Report of the Meeting of the WOAH Biological Standards Commission

Original: English (EN)

5 to 9 September 2022
Paris

A meeting of the WOAH Biological Standards Commission (hereinafter called 'the Commission') was held from 5 to 9 September 2022 at the WOAH Headquarters in Paris, France. During the meeting, 16 *Terrestrial Manual* chapters were approved for circulation for first-round Member comment. Your participation in the WOAH Standard-setting process is valued. Thank you for your engagement in the process!

Chapters

The chapters can be downloaded from the following address:

http://web.oie.int/downld/Terr_Manual/MAILING_OCT_2022.zip

How to submit comments

Members are reminded that they should submit the rationale for all their proposed changes to the texts, and include references where relevant for the Commission to consult. The guidance should be followed when submitting comments:

1. Comments may be general or specific, but specific comments are more valuable. General comments should be such that some conclusion and action can be taken in response to them. For example, instead of stating "This test is no longer used in our laboratory", indicate the reasons the test is no longer used and what test is used instead.
2. Specific comments should be identified by indicating the line number in the text, to facilitate the editorial process.
3. Highlighting typing or technical errors is welcome, but the correct word or figure should be indicated in its place. For example, instead of indicating simply "0.8 M is too high", the preferred value should also be indicated.
4. Bear in mind that the introductory chapters (Part 1 of the *Terrestrial Manual*) set general standards for the management of veterinary diagnostic laboratories and vaccine facilities and are not intended to be exhaustive, and indeed none of the chapters can give a completely comprehensive cover of the subject, otherwise the *Terrestrial Manual* would be too long. However, assistance in indicating priorities is always helpful.
5. The *Terrestrial Manual* is intended for world-wide use. The chapters need to reflect the development of new technology, while maintaining the established methods, usually requiring less sophisticated apparatus. New technology should not be described in detail until it has gained wide acceptance as a reliable method.
6. We recommend that if you have no specific comments, please respond to the WOAH to that effect.
7. Any comments, proposed changes or revisions should be supported by clear evidence (the scientific rationale) such that some conclusion and action can be taken in response to them.

Deadline to comment

Comments on relevant texts in this report must reach the Headquarters by 16 December 2022 to be considered at the February 2023 meeting of the 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 Commission noted the dates for its next meeting: 6 to 10 February 2023

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1. Welcome from the directors

1.1. Director General

Dr Monique Eloit met with the Commission and thanked its members for their support and commitment to achieving WOAH objectives. She recognised the difficulty posed by 2 years of working remotely and thanked the Commission for its efforts and adaptability. She believes that momentum has now been developed and a balance between physical and virtual meetings has been found. Dr Eloit provided an update on the rebranding and how it will be progressively applied to the WOAH Standards.

1.2. Deputy Director General International Standards and Science

Dr Montserrat Arroyo, WOAH Deputy Director General, International Standards and Science, welcomed members of the Biological Standards Commission and thanked them for their ongoing contributions to the WOAH's work programme. Dr Arroyo commended the Commission for its ambitious agenda and extended her appreciation to the members' employing institutions and national governments.

Dr Arroyo briefed the Commission on the intent to host the 90th General Session as a physical meeting with a focus on reconnecting after the previous two virtual and hybrid General Sessions. She encouraged the members of the Commission to participate in regional webinars to present the September report of the Commission to Members. Dr Arroyo provided a summary of ongoing WOAH initiatives for digitalisation, including the development and planning for new digital tools and an update on the analysis of the online pilot commenting system.

Dr Arroyo updated the Commission on other WOAH activities such as the Research Coordination Network. She also explained that the WOAH Secretariats will be participating in different activities to enable enhanced coordination between the different Specialist Commissions and increase transversal work.

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

2. Adoption of the agenda

The proposed agenda was presented and adopted. Dr 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 Specialist Commissions

3.1.1. Update on the procedure for reviewing case definitions

The Commission commended the work of the WOAH staff and the experts who have been involved in the preparation of the case definitions to date. They noted the improved clarity in the process for managing the progression of the case definition from draft to its eventual incorporation in the *Terrestrial Code*, and discussed the steps to be followed by the Commission when conflicts between the *Terrestrial Manual* and the case definition endorsed by the Scientific Commission for Animal Diseases are identified.

3.1.2. Capturing genotype information in WAHIS[1]

WOAH Members have the obligation to report disease information through WAHIS, in accordance with Articles 1.1. of the Terrestrial and Aquatic Animal Health Codes. For each listed disease in WAHIS, WOAH can choose to activate or not an optional additional field called "serotype/subtype/genotype", therefore allowing Members to report information to this level of detail in a standardised way. There are currently 12 listed diseases for which this optional field is activated. From a technical point of view, the serotype/subtype/genotype optional field can be activated by WOAH for any listed disease in WAHIS. This has been already done in the past based on needs, but there has been no standardised approach to this decision. On the one hand, the collection of more detailed information is interesting for the international community. On the other hand, WOAH should not create unnecessary burden for reporting Members. WOAH is now assessing the need to activate the serotype/subtype/genotype optional field for other identified diseases in WAHIS, starting from January 2023. The Commission was asked if the "serotype/subtype/genotype" identification in affected Members is feasible for each disease considered in the assessment.

[1] WAHIS: World Animal Health Information System https://wahis.woah.org/#/home

The Biological Standards Commission considered genetic analysis to be an integral part of diagnosis. Indeed supporting WOAH to develop policies and standards for the use of diagnostic technologies, including HTS-BCG[2] was one of the recommendations from the Third Global Conference of WOAH Reference Centres, held in Korea (Rep. of) in 2014. In answer to the question, the Commission felt that the information is useful for all pathogens and would not limit it to some diseases as proposed. The Biological Standards Commission also agreed to integrate genetic analyses into the disease-specific chapters of the Terrestrial Manual.

3.2. Scientific Commission for Animal Diseases

3.2.1. Case definitions: infection with avian metapneumovirus (turkey rhinotracheitis) and infection with pathogenic rabbit lagoviruses (rabbit haemorrhagic disease)

The Biological Standards Commission jointly discussed the case definitions for infection with avian metapneumovirus (turkey rhinotracheitis) and infection with pathogenic rabbit lagoviruses (rabbit haemorrhagic disease) with the Scientific Commission for Animal Diseases (see agenda items 12.3.2.1 and 12.3.2.2 of the report of the meeting of the Scientific Commission for Animal Diseases, 19–23 February 2022).

One outcome of these discussions was the need to amend Terrestrial Manual Chapter 3.7.2 Rabbit haemorrhagic disease, in particular Table 1 Test methods available for the diagnosis of rabbit haemorrhagic disease and their purpose. The Reference Laboratory expert reviewed the chapter to remove any conflict between the proposed case definition and the Terrestrial Manual. The amended chapter will be included in the batch of chapters that will be sent for first-round comment in October 2022 (see agenda item 5.1).

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 February 2022 Code Commission meeting

The Biological Standards Commission was updated by the Secretariat on the current topics under review by the Code Commission to ensure complementarity and alignment of the two Commission's respective work plans. The first of what would be regular meetings between the Bureaus of both Commissions would be held virtually just after the meeting of the Biological Standards Commission. The purpose is to have a mechanism to ensure alignment of relevant items on the work programmes and agendas of both Commissions.

3.3.2. Question on draft Chapter 8.8. *Infection with foot and mouth disease virus*

At the meeting in February 2022, the Code Commission had sought the advice of the Biological Standards Commission on a number of technical issues in the draft *Terrestrial Code* chapter on Infection with foot and mouth disease. The Biological Standards Commission had in turn sought the advice of the WOAH Reference Laboratory experts on the issues in question. Following review of the Reference Laboratory experts' opinion, the Biological Standards Commission's advice is:

3.3.2.1. Article 8.8.1 General provisions, point 3:

The Biological Standards Commission agreed with the Reference Laboratory experts' feedback that the proposed texts by the Members does not address an inconsistency that exists with the corresponding text in the *Terrestrial Manual*. The *Terrestrial Code* chapter places greater emphasis on the isolation of FMDV to define the occurrence of infection with FMDV (i.e. an FMDV isolate is sufficient to confirm a case in the absence of clinical/epidemiological evidence), while detection of FMDV antigen or genome requires supporting clinical or epidemiological evidence.

In this regard, the Biological Standards Commission agreed with the alternative text proposed below by the Reference Laboratory experts, which attempts to harmonise the two WOAH standards (Code and Manual) and also clarifies that virus isolation requires confirmatory testing with an antigen or a nucleic acid detection test. Furthermore, this revised text provides wider context for the case definition of *infection* with FMDV where it is expected that animals should show clinical signs or have epidemiological connections to other FMD cases.

3) The following defines the occurrence of infection with FMDV in an animal listed in point 2 showing clinical signs consistent with FMD, or epidemiologically linked to a suspected or confirmed

[2] HTS-BCG/ high throughput genetic sequencing, bioinformatics and computational genomics (HTS-BCG)

outbreak of FMD, or giving cause for suspicion of previous association or contact with FMDV from which a sample has been tested:

a) viral antigen or viral ribonucleic acid specific to FMDV has been identified after direct testing of the sample or following virus isolation in cell culture

b) antibodies to structural (SP) or non-structural proteins (NSP) of FMDV, that are not a consequence of vaccination, have been detected

The Biological Standards Commission's view therefore is that the text proposed by the reference Laboratory experts provides greater clarity on the definition of *infection* with FMDV. The Biological Standards Commission however, does recognise that the circulation of subclinical infection with FMDV in endemic settings (particularly where vaccination is used) may blur this definition. As the epidemiological connections between subclinical cases can be difficult to identify, it may be appropriate that the text of the *Terrestrial Code* is further revised to clarify this point, otherwise there is a danger that FMDV circulation may not be correctly recorded or reported.

