. Update on the virtual biobank project

The Commission was updated on the Virtual Biobank project. The project is managed by the WOAH Collaborating Centre for Veterinary Biological Biobank, hosted by the Istituto Zooprofilattico Sperimentale della Lombardia e

16 VICH is a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration. Its full title is the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

dell'Emilia Romagna (IZSLER), Italy, and WOAH. This project consists of a web-based catalogue of biological resources held in biobanks, representing a source of information to search, locate, and retrieve samples, especially diagnostic reagents and reference reagents, along with associated metadata.

After the project's reactivation in April 2023, the Collaborating Centre held monthly meetings with WOAH for its development. The Commission was informed that since the last meeting, functionalities of the system, such as catalogue search, cart management, and request panel, have been developed. The website is currently under development to add features like access to WOAH Standards, a news section, and multilingual capabilities.

The Commission was provided with a demonstration of the latest advancements in the web platform. During this presentation, it was emphasised that the system is not designed as a direct purchasing. Instead, its primary function is to offer a biological resources catalogue and serve as a facilitative intermediary, connecting laboratories possessing biological resources with potential buyers. This approach is intended to streamline the process of accessing these resources, ensuring efficient and effective communication between laboratories and interested parties.

The Commission congratulated the Collaborating Centre on the progress and development of the project. Nonetheless, they underscored the critical need to maintain high quality standards for both the supplier laboratories and the products offered. The Commission particularly stressed the significance of adhering to ISO 17025 quality standards for this system. Moreover, concerns were raised about the ongoing maintenance of WOAH Standards and the potential implications of WOAH's responsibility in relation to these products. The question of whether to restrict this system to Reference Centres was also raised in regard to ensuring the quality of the products in the biobank. The Commission decided to table this suggestion for further evaluation during the system's next presentation.

While the Commission is interested in the correct development of this system, the Commission members want to closely monitor it to ensure that it guarantees the quality of the laboratories, their products and the maintenance of WOAH Standards, while remaining sustainable.

11.7. WAHIAD[17] and WAHIS[18] Platform updates

The Commission was updated on the state of play and timeline of the development and evolutions of the platform in 2023, which included the optimisation of the early warning and 6-monthly report modules, and the development of the annual report module.

The Commission was informed that sessions were organised in 2023 with members of the commissions to demonstrate how to use WAHIS functionalities and to gather feedback on their needs. Similar sessions will follow in 2024 and the Commission was encouraged to take part in them. The Commission was briefed on the relevant updates of the WAHIS Reference Tables done in December 2023. The objective of this work was to align with the changes adopted in the Terrestrial and Aquatic Animal Health Codes and Manuals at the 2023 General Session. The Commission commended this work and agreed that good communication between the Secretariat and WAHIAD regarding the work that may result in changes to the Codes/Manuals that will need to be reflected in WAHIS behaviour or functionality will allow WAHIAD to advise of any limitations or constraints that may exist from a platform reporting perspective. Finally, the Commission was informed that WAHIAD will collaborate with Standards Department. This work will allow WAHIAD to actively participate in the standard-setting process by providing inputs to the relevant Commission. This collaborative work will start with the Terrestrial Animal Health Standards Commission, but the aim is to progressively extend it to the other Commissions.

11.8. PVS tool

The Commission was updated on the advancements of the development of the Performance of Veterinary Services Pathway Information System (PVS IS). The PVS IS caters to the direct stakeholders of the PVS Pathway, which include Delegates and National Focal Points, institutional partners and donors, as well as PVS Experts who provide expertise and conduct PVS missions upon the request of WOAH Members. Delegates and National Focal Points will have a wealth of data at their disposal via interactive visuals and graphics showing the strengths, weaknesses, and recommendations to decision-makers for more impactful investment case development for the Veterinary Services. The PVS IS aims to meet the evolving needs of Veterinary Services, to facilitate performance improvements by offering greater insight in addition to the narrative-based PVS Reports. Offering a complete documentation of the performance of the Veterinary Services, the PVS Report contains insights unlocked by WOAH so that governments, investors, and partners can access, use, and act upon their recommendations more easily.

The innovation behind the PVS IS unlocks the power of historical data and insight contained in PVS Reports. Focusing on the strengths, weaknesses, and recommendations for each PVS Critical Competency, WOAH has migrated all

17 WAHIAD: World Animal Health Information and Analysis Department
18 WAHIS: World Animal Health Information System

essential information to its database. This allows for a quick and systematic analysis of PVS trends. For the first time, WOAH is using natural language processing and machine learning. A key result of this novel approach is greater insight into the most common and persistent recommendations, strengths and weaknesses of the Veterinary Services across the globe. Members can access this analysis via interactive dashboards with major indicators updated in real time as new data becomes available. A soft launch will progressively unveil the Information System to WOAH's network – its staff, Members, PVS experts, partners, and donors – before culminating in its global launch in May 2024.

11.9. Update on the Grand Challenge for sustainable laboratories

For over 10 years WOAH has been working with Global Affairs Canada, UK's International Biosecurity Programme, Chatham House, and WHO to improve sustainability of labs (particularly in low resource settings). One stream of this work programme has focused on exploring the use of open innovation to find solutions to improve laboratory sustainability. Over the past year, WOAH has led a study (subcontracted to Grand Challenges Canada) to assess the feasibility of running an open innovation initiative. The final report was delivered in July 2023.

WOAH, GAC[19], and WHO could not run an open innovation initiative successfully on their own because they need additional resources (beyond what can be offered by existing investment partners); additional expertise (fund raising, private sector engagement, innovation specialists), and representation of the development and philanthropy sectors, and in November 2023, WOAH held a meeting at Wilton Park, UK to engage key stakeholders in a consortium to take forward an open innovation initiative to improve the sustainability of diagnostic laboratories.

Forty participants had been invited including potential investment partners, technical experts (laboratories and innovation). The meeting was a success and achieved its objectives: 1. The whole group agreed that laboratory sustainability was a problem that needed to be addressed. 2. A core group of high calibre representatives (from key sectors) showed strong interest and agreed to be part of a working group to develop a work plan to take forward the initiative, the workplan would include fund raising, advocacy, technical innovation. This group included the White House/USA (Maj. Gen. Paul Friedrichs); European Commission (Anne Sophie Lequarre); African Union (Aggrey Ambali); Global Health Security Fund (Andrew Nerlinger); Effective Giving (Joshua Monrad); Gates Foundation (David Blazes); Australian Government (Phoebe Readford) plus existing leaders (WOAH, UK, Canada, WHO).

Since then, WOAH has developed an elevator pitch and the initiative has been branded as BIO-PREVAIL, which stands for Biological Preparedness and Resilience through Evolution and Innovation of Laboratories.

The informal working group formed at the Wilton Park meeting will develop a work plan and governance structure; look for opportunities for engagement and advocacy, including the possibility of a side event at UN General Assembly

11.10. Biosafety Research Roadmap

After meeting regularly for 2 years the WOAH Technical Working Group delivered six scientific papers to support the implementation of evidence-based laboratory biological risk management[20]. Following peer review, the papers were published as open access in Applied Biosafety. One paper provides an overview of the project, five others provide a review of the evidence base to support commonly used biosafety measures for selected pathogens (*Bacillus anthracis, Brucella melitensis*, SARS-CoV-2, Mpox virus, avian influenza, *Mycobacterium tuberculosis, Shigella* spp., FMD virus)

The project has also delivered a 20-year review of laboratory accidents and laboratory escapes in human and animal health laboratories. The study itself and a commentary paper were published in *The Lancet Microbe* in December 2023[21]. The papers call for more transparency around laboratory accidents to support biological risk management, ultimately mitigate against future accidents, and for greater investment in biosafety professionals.

A joint WOAH, WHO and Chatham House workshop also developed a paper which was aimed at high level decision makers and funders. It has been published as a Chatham House paper[22].

19 GAC: Global Affairs Canada
20 https://www.liebertpub.com/doi/10.1089/apb.2022.0040
https://www.liebertpub.com/doi/10.1089/apb.2022.0042
https://www.liebertpub.com/doi/10.1089/apb.2022.0039
https://www.liebertpub.com/doi/10.1089/apb.2022.0045
https://www.liebertpub.com/doi/10.1089/apb.2022.0038
https://www.liebertpub.com/doi/10.1089/apb.2022.0046
21 https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(23)00288-4/fulltext
22 https://www.chathamhouse.org/laboratory-accidents-and-biocontainment-breaches/issues-need-be-addressed

The Biosafety Research Roadmap was also discussed at a side event at the 2024 Prince Mahidol Award Conference in Thailand during a panel discussion. This panel also discussed the need to manage risk all along the pathogen value chain including from sample collection all the way through to pathogen destruction or inactivation. Traditionally, biological risk management has focussed on certain critical control points along the pathogen value chain such as sample shipment or sample/pathogen manipulation in the laboratory. However, there is increasing recognition that biological risk management should be applied all along the chain. WOAH suggested that there may be gaps in WOAH standards (which focus on laboratories and shipment) and that there could be value in WOAH developing some standards to manage risks all along the pathogen value chain. The Commission agreed that this would be a good idea and that work could be initiated in this area.