3.3.2.2. Article 8.8.11: Importation of vaccinated animals into a country or zone free from FMD where vaccination is not practised

The Biological Standards Commission agrees with the Member comment on point 3, that serological testing alone will be sufficient for non-vaccinated animals (i.e. the requirement to perform virological analyses can be removed from the text). However, for vaccinated animals, neither serological nor virological testing of samples collected from an individual animal at a single time point can exclude the possibility of infection with FMDV with a high level of confidence. Batch testing of larger numbers of vaccinated animals could improve sensitivity but this option is not possible for individual animals nor is specified in the *Terrestrial Code*. A pragmatic suggestion would be to retain the requirement for virology and serological (NSP) testing for this scenario, where virological (probang) testing could provide a modest increase in the confidence of the negative status of animals

Proposed alternative text

a) if not vaccinated were subjected to a virological and serological tests for FMD with negative results on samples collected not earlier than 14 days before the shipment;

b) if vaccinated were subjected to a virological (probang) and NSP serological tests for FMD with negative results on samples collected not earlier than 14 days before the shipment;

Finally, in reply to concerns raised by a Member regarding the reliability of laboratory tests to detect infection in vaccinated animals, the Commission agrees that it is not possible to guarantee that virological and NSP serological tests for FMD with negative results on individual animals are sufficient to assure the safe trade of vaccinated animals. Members must mitigate against these risks.

3.3.3. Question on draft Chapter 6.12 *Zoonoses transmissible from non-human primates*

The Biological Standards Commission's advice had been sought on comments received from two Members on Articles 6.12.4 and 6.12.6 of Chapter 6.12. *Zoonoses transmissible from non-human primates*.

In the tuberculosis section of the table in Article 6.12.4., a Member proposed to include serological tests and Ziehl–Neelsen staining in the column on [testing] methods. The Biological Standards Commission suggested the following changes:

Disease/agent	Animal groups	Schedule	Methods
Tuberculosis (*Mycobacterium tuberculosis* complex)	~~Marmosets and tamarins~~	~~Two tests at an interval of 2 to 4 weeks.~~	~~Skin test or serology. In-vitro gamma interferon assay or polymerase chain reaction (PCR) assay. The skin test using mammalian tuberculin (old tuberculin) is the most reliable of all. Skin tests in marmosets, tamarins or small prosimians should be performed in the abdominal skin rather than in the eyelid. In some species (e.g. orang utan), skin tests for tuberculosis are notorious for false positive results. Comparative tests using both mammalian and avian PPD, together with cultures, radiography, ELISA, in-vitro gamma interferon assay and PCR of gastric or bronchial lavage, faeces or tissues may eliminate confusion.~~
	All species ~~Prosimians, New World monkeys, Old World monkeys, gibbons and great apes~~	At least three tests at intervals of 2 to 4 weeks.	Skin test and complementary serological tests. In-vitro gamma interferon assay or polymerase chain reaction (PCR) assay. The skin test using mammalian tuberculin (old tuberculin) is the most reliable of all. Skin tests in marmosets, tamarins or small prosimians should be performed in the abdominal skin rather than in the eyelid. In some species (e.g. orangutan), skin tests for tuberculosis are notorious for false positive results. Comparative tests using both mammalian and avian PPD, together with cultures, Ziehl–Nelsen staining, radiography, ELISA, *in-vitro* gamma interferon assay and PCR of gastric or bronchial lavage, faeces or tissues may eliminate confusion.

In the tuberculosis section of the table in Article 6.12.6., the Commission agreed to include 'Two tests repeated at 2 – 4 weeks intervals' in the 'schedule' column.

Disease/agent	Animal groups	Schedule	Methods
Tuberculosis *(Mycobacterium tuberculosis* complex)	All species	~~One test.~~ Two tests repeated at 2–4 week intervals	Skin test or serology. *In-vitro* gamma interferon assay or polymerase chain reaction (PCR) assay. (See further comments in the Table of Article 6.12.4.)

3.3.4. Question on draft Chapter 11.4 *Bovine spongiform encephalopathy*

The Biological Standards Commission was requested to consider a Member's comment to use the terms 'PrP^{BSE}' and 'PrP^{TSE}' rather than 'PrP^{Sc}' in the *Terrestrial Code* and to subsequently use the same terminology in the *Terrestrial Manual*. The Biological Standards Commission agreed with the *ad hoc* Group on bovine spongiform encephalopathy, which advised that PrP^{BSE} of PrP^{TSE} are less commonly used terminologies and that despite proposals to modify the nomenclature in the prion field, PrP^{Sc} for abnormal PrP associated with prion replicative agents (regardless of the species) has remained the most largely admitted terminology. Therefore, the Biological Standards Commission disagreed with the comment to replace PrP^{Sc} with PrP^{BSE} or to change to PrP^{TSE}.

3.3.5. Questions on draft Chapter 12.7 *Infection with* Theileria equi *and* Babesia caballi (*equine piroplasmosis*)

The advice of the Biological Standards Commission was sought regarding a Member comment on draft Chapter 12.7 *Infection with* Theileria equi *and* Babesia caballi (*equine piroplasmosis*), Article 12.7.5 *Recommendations for the importation of equids*. A Member had disagreed with the requirement to present an international veterinary certificate attesting that the animals were subjected to a serological and agent identification test with molecular techniques for the detection of *T. equi* and *B. caballi*. The Member proposed removing the requirement for agent identification test and clarifying that the serological test be validated to international standards. The Biological Standards Commission reiterated that the requirement to use a combination of PCR[3] and serological tests was based on expert advice (confer Biological Standards

[3] PCR: polymerase chain reaction

Commission reports of the February 2020 and February 2021 meetings), and stressed that the use of PCR alone is not recommended. The Biological Standards Commission therefore did not support the proposal.

Regarding Table 1 *Test methods available for the diagnosis of equine piroplasmosis and their purpose* of the *Terrestrial Manual* Chapter 3.6.8 *Equine piropolasmosis,* the Member did not support the deletion of the CFT[4] from the list of recommended tests and requested that it be reinstated. The Biological Standards Commission stressed that the CFT had been proposed for deletion in September 2019 as it was no longer recommended to qualify horses for movement. The draft chapter was circulated three times for Member comment and adopted in May 2021. According to expert advice and current scientific knowledge the CFT is not sensitive and does not detect subclinically infected carriers so is not suitable for certifying animals for movement. The Commission would consider reinstating the test when the chapter is next updated should evidence of its suitability be submitted.

Additionally, in Article 12.7.5 *Recommendations for the importation of equids* of *Terrestrial Code* Chapter 12.7, a proposal had been received to add a new point iii) stating that horses have not been treated with antiparasitic drugs capable of masking an *infection* with *T. equi* and *B. caballi* for at least 6 months prior to sampling. The Biological Standards Commission agreed with this proposal as animals treated in this way could give false negative results.

3.4. Aquatic Animal Health Standards Commission

Nothing for this meeting.

4. Work Plan

The updated work plan 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 OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*).

5.1. Review of draft chapters received for endorsement for circulation for first round Member comment

The Commission reviewed 18 draft chapters and approved 15 for circulation, some subject to clarification of certain points by the experts, for first-round Member comment and eventual proposal for adoption by the Assembly in May 2023. The 15 chapters and a brief summary of the main amendments are provided below:

Glossary of terms: a definition of robustness was added as the term is used in updated chapter 1.1.6 on validation of diagnostic assays.

1.1.6 Principles and methods of validation of diagnostic assays for infectious diseases: added reference to POCTs[5] and virtual biobanks given their increasing use and importance; improved presentation of criteria for assay development and validation; added a table highlighting test purposes and relative importance of different performance parameters; updated Fig 1 to include extra field validation step for POCTs; further elaborated text on analytical specificity including providing examples; added definition of likelihood ratios; included elaboration on Bayesian latent class models and data management; included a summary table on challenges and opportunities for diagnostic test validation; added new sections on new technologies and conclusions.

1.1.10. Vaccine banks: updated the definition of a vaccine bank; revised and improved the section on types of banks stressing the need for compliance with the principles of GMP[6]; in the Section on *Selection of vaccines for a bank*, emphasised the need for cooperation between all players to ensure that newly emerging strains are rapidly identified and made available to manufacturers for evaluation as potential new vaccine seed strains, and the need for structured risk assessment to manage potential bioterrorism risks using FMD[7] as an example; thoroughly updated the sections on *Regulatory considerations, Storage of vaccines or antigens in a bank* and *Deployment planning,* for example by expanding the information on DIVA[8] vaccines.

4 CFT: complement fixation test
5 POCTs: point-of-care tests
6 GMP: Good Manufacturing Practice
7 FMD: foot and mouth disease
8 DIVA: differentiation of infected from vaccinated animals

3.1.1. Anthrax: updated the capsule visualisation (staining) method to include a new capsule stain that is quicker to make and thus more readily available and convenient.