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…/Annexes

Annex 1. Adopted Agenda

MEETING OF THE WOAH BIOLOGICAL STANDARDS COMMISSION

Paris, 5–9 February 2024

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1. Welcome
   - 1.1. Director General
   - 1.2. Deputy Director General, International Standards and Science
   - 1.3. Updates from the WOAH Headquarters
2. Adoption of Agenda
3. **Collaboration with other Commissions**
   - 3.1. Horizontal issues among the Specialist Commissions
     - 3.1.1. Review of case definitions: tularemia, infection with avian metapneumovirus (turkey rhinotracheitis)
   - 3.2. Scientific Commission for Animal Diseases
     - 3.1.1. Nothing for this meeting.
   - 3.3. Terrestrial Animal Health Standards Commission
     - 3.3.1. Updates from the September 2023 Code Commission meeting
     - 3.3.2. Biological Standards Commission's recommendations to the Terrestrial Animal Health Standards Commission
     - 3.3.3. Update from the Biological Standards Commission on the request from the Code regarding *Terrestrial Code* Chapter 6.10 Responsible and prudent use of antimicrobial agents in veterinary medicine
     - 3.3.4. Question on the chapter on bovine viral diarrhoea
     - 3.3.5. Framework for Terrestrial Code standards (disease-specific chapters)
   - 3.4. Aquatic Animal Health Standards Commission
     - 3.4.1. Nothing for this meeting.
4. Work Programme
5. Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
   - 5.1. Format of the report and commenting system
   - 5.2. Review of Member comments received on draft chapters and their endorsement for circulation for second-round comment and proposal for adoption in May 2024
   - 5.3. Fast-track revision of the chapter on avian influenza: Follow-up from the Animal Health Forum and the adopted Resolution on avian influenza
   - 5.4. Update on Chapter 2.3.1 The application of biotechnology to the development of vaccines for veterinary use
   - 5.5. Update on draft chapter on diagnostic validation of point-of-care tests for WOAH-listed viral diseases using field samples
   - 5.6. Follow-up from September 2023: conclusions and recommendations from the WOAH *Scientific and Technical Review* issue on diagnostic test validation science
     - 5.6.1. Progress on development of a validation report form for tests recommended in the *Terrestrial Manual*
     - 5.6.2. Progress on development of a template for a new *Terrestrial Manual* section on the rationale behind the selection of tests included in Table 1. *Test methods available and their purpose*
   - 5.7. Application of the criteria for keeping chapters in the *Terrestrial Manual* on non-listed diseases
   - 5.8. Review of advice submitted by experts of seven *Terrestrial Manual* chapters updated and circulated in October 2023 on whether the update had an impact on the corresponding chapter in the *Terrestrial Code*
   - 5.9. Update on the request from the Code Commission regarding Chapter 2.1.1 Laboratory methodologies for bacterial antimicrobial susceptibility testing
   - 5.10. Request to reconsider inclusion of foot and mouth disease virus-like particles in the WOAH *Terrestrial Manual*
   - 5.11. Follow-up from the General Session: proposal to include a vaccine in the chapter on American foulbrooD

5.12. *Terrestrial Manual* status: update on chapters selected for the 2024/2025 review cycle

5.13. Update on WOAH Standards Online Navigation Tool Project

6. WOAH Reference Centres

6.1. Update on the annual reporting system

6.2. Applications for WOAH Reference Centre status

6.3. Changes of experts at WOAH Reference Centres

6.4. Review of new and pending applications for laboratory twinning

Reference Laboratories – Implementation of the SOPs

6.5. Feedback from Laboratories that are not complying with the key ToR

6.6. Review the template for the curriculum vitae for nominations of replacement experts

Collaborating Centres – Implementation of the SOPs

6.7. Feedback from Centres that are not complying with the key ToR

6.8. Review the proposed procedure of how to evaluate Centres at the end of their 5-year mandate

6.9. Review ways to improve the output of Collaborating Centres for the benefit of WOAH and Members

Reference Centre networks

6.10. Update on the three Reference Laboratory networks (African swine fever, peste des petits ruminants and rabies)

6.11. Collaborating Centres and Reference Laboratories reporting system

7. *Ad hoc* Groups: Update on activities of past *ad hoc* Groups

7.1. *Ad hoc* Group on Replacement of the International Standard Bovine and avian Tuberculin (ISBT): update on the replacement ISBT and ISAT