3.1.5. Crimean–Congo haemorrhagic fever: removed all mention of intracerebral inoculation of suckling mice for animal welfare reasons; in Table 1. *Diagnostic test formats for Crimean-Congo haemorrhagic fever virus infections in animals*, amended the ratings for the agent identification tests for the purpose "confirmation of clinical cases in animals" and added footnotes to clarify the diagnostic use of the tests; in the Section on *Nucleic acid detection* updated the classification of the virus clades, added text emphasising that it is necessary to combine at least two molecular assays to ensure detection of the different CCHFV clades and added a table of corresponding recommended primer sequences, which replaces the sequences and cycling parameters currently given for a real-time RT-PCR[9]; in accordance with WOAH policy, deleted a Table of commercial kits available for the detection of CCHFV-specific antibodies or the detection of viral antigen; updated the references.

3.1.18 Rabies (infection with rabies virus and other lyssaviruses): added a sentence to Section A *Introduction* highlighting the cost of the virus in terms of human fatalities; deleted the antigen detection ELISA[10] from Table 1. *Test methods available for the diagnosis of rabies and their purpose* and replaced it with LFD/RICT[11] antigen detection tests, and changed "cell culture" to "RTCIT"[12] and amended its rating for the purpose "Population freedom from infection"; in Section B *Diagnostic techniques,* 1.1.1 *Collection of brain samples,* updated the method for sampling the brain by the occipital foramen route; in Section B.1.3 *Laboratory tests*, deleted the ELISA, renamed cell culture as rabies tissue culture test and added Rapid immunochromatographic tests (lateral flow devices); in Section C *Requirements for vaccines, General background*, added a paragraph mentioning rabies virus glycoprotein biotechnology-derived vector vaccines and the possible future availability of non-replication-competent constructs or replication-restricted rabies vaccine constructs, which may need additional safety considerations: the amendments to Section C were in response to a comment from a Member to incorporate RNA-based vaccines, including RNA particle vaccines, as an accepted technology for rabies prevention and control into the chapter.

3.1.19. Rift Valley fever (infection with Rift Valley fever virus): removed all mention of virus isolation in suckling mice for animal welfare reasons; in Section B *Diagnostic techniques*, updated the protocols for the agarose gel-based RT-PCR, the antigen ELISA, the plaque reduction neutralisation test, and added a pen-side rapid diagnostic test (lateral flow device) and a blocking IgG ELISA; in Section C *Requirements for vaccines, Background*, added MP-12 attenuated virus vaccine to Table 2. *Summary of the current RVF vaccine strains* and to the text, and deleted TSI–GSD–200 inactivated human vaccine as it is presently not available.

3.1.22. Trichinellosis (infection with *Trichinella s*pp): re-ordered the preferred samples to be taken to maximise test sensitivity; updated the taxonomy of the genus *Trichinella*; deleted antigen detection from Table 1 *Test methods available for detecting* Trichinella *infections in pigs and their purpose* as it is not fit for any of the purposes, and added two footnotes to the Table to clarify which tests can be used in combination as confirmatory tests; in Section B. *Diagnostic techniques*, updated the digestion and detection methods, and added three new direct detection methods: *mechanically assisted pooled sample digestion method/'on filter isolation' technique*, *magnetic stirrer method for pooled sample digestion/'on filter isolation' and larva detection by a latex agglutination test* and *artificial digestion commercial test kit for in-vitro detection of* Trichinella *spp. larvae in meat samples*; updated the references.

3.2.2. American foulbrood of honey bees (infection of honey bees with *Paenibacillus larvae*): updated the text throughout to take account of the new genotype (ERIC V) including adding it to Table 2. *Phenotypic characteristics of* Paenibacillus larvae *ERIC genotypes*; stressed that whole genome sequencing showed a good correlation with conventional typing methods and was used efficiently for cluster delineation in American foulbrood outbreak epidemiological investigations; added explanatory text on real-time PCRs; reviewed and updated the references.

3.2.3. European foulbrood of honey bees (infection of honey bees with *Melissococcus plutonius*): updated the text to include information on atypical strains, thoroughly updated the section on *Epizootiology and clinical signs*; updated the section on culture methods; added explanatory text on real-time PCRs; updated the references.

3.3.10. Fowlpox: thoroughly updated Table 1. *Test methods available for diagnosis of fowl pox and their purpose:* added [conventional] PCR and separated it from RT-PCR, replaced IFAT[13] with VN[14] added a new test –

[9] RT-PCR: reverse transcription PCR
[10] ELISA: enzyme-linked immunosorbent assay
[11] LFD/RICT: lateral flow devices/rapid immunochromatographic antigen detection tests
[12] RTCIT: rabies tissue culture test
[13] IFAT: indirect fluorescent antibody test
[14] VN: virus neutralisation

MIFI[15], and changed the rating of all the tests in the Table except AGID[16]; updated the molecular methods including the primer sequences; deleted passive haemagglutination, fluorescent antibody tests, immunoperoxidase and immunoblotting methods as they are no longer used; mentioned the availability of recombinant fowlpox vaccines; updated the references.

3.3.13. Marek's disease: in Section A Introduction, added new sections on the Nature and classification of the pathogen, Zoonotic potential and biosafety and biosecurity requirements and Differential diagnosis; amended the rating of the PCR for the purpose "confirmation of clinical cases" in Table 2 Test methods available for the diagnosis of Marek's disease and their purpose and added the LAMP[17] method; in Section B Diagnostic methods, updated the antigen detection section by adding information on immunolabelling techniques, and updated the molecular methods, including the primer and probe sequences; revised Section C Requirements for vaccines and added new sections on Validation as a vaccine strain, Manufacturing process, Vaccines permitting a DIVA strategy, Duration of immunity and Special requirements for recombinant vaccines, updated the references.

3.4.12. Lumpy skin disease: in Section A *Introduction* added a paragraph on the findings of phylogenetic analysis of LSDV strains – that the majority of LSDV strains group into two monophyletic clusters – and that recently recombinant LSDV strains have been isolated from clinical cases of LSD in the field, which show unique patterns of accessory gene alleles consisting of sections of both wild-type and "vaccine" LSDV strains; updated the PCR section to include information on quantitative real-time PCR assays that have been designed to differentiate between vaccines and wild-type strains and the limitation of these assays. Section C *Requirements for vaccines* is currently under review in the 2023/2024 revision cycle.

3.6.11. Glanders and melioidosis: updated the information in the *Summary* on the description and importance of the disease; amended the following ratings in Table 1. *Test methods available for the diagnosis of glanders and their purpose:* PCR and CFT for the purpose "confirmation of clinical cases in animals", the ELISA for all purposes and clarified that some ELISAs have not been validated in mules and donkeys; included information on a novel selective agar that can isolate *B. mallei* from horse specimens; added a PCR assay for *B. pseudomallei* detection; in Section B.3 *Serological tests* confirmed that *Burkholderia pseudomallei* and *B. mallei* cross react and cannot be differentiated by serology; added information on a commercial recombinant double antigen-based ELISA for the detection of antibodies for *B. mallei,* which is a suitable confirmatory test and an alternative for serological testing of horses for trade or movement; mentioned a new competitive ELISA for *B. mallei* infection based on a monoclonal antibody against the lipopolysaccharide of *B. mallei;* clarified that the immunoblot assay is a suitable confirmatory test preferably for individual samples.

3.9.7. Influenza A virus of swine: updated Section A *Introduction* to include information on the classification of the H1 virus into clades; in Table 1. *Test methods available for diagnosis of swIAV-s and their purpose* amended the rating of virus isolation for the purposes "Individual animal freedom from infection prior to movement" and "Prevalence of infection – surveillance", the real-time RT-PCR for the purpose "Prevalence of infection – surveillance", and the ELISA for the purposes "Contribute to eradication policies" and "Immune status in individual animals or populations post-vaccination"; thoroughly updated most of the protocols in Section B *Diagnostic techniques,* in particular the RT-PCR, and included a new section on gene sequencing; in Section C Requirements for vaccines, expanded the text on the rationale and intended use of the product; updated the references.

3.10.1. Bunyaviral diseases of animals (excluding RVF fever and Crimean–Congo haemorrhagic fever): included three completed examples of Table 1 *Test methods available for the diagnosis of* [*pathogenic agent*] *and their purpose*: Table 1.2. for Akabane virus, Table 1.3. for Schmallenberg virus and Table 1.4. for Nairobi sheep disease (Table 1.1. for of Cache Valley virus is in preparation); added real-time RT-PCR protocols for Schmallenberg virus and Nairobi sheep disease; for Nairobi sheep disease amended the description of virus isolation and added a protocol for VN in cell culture.

The batch of draft chapters will also include the chapter on rabbit haemorrhagic disease (see agenda item 3.2).

The chapters are available on the Delegates website and on the website of the Biological Standards Commission. They can be downloaded from the following address:

http://web.oie.int/downld/Terr_Manual/MAILING_OCT_2022.zip

[15] MIFI: multiplex fluorometric bead-based immunoassay
[16] AGID: agar gel immunodiffusion
[17] LAMP: Loop-mediated isothermal amplification

5.2. Follow-up from September 2021

Conclusion and recommendations from the WOAH Scientific and Technical Review issue on diagnostic test validation science.

5.2.1. Discussion on updated chapter 1.1.6. Principles and methods of validation of diagnostic assays for infectious diseases

See also agenda item 5.1.