7.2. *Ad hoc* Group on Alternative Strategies for the Control of *Mycobacterium tuberculosis* Complex (MTBC) Infection and Bovine Tuberculosis (BTB) Disease in Livestock Species

7.3. *Ad hoc* Group to Review *Terrestrial Code* Chapter 4.7. Collection and processing of bovine, small ruminant and porcine semen

7.4. *Ad hoc* Group on Emerging Diseases

8. International Standardisation/Harmonisation

8.1. WOAH Register of diagnostic kits: update and review of new or renewed applications

8.1.1. Addition of a new diagnostic kit to WOAH's register: Genelix™ ASFV Real-time PCR Detection kit

8.1.2. Addition of a new diagnostic kit to WOAH's register: Sentinel® ASFV Antibody Rapid Test)

8.1.3. Decision of the 5 year-Renewal and a Resolution's: Avian Influenza Antibody test kit (registration number 20080203) BioChek (UK) Ltd

8.1.4. Decision of the 5 year-Renewal and a Resolution's: Newcastle Disease Antibody test kit (CK116; re

8.2. Standardisation programme

8.2.1. Project to extend the list of WOAH approved reference reagents: review of guidelines

8.2.2. Association française de normalisation: follow-up from September 2023

9. Resolutions for the General Session

10. Conferences, Workshops, Meetings

10.1. Update on the WOAH seminar to be held during the WAVLD Symposium in Calgary, Canada in 2025

10.2. Vaccination and Surveillance for HPAI in poultry: Current situation and future perspectives; week of 21 October 2024 at WOAH Headquarters. A 2- to 3-day meeting, organised by IABS in partnership with WOAH

11. Matters of interest for consideration or information

11.1. Update on OFFLU

11.2. Update on rinderpest

11.3. Update on Global Burden of Animal Diseases programme

11.4 Update on DIVA[23] vaccines for peste des petits ruminants

[23] DIVA: Detection of infection in vaccinated animals

11.5. Update on VICH activities: the 42th VICH Steering Committee and 16th Forum meeting took in Tokyo 13–16 November 2023
11.6. Update: Health for Animals
11.7. Update on the virtual biobank project
11.8 WAHIAD and WAHIS Platform updates
11.9. PVS tool
11.10. Update on the Grand Challenge for sustainable laboratories
11.11. Biosafety Research Roadmap
11.12. Update on activities under the IHSC[24]-WOAH collaboration agreement and consultancy project in Asia (Horse related matters: Consultancy projects in Asia and South America)

24 IHSC: International Horse Sports Confederation

Annex 2. List of Participants

MEETING OF THE BIOLOGICAL STANDARDS COMMISSION

Paris, 5–9 February 2024

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MEMBERS OF THE COMMISSION

Prof. Emmanuel Couacy-Hymann
(President)
Professor of Virology
CNRA/LIRED
Abidjan
CÔTE D'IVOIRE

Prof. Ann Cullinane
(Vice-President)
Head of Virology Unit
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Naas
IRELAND

Dr John Pasick
(Vice-President)
Formerly National Centre for Foreign Animal Disease
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Dr Joseph S. O'Keefe
(Member)
Head of Animal Health Laboratory
Ministry for Primary Industries
Upper Hutt
NEW ZEALAND

Dr Satoko Kawaji
(Member)
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TRINIDAD AND TOBAGO

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WOAH HEADQUARTERS

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Head
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Ms Sara Linnane
Senior Scientific Officer
Science Department