Considering the increasing use and importance of POCTs in the diagnosis of animal diseases, the Commission recommended including coverage of POCTs in Chapter 1.1.6. The Commission noted that POCTs are often used in the field on a range of sample types, under varying environmental conditions, with varying operator proficiency. Therefore, it concurred that additional steps should be applied to the validation of POCTs and the proposal from Halpin *et al* 2021 to include an extra step for field validation in Figure 1 *The assay development and validation pathways with assay validation criteria highlighted in bold typescript within shadowed boxes*. Going forward, the Commission also proposed to include a section in the disease-specific chapters of the *Terrestrial Manual* to describe the use of POCTs where they exist.

5.2.2. Progress on development of a template of the validation data requested for addition to a future online list of validated tests: results of the pilot scheme to test the template's suitability

At the meeting in September 2021, the Commission had developed a template for the validation data that would be requested of applicants wishing to add their test to a future online list of WOAH validated tests. As a first step in a pilot scheme to test the template's suitability and usability, the document was shared with selected WOAH Reference Laboratories to complete and to provide their feedback. The Commission thanked the Reference Laboratories that participated in this pilot scheme.

After considering the replies received, the Commission agreed first to simplify the template to facilitate user entry. The exercise called into question the original purpose of the project: to produce a future online list of WOAH validated tests. Regarding its role in designating tests as 'WOAH-validated', the Commission expressed reservation with having to retrospectively validate diagnostic tests as fit-for-purpose, given that the majority of these tests are already described in the *Terrestrial Manual* and are being used by Members for the identified purposes. The Commission agreed that the template could be better used as a 'validation report' form for tests recommended in the *Terrestrial Manual*. Reference Laboratories would be invited to fill in the 'validation report' form, which would be made available in a repository on the website for anyone seeking the validation data available for the test.

Regarding proposals for new tests to be added to the *Terrestrial Manual*, the Commission agreed that the template could also be used for this purpose. The Commission agreed to further simplify the template in line with the comments received. The streamlined template would then be circulated to the participating WOAH Reference Laboratories for further feedback on its utility.

Finally, the Commission also noted that additional test methods had been proposed for inclusion in the *Terrestrial Manual* chapter on lumpy skin disease (LSD). The WOAH Secretariat was requested to seek the inputs of the Reference Laboratories for LSD on these proposals.

5.2.3. Discussion on inclusion of molecular epidemiology in the *Terrestrial Manual*

The Commission discussed the proposal to gradually include molecular epidemiological information in the *Terrestrial Manual* chapters. Molecular methods are increasingly being used to diagnose infectious diseases in humans and animals. With advances in science, many public and animal health laboratories are routinely involved in characterisation of pathogens for diagnostic procedures. The Commission agreed to start including molecular characterisation information rather than molecular epidemiology in the *Terrestrial Manual* chapters as each disease chapter is revised.

5.3. Request to include foot and mouth disease virus-like particles in the *Terrestrial Manual*

A group of researchers that had developed a novel FMD vaccine based on recombinantly expressed virus-like particles (VLP) requested that VLP vaccines be included in the Terrestrial Manual. The Commission, in consultation with the WOAH Reference Laboratories for FMD, concluded that it is too early for such an addition to the Terrestrial Manual, which does not include vaccines not yet in use. The first VLP vaccines are expected to receive market authorisation within the next 5 years and the Commission will review the topic once the vaccines are available.

5.4. Update on the development of guidelines on the manufacture of safe vaccines for African swine fever.

The Commission was informed that under a Cooperative Agreement between the USDA-ARS[18] and WOAH, a consultant has been engaged to facilitate a subject-matter expert consultation to enable the creation of internationally acceptable guidelines for the manufacturing and development of safe and effective African swine fever (ASF) vaccines. Through undertaking a literature review, surveying key laboratories involved in Research and Development for ASF vaccines and exchanging with experts at the scientific meeting of the Global African Swine Fever Research Alliance (GARA), the consultant has produced a draft review paper on current approaches in ASF vaccine development, and draft guidelines on the manufacture of vaccines including key vaccine performance and quality criteria, with the view that the guidelines could serve as a precursor for the development of standards on ASF vaccines in the *Terrestrial Manual*. The Commission also noted that there were plans to conduct further consultations on the guidelines, including consulting with representatives from the scientific community and the regulatory authorities. A representative from the Commission was nominated to follow the discussions and participate in the consultations. Meanwhile, the Commission will also provide its feedback on the draft review paper and guidelines.

5.5. Chapter 1.1.2. *Collection, submission and storage of diagnostic specimens:* proposal to develop a separate section for wildlife

The Collaborating Centre for Research, Diagnosis and Surveillance of Wildlife Pathogens was asked if an expert in wildlife disease diagnosis could review the chapter on collection, submission and storage of diagnostic specimens and determine if it is missing important information of relevance to wildlife specimens. The expert concluded that procedures are sufficiently different to warrant the creation of a separate section for wildlife. The Commission agreed to this proposal and the expert would be asked to draft the new section.

5.6. *Terrestrial Manual* status: update on chapters selected for the 2023/2024 review cycle

The Commission examined the status of chapters that had previously been identified for update in the 2022/2023 review cycle but had not been received. As there are 34 chapters on the list, the Commission did not add the remaining chapters last adopted in 2018. The Commission would like to encourage those Reference Laboratories with outstanding chapters to try to deliver by the deadline. The following chapters have been identified for update in 2023/2024 (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)

1.1.5. Quality management in veterinary testing laboratories (2017)

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

1.1.9. Tests for sterility and freedom from contamination of biological materials intended for veterinary use (2017)

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

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)

2.2.4 Measurement uncertainty (2014)

2.2.5 Statistical approaches to validation (2014)

2.2.6 Selection and use of reference samples and panels (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)

2.3.1. The application of biotechnology to the development of veterinary vaccines (2010)

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)

[18] USDA-ARS: United States Department of Agriculture-Agriculture Research Service

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

3.2.4. Nosemosis of honey bees (2013)

3.3.6 Avian tuberculosis (2014)

3.3.8. Duck virus hepatitis

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

3.4.1. Bovine anaplasmosis (2015)

3.4.7. Bovine viral diarrhoea (2015)

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)

3.6.10. Equine viral arteritis (2013)

3.6.9. Equine rhinopneumonitis (infection with equid herpesvirus-1 and -4) (2017)

3.8.1. Border disease (2017)

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

3.8.12. Sheep pox and goat pox (2017)

3.9.9. Teschovirus encephalomyelitis (2017)

3.9.10. Transmissible gastroenteritis (2008)

3.10.4. Infection with *Campylobacter jejuni* and *C. coli* (2017)

3.10.8. Toxoplasmosis (2017)

3.10.9. Verocytotoxogenic *Escherichia coli* (2008)

6. WOAH Reference Centres

In the past, WOAH organised an international conference of all Reference Laboratories and Collaborating Centres to discuss issues of relevance but also to improve communication in the network by uniting all the experts in one place. The last such conference took place in 2014, and there is currently no plan to organise another one. With this in mind and given that the network comprises an important group of stakeholders who belong to a large group but may not feel fully connected, the Commission is interested in hearing from the experts on their experience of being a WOAH Reference Centre. A member of the Commission will develop a questionnaire, to be reviewed at the next meeting in February 2023. Once finalised it will be sent to all members of the network and the replies analysed at the September 2023 meeting.

6.1. Applications for WOAH Reference Centre status

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

WOAH *Collaborating Centre for Day-One Veterinary Competencies in the Middle East*
Faculty of Veterinary Medicine, Cairo University, El-Shaheed Gamal El-Deen Afify, Oula, Giza District, Giza Governorate, EGYPT
Tel.: (+20-2) 35.72.03.99
E-mail: vet.dean@cu.edu.eg / imanshaheed@cu.edu.eg
Website: https://vet.cu.edu.eg/new-web/Home/index.php
Contact Point: Prof. Iman Bakr Mohammed.

WOAH *Collaborating Centre for Animal Reproductive Health in the Middle East*
Animal Reproduction Research Institute (ARRI), 5 Hadaek Elbehoth st, Alharam, Giza, EGYPT
Tel.: (+20-2) 376.43.25
E-mail: arc_arri@yahoo.com Website: http://arri-egy.com
Contact Point: Prof. Inas Mohamed Gamal.

WOAH *Collaborating Centre for* Wildlife Health Risk Management
Wildlife Health Australia (WHA), Cammeraigal/Dharawal Country, Suite F, 32 Suakin Drive, Mosman, New South Wales 2088, AUSTRALIA
Tel.: (+61-2) 99.60.63.33

E-mail: admin@wildlifehealthaustralia.com.au Website: www.wildlifehealthaustralia.com.au
Contact Point: Dr Steve Unwin.

WOAH *Collaborating Centre for Quality Control of Veterinary Vaccines in the Middle East*
The Central Laboratory for Evaluation of Veterinary Biologics (CLEVB), El-Seka El-Baida St, Abbasia, 11381 Cairo, EGYPT
Tel.: (+20-2) 23.42.92.04
E-mail: support@clevb.gov.eg Website: http://www.arc.sci.eg
Contact Point: Prof. Hanan Ali Ahmed.

WOAH *Collaborating Centre for Safety of Animal Feed in the Middle East*
Regional Center for Food and Feed (RCFF), Agricultural Research Center, 9 El Gamaa St., Giza, Cairo, EGYPT
Tel.: (+20-2) 35.71.11.62
E-mail: rcff@intouch.com Website: www.rcff.com.eg
Contact Point: Prof. Gihan Mohamed El Moghazy.

WOAH *Collaborating Centre for Residue Analysis of Pesticides and Heavy Metals in Food in the Middle East*
Central Laboratory of Residue Analysis of Pesticides and Heavy Metals in Food (QCAP) 7 Nadi El-said St, Dokki, 12311 Giza, EGYPT
Tel.: (+20-2) 37.61.13.55
E-mail: info@qcap-egypt.com Website: https://www.qcap-egypt.com
Contact Point: Prof. Hend Mahmoud Abd-Allah.

Following the meeting and in accordance with protocol, the applications were presented to the WOAH Council. Regarding the last application for a WOAH Collaborating Centre for Residue Analysis of Pesticides and Heavy Metals in Food in the Middle East, the Council expressed the view that the scope of the proposed Centre is outside the remit of the WOAH. Therefore the application will not be taken any further.

An application had been received for a Reference Laboratory for mammalian tuberculosis. This Commission was fully satisfied with the quality and scientific excellence of the applicant institution and the services it could provide to WOAH Members. However, the Commission questioned the choice of designated expert and would seek clarification of the nominee's experience in diagnosis and research, and role in the laboratory. The Commission would review any supplementary information provided at the meeting in February before making a final decision on the application.

Finally an application had been received for a Collaborating Centre for Emerging Infectious Disease Risks at the Socio-Agroecosystem Interfaces in a Context of Global Change and Biodiversity Loss. The Commission found that the application lacked clarity: the applicant, which is a large, highly regarded institution of international repute, described its many and varied activities but not what it proposes to do as a WOAH Collaborating Centre. The applicant would be asked to re-draft the application so that it is more focused and precise. The Commission asks that the applicant also review the proposed title to clarify its area of activity.

The Commission noted that there is no longer a WOAH Reference Laboratory for West Nile fever in the Americas though it is an important disease in this region. The Commission would welcome applications from suitable candidates.

6.2. Changes of experts at WOAH Reference Centres

The Delegate of the Member concerned had submitted to WOAH the following nomination for a change of expert at a WOAH Reference Laboratory. The Commission recommended its acceptance:

Peste des petits ruminants and rinderpest Dr Arnaud Bataille **to replace** Dr Geneviève Libeau **at the** CIRAD-Département Systèmes Biologiques UPR Groupe Virologie, Campus International de Baillarguet, Montpellier, FRANCE

6.3. Review of new and pending applications for laboratory twinning

As of September 2022, 70 projects have been completed and 32 projects are underway. Of the completed projects, 11 Reference Laboratories and four Collaborating Centres have achieved WOAH designation status.

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

1. ***Germany – Kyrgyzstan*** for brucellosis: the Commission requested that the technical proposal be revised to provide more detail on previous collaboration between the institutes, the techniques covered in the trainings, and the beneficiaries of the twinning.
2. ***South Africa – China*** **(*People's Rep. of*)** for lumpy skin disease: the Commission asked that the technical proposal be revised to provide more detail on the objectives and suggested that the project partners meet in person to discuss the activities in detail.
3. ***United Kingdom – China*** **(*People's Rep. of*)** for bovine tuberculosis: the Commission requested that the technical proposal be revised to provide more detail on the techniques covered in the trainings and the beneficiaries of the twinning
4. ***United Kingdom – Kenya*** for FMD: the Commission supported the technical contents of this project proposal.
5. ***United Kingdom – Oman*** for avian influenza and Newcastle disease: the Commission supported the technical contents of this project proposal.
6. ***United Kingdom – India*** for IBR: the Commission supported the technical contents of this project proposal and noted that the distance training methodology should be closely monitored by WOAH in order to inform decisions on the use of this approach in future projects.

6.4. Follow-up February 2022: inconsistencies among WOAH Reference Laboratories in results obtained using the RT-PCR for African horse sickness

In reply to the Commission's recommendations and further follow-up activities following the February meeting, the WOAH Reference Laboratories had submitted responses to the Commission's questions, a table of data sets with results, presentations, scientific evidence, and further information needed to solve this issue.

The Commission reviewed the submitted responses and suggested two actions for follow up by the Secretariat.

1. The Commission asked the Reference Laboratories to identify the Member and laboratory that tested the horses prior to entry to a quarantine station located in another Member so as to be able to engage in future discussions and action plans to avoid discrepancy between laboratory results. As the Reference Laboratory did not have this information, the Commission asked WOAH to contact the Member with the request that the quarantine station identify the laboratory that undertook the testing so that a copy of the report can be submitted to the Commission.

2. A non-WOAH laboratory had reported that there are inconsistencies in the results obtained between the two RT-PCR methods for African horse sickness that are described in the *Terrestrial Manual* and suggested one of the RT-PCR test procedure needs modification (and further validation) to detect virus variants. The Commission asked that the laboratory expert be contacted and requested to share relevant strains or clinical material with a WOAH Reference Laboratory so that the results can be cross checked to confirm this finding.

6.5. Reference laboratories – implementation of the SOPs

6.5.1. Follow-up from February 2022

The Commission reviewed the feedback received from one Reference Laboratory that was not complying with the key performance criteria according to its 2018 annual report. At the last meeting in February 2022, the Commission asked the laboratory to submit an official letter requesting that their WOAH Reference Laboratory designation be voluntarily revoked in accordance with Article 9 of the Internal rules for WOAH Reference Centres. The Delegate replied explaining the importance of maintaining the Reference Laboratory's designation for the benefit of the region, and the associated challenges encountered with availability and acquisition of samples as the country is free of the disease. The Delegate requested that the status be retained and gave assurances that steps would be taken to improve the laboratory activities. The Commission accepted this request: the Reference Laboratory would be asked to submit evidence of current activity to improve diagnostic and research activities for review at the next meeting in February 2023, including efforts to improve submission of samples from countries in the region.

6.5.2. In-depth review of all annual reports for activities 2021

The Commission reviewed the performance of all the WOAH Reference Laboratories by an in-depth analysis of the annual reports submitted in 2021 to ensure that each laboratory is fulfilling the Terms of Reference (ToRs) to the benefit of WOAH Members and performance criterion iii) of the *Procedures for Designation of WOAH Reference Laboratories* (the SOPs).

The Commission identified 11 Reference Laboratories that were not complying with the key ToRs. The Reference Laboratories concerned would be informed of the outcome of the review and asked to provide feedback and an explanation of their situation and possible reasons for the lack of activity; the Delegate will be in copy of all correspondence. The Commission also identified 32 Reference Laboratories that have low level of activities and placed them on a watch list for follow-up review in the next annual report review process.

A small number of the Reference Laboratories did not perform any diagnostic testing but were performing well in other activities in the ToRs. The Commission reviewed the special arrangements operating in these laboratories and considered that they were performing satisfactorily.

Seven Reference Laboratories did not have a designated expert in 2021, but had submitted an annual report. Since then three replacement expert nominations had been accept. The remaining four laboratories will be asked to submit a nomination for a replacement expert for evaluation at the next February meeting.

One Laboratory reported that it did not maintain a biorisk management system and risk assessment for activities, and some other laboratories mentioned that they are not accredited to ISO 17025 or equivalent quality management system. These laboratories will be asked to clarify their situation.

6.6. Collaborating Centres – implementation of the SOPs

6.6.1. Follow-up from September 2021

As a follow up from previous meeting, the Commission reviewed the feedback received from two Collaborating Centres on their 5-year work plans.

One Centre was asked to fill in a detailed work plan for each of the ToRs. The Commission reviewed the re-submitted work plan and approved it. The Centre will be asked to include an authorisation signature as one is missing in the document.

The Commission also approved the late submission of a 5-year work plan from one Centre. The Commission expected the Centre to improve its performance as detailed in the submitted plan.

6.6.2. In-depth review of all annual reports for activities in 2021

As for the Reference Laboratories, the Commission also undertook an in-depth analysis of all the annual reports of the Collaborating Centres submitted in 2021 to ensure fulfilment of the ToRs.

The Commission noted that most of the Centres were complying with the performance criteria. Three Centres that have a low level of activities were placed in a watch list for follow up review at the next annual report review process.

6.7. Reference Centre networks

6.7.1. Review of annual report template

The Commission reviewed the annual report template currently used by the Reference Centres with the aim of improving the questions asked so as to receive clearer responses and improve the quality of the data collected. To assist with the annual performance evaluation, the Commission identified those activities that are essential for Reference Laboratories and those that are not essential but recommended: by “weighting” the questions in the template, the Commission will more fairly grade the annual reports, which is important for their analyses.

The main amendments to the annual report template included:

- Collection of specific information on meetings attended by designated expert that are specific to the disease;
- Added the option ‘Not applicable’ rather than ‘No’ to the question on the production and of supply vaccines;
- Request for information on the publication source for validated diagnostic methods;
- Request the type of diagnostic tests used while carrying out testing for other WOAH Members;

- Added a new question on sharing any research needs relevant for WOAH while exercising their activities;

- For the question on conferences attended and articles published, clarifying that details should be provided rather than just the number in each category;

- Collection of more details on scientific and technical training provided to other laboratories;

- Details of measures taken to manage biorisks and reasons if there are none;

- Details on proficiency testing organised or in which the Reference Laboratory participated;

- Details on development of any procedure to facilitate harmonisation of international regulations applicable to the main focus are for which the Centre is designated;

- Achievements in the past year to advance the Centre in its main focus area.