Dr Gounalan Pavade
Senior Scientific Coordinator
Science Department

Dr Charmaine Chng
Deputy Head
Science Department

Dr Mariana Delgado
Scientific Secretariat Officer
Science Department

Annex 3. Work Programme for the WOAH Biological Standards Commission

MEETING OF THE BIOLOGICAL STANDARDS COMMISSION

Paris, 5–9 February 2024

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Subject	Issue	Status and Action
Updating the *Terrestrial Manual*	1) Circulate the chapters approved by the BSC to Members for second-round comment and proposal for adoption in May 2024	March 2024
	2) Remind authors of the chapters identified previously for update but not yet received and invite authors of chapters newly identified for update	On-going
	3) Upload, publicise and inform Reference Laboratories experts about the database of validation reports to be published on the WOAH Website for tests recommended in the *Terrestrial Manual*	On-going
	4) Include as appendices at the end of the disease-specific chapters, the tables explaining the scores given to the tests in Table 1 *Test methods available and their purpose*. Add links to the validation reports when available (point 3 above).	Accomplished
	5) Ask Reference Centres to provide links to suitable instructional videos to be added to the end of the disease-specific chapters. Videos to be reviewed by the Commission when the chapter is up for review	On-going
	6) Develop criteria for removing chapters for non-listed diseases and assess those chapters against the criteria	Accomplished
	7) Review new developments in diseases causing significant global impacts (e.g. avian influenza, African swine fever) and prioritise those chapters	On-going
	8) Start the process of addressing the request to have access to the previous versions and evolution of the *Terrestrial Manual* as done with the *Terrestrial Code*	On-going
Collaborating Centres	1) Implementation of the adopted SOPs:	
	a) Develop a template for the Collaborating Centres for the report of their assessment of their performance in the past 5-years to be compared with their initial 5-year work plan	Accomplished
	b) Send the 5-year working plan evaluation template to the appropriate Collaborating Centres	July 2024
	2) Evaluate the feedback from those Centres that completed 5 years and assess the current relevance of the scope of their activities for renewal	February 2025
	3) Increase visibility of current Centres: ask to submit maximum of 5 bullet points to be added to their website entry under the title “How can we help?”	For September 2024

Subject	Issue	Status and Action
	4) Explore mechanisms to improve collaboration by bringing together the Centres with the same main focus area (currently six): involvement of industry or other partners for fundings	On-going
	5) Develop a questionnaire to gather feedback from the Collaborating Centres on their experiences being a WOAH CC, similar to the one for the Reference Laboratories	September 2024
Reference Laboratories	1) Put under-performing laboratories on watch list and monitor their performance.	On-going
	2) Implement the new system for evaluating annual reports and provide list of assigned reports to Commission members	Accomplished
	3) Send feedback to the Reference Laboratory network on the questionnaire	Accomplished
	4) Explore enhancements to the annual report process: the possibility of filling in the annual report template throughout the year	May 2024
Reference Centre Networks	1) Follow up with the three Reference Laboratory networks (ASF, PPR and rabies)	On-going
Standardisation/ Harmonisation	1) Project to extend the list of WOAH-approved reference reagents	
	a) Ask the other networks if they accept the minimum standards document proposed by PPR network. Once finalised, upload the document for implementation	For September 2024
	2) Project to develop Replacement International Standard Bovine and Avian Tuberculin: finalise report and propose for adoption	On-going
***Ad hoc* Groups**	1) *Ad hoc* Group on Sustainable Laboratories	On-going
	2) Contribute on the review on the *Terrestrial Code* Chapter 4.7. Collection and processing of bovine, small ruminant and porcine semen	On-going
	3) Contribute to the *Ad hoc* Group on Emerging Diseases and Drivers of Disease Emergence in Animals	On-going
Projects	1) Veterinary Biobanking (project)	On-going
Conferences, Workshops and Meetings with participation by BSC Members	1) Biosafety research roadmap	Accomplished
	2) ISWAVLD WOAH Seminar, June 2025 in Canada: develop a theme and programme and speakers	September 2024
Performance	1) Engage with the ongoing processes around performance issues with Reference Laboratories	On-going
Develop laboratory standards for emerging diseases	1) Discuss the *Terrestrial Code* chapter once adopted and consider introducing a corresponding chapter for the *Terrestrial Manual*	After May 2024
Case definitions	1) Follow up the implementation of the SOPs for case definitions	On-going

Annex 17. Template for curriculum vitae for Reference Laboratory experts

MEETING OF THE BIOLOGICAL STANDARDS COMMISSION

Paris, 5–9 February 2024

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Surname		Forename(s)	
Email address		Telephone number	
Name of the Laboratory		Disease name	
Country of the Laboratory		Date of submission	

1. Degrees and qualifications, please provide details and year.

2. Relevant experience including posts held, with dates and responsibilities (demonstrating experience in laboratory diagnostics)

3. Information demonstrating international recognition of your expertise: appointments, awards, membership on committees and working groups (relevant to the disease for which you are applying for designation)

4. Publications in peer-reviewed journals and papers in press, related to the disease or pathogen for which you are applying for designation (*Please provide those publications that emphasise your expertise in the specific-disease: **bold** your name in the title of your publications and the pathogen in question*)

Number of publications as first author: *Number of publications as last author:* *Number of publications in other positions:* *Please provide the full list of publications in chronological order*