6.7.2. Update on the three Reference Laboratory networks (rabies, peste des petits ruminants and ASF)

The WOAH ASF Reference Laboratory network held regular virtual meetings to exchange scientific and technical expertise, including recent developments regarding ASF vaccines, and discussed activities in developing training programmes to assist at-risk countries, including the organisation of proficiency tests. The network is working on a laboratory manual including diagnostic algorithms to detect low virulent and novel emergent variants, and exploring user requirements on an open-access information sharing platform for ASFV genome sequence data. In addition, the first laboratory expert network meeting on ASF for the Asia and the Pacific region is being planned for later this year: the meeting will be in person.

The WOAH PPR[19] Reference Laboratory network released its first newsletter summarising the activities since its launch in November 2020. Two new laboratories joined the network. The network, which has developed its own website (https://www.ppr-labs-oie-network.org/), disseminated information on its activities including diagnostic protocols, available reagents, proficiency testing, capacity building and training materials. The network is planning to conduct its next workshop involving many national laboratories in December 2022. The network is working to collect pictures and videos showing the variability of PPR signs across regions impacted by the disease for the benefit of laboratories in PPR-free countries to better prepared in the field.

The WOAH Rabies Reference Laboratory Network is supporting the International Atomic Energy Agency to produce anti-rabies reference serum, and is developing guidelines for countries on appropriate use of this serum to calibrate in-house standards. The network reviewed WOAH Member comments to the proposed amendments of the *Terrestrial Code* Chapter 8.14, on the provisions for importation of dogs from countries or zones infected with rabies virus, and provided a scientific rationale in response to Member comments. The network provided draft text for the inclusion of LFDs in the *Terrestrial Manual*, noting that these tests are available for use, but vary considerably in sensitivity and specificity. The RABLAB network continues to participate in several twinning programmes to build laboratory capacity, with several network members also supporting countries in the development and implementation of national control programmes for rabies.

The Commission considered that basic rapid test kits for detecting antigens or antibodies using LFD that are simple to use, require minimal training and can provide a result quickly in field settings. The ASF network had developed a document that provides an overview of ASF diagnostic tests for field application. The Commission also asked the rabies, PPR and animal influenza networks to develop a similar document that provides an overview on the commercially available POCTs for rapid field applications.

The Commission appreciated the efforts of all the three network Reference Laboratories in establishing scientific collaboration and exchange of technical information to contribute to the global eradication efforts.

[19] PPR: peste de petits ruminants

7. *Ad hoc* Groups: Update on activities

7.1. Replacement of the International Standard Bovine Tuberculin

The Commission was updated on the activities of the *ad hoc* Group on the ISBT[20]. The Commission commended the Group's efforts to date and looks forward to the results of the trials that are expected to be completed in November 2022.

The Commission was informed of recent information received by WOAH on the complete depletion of stock of ISAT[21]. The Commission confirmed the importance of having both bovine and avian international standards, given the importance of avian tuberculin in the control of bovine tuberculosis. The Commission strongly agreed that WOAH is the appropriate organisation to progress the effort to identify a replacement candidate for the current ISAT, emphasising the need to initiate the work as soon as possible. They further noted that the effort would be best undertaken by the same *ad hoc* Group currently working on ISBT. The Commission also raised the potential need for availability of funds to progress this very relevant work in a timely manner.

The Commission noted that while avian tuberculosis has Chapter 3.3.6 in the *Terrestrial* Manual (last updated in 2014), it is not a WOAH listed disease. The avian tuberculin test is extensively used as a comparative intradermal tuberculin test for bovine tuberculosis. The Commission agreed to invite the *ad hoc* Group experts to update the section on avian tuberculin in chapter 3.3.6; a reference to the updated text could be added to Section C.2 *Production of tuberculin* Chapter 3.1.13 *Mammalian tuberculosis* (*infection with* Mycobacterium tuberculosis *complex*).

7.2. *Ad hoc* Group on Sustainable Laboratories, 31 May 2022

WOAH convened a virtual meeting of the *ad hoc* Group on Sustainable Laboratories in May 2022. The Group took stock of the work done to date related to the PVS Sustainable Laboratories data and revisiting the definition proposed.

The outputs of the data analysis conducted using the PVS Sustainable Laboratories Cohort and Laboratory Equipment Management and Sustainability results were presented from the new Sustainable Laboratories Programme webpages. The data show that while capacity-building efforts may have improved laboratory bench-top capacity for some diseases, that capacity is unsustainable: it is underused, unleveraged, and inefficient, leading to waste, begging reflection on capacity building approaches, coordination, and methods. The data show that for laboratory networks to provide relevant, accurate, and timely results to the health system, countries must understand their overall laboratory capacity, ability to respond to needs, the real costs, and have a sustainable business model in place. Key data were:

- Countries are using only a fraction of their potential capacity: laboratory in the Cohort are currently using between 30% and 51% of their potential annual testing capacity based on equipment and human resources.
- Public laboratories view their main clients as the government (44%) and private veterinarians and small holder farmers (19%), but fall short of meeting the needs of the private sector (21%).
- On average, it costs 59% more to provide laboratory services in country than to send samples to international reference laboratories, with varying service quality, compared with international reference laboratory services.
- Among the Cohort, 38% of laboratories charged fees for testing to private sector clients, and 21% to the public sector, but only 13% of laboratories can use their revenue directly, and given that only 40% have cost accounting systems, the fees charged are often not based on real costs.

The Group was also updated on the status of mission delivery using new remote and blended methodologies and tools. Four remote PVS Sustainable Laboratories missions have occurred (Liberia, Nigeria, Sierra Leone, and United Arab Emirates).

The next and final *ad hoc* Group meeting is tentatively targeted for the first semester of 2023. During the next meeting, the experts will have reviewed the PVS Sustainable Laboratories Manuals and toolbox, provide feedback and recommendations, finalise values and unit costs for the models, and endorse the streamlined data collection and visualisation tools.

[20] ISBT: International Standard Bovine Tuberculin
[21] ISAT: International Standard Avian Tuberculin

8. International Standardisation/Harmonisation

8.1. WOAH Register of diagnostic kits

8.1.1. Update and review of new or renewed applications

The Secretariat for Registration of Diagnostic Kits (WOAH SRDK) informed the Commission of the current status of the WOAH Register of diagnostic kits. At present, there are 14 diagnostic test kits on the WOAH Register of Diagnostic Kits. There are eight active Terrestrial Diagnostic Kit applications that are being managed by the WOAH SRDK:

- The assessment of the application of Enferplex Bovine TB antibody test (Enfer Group) – for approval of supplementary data for validation of milk testing (currently provisionally approved claim) is completed and has been approved by the Commission. Written endorsement is requested prior to proposal for adoption by WOAH Resolution in May 2023.

- The assessment of the application of VDRG FMDV 3Diff/PAN Ag Rapid kit (Median Diagnostics Inc.) – for approval, is completed and has been approved by the Commission. Written endorsement is requested prior to proposal for adoption by WOAH Resolution in May 2023.

- The renewal process of the *Mycobacterium bovis* Antibody Test Kit (IDEXX Laboratories) Submission No. 20120107 (2012, renewed 2017) – for decision to renew test based on reviewers' renewal feedback is completed and requires some clarification prior to request for the written endorsement by the Commission prior to proposal for adoption by WOAH Resolution in May 2023.

- The renewal process for Rapid MERS-CoV Ag Test (BioNote Inc.) Submission No. 20160212 (2016, renewed 2021) is ongoing. The applicant has provided a new dossier that is under evaluation by PoE.

- The assessment of the application for ASF Sentinel Antibody LFD (Excelsior Bio-Systems Inc.) is ongoing. The applicant has submitted their validation dossier and it is under evaluation by PoE.

- The assessment of the application for GenelixTM ASFV Real-time PCR detection kit (Sanigen) is ongoing. The applicant has submitted their validation dossier and it is under evaluation by PoE.

- The BITRI-CFIA FMDV LFD test kit was formally withdrawn on 3rd March 2022, following feedback from the PoE undertaking review of this test application. The applicant is willing to resubmit the application when they are able to address the issues raised during the expert assessment of the application.

- The assessment of the application of BOVIGAM *Mycobacterium bovis* Gamma Interferon Test for cattle – addition of a new claim – water buffalo (Thermofisher Prionics) - for approval of addition of a new claim – water buffalo, is completed. SDRK requested and secured agreement for members of the BSC to provide oversight of the dossier prior to written endorsement by the Commission prior to proposal for adoption by WOAH Resolution in May 2023.

During discussion between the BSC and SRDK, the President requested that consideration be given to identifying a mechanism for the input from field diagnostic laboratories, when undertaking test kit renewal procedures. The Commission and the SRDK discussed the potential for providing greater transparency for test kit performance to members. These issues will be raised within the AMR & VMP department to seek to identify workable solutions.

8.2. Standardisation programme

8.2.1. Project to extend the list of WOAH-approved reference reagents: development of a template for the data to be submitted with a request to be added to the list

The Commission noted the background of the project to extend the list of WOAH approved reference reagents for diagnostic assays for animal diseases given that only a handful of laboratories have submitted applications to be added to the list. The aim of providing this list is to harmonise diagnostic testing and encourage the mutual recognition of test results for international trade. Applicant laboratories would have to submit supporting

information that the reagents have been produced in accordance with the guidelines for antibody, antigen and PCR standards.

To facilitate applications, the Commission, at its September 2019 meeting, had agreed to review the guidelines considering they have not been reviewed since 2008, and to develop a template to be attached to each guideline to facilitate data collection and submission from applicant laboratories. At this meeting, the Commission members noted that the guidelines were still relevant and found them easy to read, but agreed to finetune some details to ensure they were up-to-date. The Commission would also like to thank a former member of the Commission who had developed a draft of the template and agreed to pilot the template with selected Reference Laboratories, along with the revised guidelines to obtain feedback.

8.2.2. Association française de normalisation: creation of a European Technical committee for diagnostic standardisation

The WOAH Secretariat informed the Commission that WOAH had entered into an agreement on liaison with AFNOR[22], which has convened a European Technical Committee (CEN/TC) with the overall objective of creating a European standardisation system in the field of animal health through the development of guidelines for the implementation of diagnostic methods and quality control of diagnostic reagents, along with data management and analytical technologies used for diagnostic methods. The project, based on available WOAH standards, will primarily produce recommendations on the implementation of existing methods, but could also address complementary issues such as quality control of reagent and dematerialised data exchange. The Commission noted that the intention of this project is not to conflict or duplicate WOAH standards but to provide complementary information to the diagnostic methodologies in the *Terrestrial Manual* and quality control of reagents. The Secretariat along with a Commission member will participate in the meeting of the Technical Committee and Working Group to present an update on Chapter 1.1.6.

9. Follow-up from the General Session: pre-General Session webinars

In preparation for the 89th General Session in May 2022, the Commission had organised a webinar to present to interested parties the *Terrestrial Manual* chapters that would be presented for adoption. During the webinar, a Member asked why is there a chapter entitled “mange” when it describes a disease caused by a large number of parasites. The Member proposed that the title of the chapter should be the disease agents rather than a sign of the disease and wondered if the chapter covered all agents that cause mange. The Commission reiterated the policy of using disease names in the *Terrestrial Manual* rather than infections, which are covered in the *Terrestrial Code* (cf Reports of Meeting of the Biological Standards Commission, September 2014 and February 2016). *Terrestrial Code* titles, when relevant, are provided in brackets after the *Terrestrial Manual* title. The Commission also noted that as mange is not a listed disease, there is no chapter in the *Terrestrial Code.*

10. Conferences, Workshops, Meetings

WOAH plans to hold its customary day-long seminar at the biennial International Symposium of the World Association of Veterinary Laboratory Diagnosticians (ISWAVLD) in Lyon, France, 29 June–1 July 2023. WOAH is a member of the Scientific Committee of ISWAVLD 2023. The Theme of the conference will be “Towards the Veterinary Diagnostics of the Future”.

The One Health concept will be a major theme of the symposium. In the light of the COVID-19 pandemic and the resulting spotlight on laboratory diagnosis along with the significant work at the WOAH related to laboratory sustainability, pandemic preparedness, and resilience, the topics of the WOAH seminar will highlight how the lessons learnt from the COVID-19 pandemic and the involvement of the veterinary laboratory sector have maintained WOAH’s seat at the policy-making table to inform more holistic and efficient disease prevention from a One Health perspective.

11. Matters of interest for consideration or information

11.1. Update on OFFLU

The Commission was briefed on OFFLU[23]’s contribution to the WHO Consultation on the Composition of Influenza Virus Vaccines on avian influenza and swine influenza for the period September 2021 to February 2022. Data for 939 H5, H7 and H9 avian influenza genetic sequences were contributed by animal health laboratories in countries representing Africa, the Americas, Asia, Europe and Oceania. Additionally, 397 H1 and H3 global swine influenza virus sequences from the reporting period 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.

[22] AFNOR: Association française de normalisation
[23] OFFLU: Joint WOAH-FAO Network of Expertise on Animal Influenza

During the current year, the avian influenza epidemic continued with a high number of detections reported in poultry and wild birds throughout the continents of Africa, Asia, Europe and Americas. In response to these outbreaks, OFFLU network experts participated in teleconferences to share epidemiological and molecular data on currently circulating viruses and released situation updates and statements needed to inform surveillance and control policies.

The swine influenza experts met virtually in June 2022 and shared data about the global swine influenza situation in pig populations by providing regional and country-specific reports from Asia, Europe, and Americas.

In July 2022, the equine influenza experts participated in the virtual meeting of the WOAH expert surveillance panel on equine influenza vaccine composition to update the vaccine recommendations for the equine industry in 2022.

The OFFLU annual report 2021 was published on the website and disseminated widely.

11.2. Update on rinderpest

The Commission was informed that the inspections of the five rinderpest holding facilities that were designated in 2015 will be done before the end of 2022. Additionally, an institute in Ethiopia will be inspected as an *ad hoc* producer of rinderpest vaccine to replenish the reserve at AU-PANVAC[24]. The rinderpest virus-containing materials (RVCM) held in two institutes in Vietnam were destroyed in June 2022 during a mission led by FAO[25]. There are currently five countries holding RVCM outside FAO-WOAH designated RHFs.

The project for undertaking a risk assessment of rinderpest re-introduction 10 years after its eradication, implemented by a consortium of WOAH Collaborating Centres, ended in July 2022. The group concluded that the risk of rinderpest virus re-introduction was estimated to have decreased compared with the previous estimation done in 2012, but remained associated with a high level of uncertainty. Contrary to the 2012 study, anti-animal biological warfare was found to be the most influential risk pathway. The increase in the probability of state actors engaging in biological warfare was likely influenced by international events over the 10-year period and at the time the expert elicitation was conducted (May 2022). The risk of rinderpest re-introduction could be further reduced, in relation to 2012, by continuing the relocation and destruction of virus and vaccine stocks and limiting their use. However, even with such measures, the risk is unlikely to become negligible, so ensuring commensurate response preparedness remains important.

11.3. Update on Global Burden of Animal Diseases Programme

The Commission was updated on the GBADs[26] analytical structure, the programme data needs and country case studies. In addition, an update was provided on the progress of the programme thus far in alignment with the third update report on the programme sent to the Commission prior to the meeting. Questions were answered concerning the scope of the programme, how the programme is addressing aspects relating to animal welfare, and the incorporation of other countries and production systems. The GBADs programme will continue to keep the Commission updated on the GBADs programme and would like to include a member in a meeting of the planned *ad hoc* Group on the economics of Animal Health to support in the creation of WOAH guidelines that can be used to support possible standards creation.

11.4. Biosafety Research Roadmap

It is known or at least suspected that some commonly prescribed laboratory biosafety and biosecurity measures are not necessarily based on evidence, either because the evidence does not exist or because a precautionary approach has been taken. To address this the WOAH, in partnership with WHO[27] and Chatham House, convened a Technical Working Group that has 1. Updated a review of laboratory acquired infections (due to be published in a peer-reviewed journal soon); 2. Reviewed the evidence base to support biosafety measures commonly used for eight selected pathogens (the results are due to be published as a series of papers in *Applied Biosafety*); 3. Developed a Biosafety Research Roadmap, identifying priority areas for further research.

11.5. Update on the Grand Challenge for sustainable laboratories

Since 2018 WOAH has been working with key partners to find solutions to improve the sustainability of diagnostic laboratories. One potential pathway to finding solutions is a Grand Challenge. This would be a high risk, but potentially high impact, project requiring significant resources. To de-risk the project, WOAH has partnered with Grand Challenges Canada and the Pirbright Institute to conduct a feasibility study which will provide concrete details on how a Grand Challenge could address laboratory sustainability, an assessment on likely success, and a funding strategy.

[24] AU-PANVAC: Pan African Veterinary Vaccine Centre of the African Union
[25] FAO: Food and Agriculture Organization of the United Nations
[26] GBADs: Global Burden of Animal Diseases Programme
[27] WHO: World Health Organization

Results of the feasibility study are expected in August 2023. A decision will then be taken on whether to go ahead with the Grand Challenge.

11.6. Update on equine activities

The Commission was updated on equine activities carried out by WOAH under the collaboration agreement with the International Horse Sports Confederation (IHSC) mainly to facilitate the safe movements of competition horses. The outcomes of a survey on the diagnostic capacities and proficiency tests for six horse-related diseases was presented based on the responses from the laboratory focal points of 25 American countries. Taking into account the results of the survey, activities are being implemented to encourage the candidacy of national laboratories as WOAH Reference Laboratories for equine diseases in the region.

The Commission was also briefed on the state of play of the revision of several equine disease *Terrestrial Code chapters* and informed on the note circulated to the Code Commission to request the revision (and update) of the *Terrestrial Code* chapters on Japanese encephalitis and the three chapters on equine encephalitis (Eastern, Western and Venezuelan) based on Members' comment that have not been updated for more than 20 years.

11.7. Update on SARS-CoV-2

WOAH has continued to gather and disseminate the latest scientific evidence on the effect of SARS-CoV-2 on animals through meetings of the *ad hoc* Group on COVID-19 at the animal–human interface. As of the 31 July 2022, 679 outbreaks of SARS-CoV-2 infection in animals have been reported to WOAH, affecting 24 species in 36 countries. Given the evolution of the pandemic in the past years, the increased knowledge of the susceptibility of different wild and domestic mammal species to becoming infected and, eventually, transmitting the virus to other animals (including humans), and the potential for continued evolution of the virus in animals, WOAH with this *ad hoc* Group to advise it, will work on redefining work priorities that would reflect a shift away from a reactive phase to a more systematic way of working. This might include establishing a group that gave advice on a whole gamut of emerging pathogens of significance as they arise, e.g. monkeypox.

11.8. Internal research coordination group

The Commission was informed that an action plan for WOAH research coordination activities was established on June 2022. The aim of the plan is to identify and disseminate research needs of importance for WOAH and engage with research communities and funders in a coordinated manner. This will facilitate the production of impactful research findings that can support WOAH activities including standard setting and global strategies.

The Commission was requested to consider if information on research needs can be collected from Reference Laboratories and Collaborating Centres in their annual report. The Commission agreed to update the annual report template of the Reference Laboratories and Collaborating Centres to collect this information.

11.9. Global Laboratory Leadership Programme

WOAH is partnering with WHO, the United States Centers for Disease Control and Prevention (CDC), the Association of Public Health Laboratories (APHL), the European Centre for Disease Prevention and Control (ECDC) and FAO to deliver the Global Laboratory Leadership Programme (GLLP) learning materials developed in a One Health approach under the One Health Joint Plan of Action.

The GLLP Learning Package materials (modules focused on laboratory surveillance, outbreak investigation, preparedness, response, recovery, biosafety, biosecurity, shipment of dangerous goods, laboratory systems, leadership, communication, and management across 42 modules) are under final development in preparation of publication on WHO's Health Security Learning Platform. Materials include instructor's guides, participant's guides, slide decks, programme implementation guide and mentoring guide in both face-to-face and virtual learning formats, targeted at health laboratory system management and leadership and supporting sustainability by investing in current and emerging health laboratory leaders and managers.

11.10. Update on monkeypox

In response to global monkeypox emergency, the WOAH has highlighted the risk of potential human to animal spread outside of endemic areas, and the possibility for new animal reservoirs to become established. WOAH has communicated with Members, asking them to notify cases in animals voluntarily in line with Article 1.1.5 of the WOAH Terrestrial Animal Health Code. The Scientific Commission for Animal Disease assessed monkeypox virus against the *Terrestrial Code* definition of emerging disease and concluded that the current evidence did not meet the *Terrestrial Code* definition of an emerging disease (see agenda item 12.7 of the meeting of the Scientific Commission

for Animal Disease, 19–23 February 2022), but this would be kept under review. The WOAH has also developed guidance on diagnostics and risk management to avoid spillover from humans to animals with the support of an external expert group.

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…//Annexes

Annex 1. Adopted Agenda

MEETING OF THE BIOLOGICAL STANDARDS COMMISSION

Paris, 5 to 9 September 2022

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1. Welcome from the directors

1.1. Director General

1.2. Deputy Director General International Standards and Science

2. Adoption of the agenda

3. Collaboration with other Specialist Commissions

3.1. Horizontal issues among Specialist Commissions

3.1.1. Update on the procedure for reviewing case definitions

3.1.2. Capturing genotype information in WAHIS

3.2. Scientific Commission for Animal Diseases

3.2.1. Case definitions: infection with avian metapneumovirus (turkey rhinotracheitis) and infection with pathogenic rabbit lagoviruses (rabbit haemorrhagic disease)

3.3. Terrestrial Animal Health Standards Commission

3.3.1. Updates from the February 2022 Code Commission meeting

3.3.2. Question on draft Chapter 8.8. *Infection with foot and mouth disease virus*

3.3.2.1. Article 8.8.1 General provisions, point 3:

3.3.2.2. Article 8.8.11: Importation of vaccinated animals into a country or zone free from FMD where vaccination is not practised

3.3.3. Question on draft Chapter 6.12 *Zoonoses transmissible from non-human primates*

3.3.4. Question on draft Chapter 11.4 *Bovine spongiform encephalopathy*

3.3.5. Questions on draft Chapter 12.7 *Infection with* Theileria equi *and* Babesia caballi (*equine piroplasmosis*)

3.4. Aquatic Animal Health Standards Commission

4. Work Plan

5. Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

5.1. Review of draft chapters received for endorsement for circulation for first round Member comment

5.2. Follow-up from September 2021

5.2.1. Discussion on updated chapter 1.1.6. Principles and methods of validation of diagnostic assays for infectious diseases

5.2.2. Progress on development of a template of the validation data requested for addition to a future online list of validated tests: results of the pilot scheme to test the template's suitability

5.2.3. Discussion on inclusion of molecular epidemiology in the *Terrestrial Manual*

5.3. Request to include foot and mouth disease virus-like particles in the *Terrestrial Manual*

5.4. Update on the development of guidelines on the manufacture of safe vaccines for African swine fever.

5.5. Chapter 1.1.2. *Collection, submission and storage of diagnostic specimens:* proposal to develop a separate section for wildlife

5.6. *Terrestrial Manual* status: update on chapters selected for the 2023/2024 review cycle

6. WOAH Reference Centres

6.1. Applications for WOAH Reference Centre status

6.2. Changes of experts at WOAH Reference Centres

6.3. Review of new and pending applications for laboratory twinning

6.4. Follow-up February 2022: inconsistencies among WOAH Reference Laboratories in results obtained using the RT-PCR for African horse sickness

6.5. Reference laboratories – implementation of the SOPs

6.5.1. Follow-up from February 2022

6.5.2. In-depth review of all annual reports for activities 2021

6.6. Collaborating Centres – implementation of the SOPs

6.6.1. Follow-up from September 2021

6.6.2. In-depth review of all annual reports for activities in 2021

6.7. Reference Centre networks

6.7.1. Review of annual report template

6.7.2. Update on the three Reference Laboratory networks (rabies, peste des petits ruminants and ASF)

7. *Ad hoc* Groups: Update on activities

7.1. Replacement of the International Standard Bovine Tuberculin

7.2. *Ad hoc* Group on Sustainable Laboratories, 31 May 2022

8. International Standardisation/Harmonisation

8.1. WOAH Register of diagnostic kits

8.1.1. Update and review of new or renewed applications

8.2. Standardisation programme

8.2.1. Project to extend the list of WOAH-approved reference reagents: development of a template for the data to be submitted with a request to be added to the list

8.2.2. Association française de normalisation: creation of a European Technical committee for diagnostic standardisation

9. Follow-up from the General Session: pre-General Session webinars

10. Conferences, Workshops, Meetings

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. Biosafety Research Roadmap

11.5. Update on the Grand Challenge for sustainable laboratories

11.6. Update on equine activities

11.7. Update on SARS-CoV-2

11.8. Internal research coordination group

11.9. Global Laboratory Leadership Programme

11.10. Update on monkeypox

Annex 2. List of Participants

MEETING OF THE BIOLOGICAL STANDARDS COMMISSION

Paris, 5 to 9 September 2022

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MEMBERS OF THE COMMISSION

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Science Department

Annex 3. Work Programme for the OIE Biological Standards Commission

MEETING OF THE BIOLOGICAL STANDARDS COMMISSION

Paris, 5 to 9 September 2022

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Subject	Issue	Status and Action
Updating the *Terrestrial Manual*	1) Circulate the chapters approved by the BSC to Member Countries for first-round comment	October 2022
	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) Create a database of validation reports to be published on the WOAH Website for tests recommended in the *Terrestrial Manual*	On-going
	a) Modify the template for the validation data for tests recommended in the *Terrestrial Manual* in the light of comments received	On-going
	4) Add a new section to the disease-specific chapters to describe the rationale behind the selection of tests for different purposes given in Table 1 *Test methods available and their purpose* and an explanation for their score. Eventually, add links to the validation reports (point 3 above).	On-going
	a) Develop a template for this new section.	On going
Collaborating Centres	1) Implementation of the adopted SOPs:	
	a) Develop a plan of how to evaluate the progress made since they submitted the 5-year work plans	February 2023
	b) Contact the Collaborating Centres for submission of progress report against the 5-year work plan	September 2023
	2) Request annual reports for 2022 with modified template	December 2022
	3) Review list of Main focus areas and specialties	February 2023
	4) Clarify the role of the Contact Point in providing advice and services to WOAH Members	For February 2023
Reference Laboratories	1) Put under-performing labs on watch list	On going
	2) Update document detailing past history of annual report reviews	For October 2022
	3) Develop a questionnaire to get feedback on their experiences as a WOAH Reference Laboratory	For February 2023
	4) Request annual reports for 2022 with modified template	December 2022
Reference Centre Networks	1) Follow up with the three newly launched Reference Laboratory networks (ASF, PPR and rabies)	On-going

Subject	Issue	Status and Action
Standardisation/ Harmonisation	1) Project to extend the list of OIE approved reference reagents	On-going
	2) Ask the networks to review the three guidelines for standard reagents and consider submitting candidate reagents	For February 2023
	3) 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
Projects	1) Veterinary Biobanking (project)	Ongoing
Conferences, Workshops and Meetings with participation by BSC Members	1) Biosafety research roadmap	Ongoing
	2) ISWAVLD OIE seminar: theme and programme and speakers	June 2023
Performance	1) Engage with the ongoing processes around performance issues with Reference Labs	On-going
Develop laboratory standards for emerging diseases	1) Discuss the *Terrestrial Code* chapter once adopted with the aim of introducing a corresponding chapter for the *Terrestrial Manual*	After May 2023
Case definitions	1) Follow up the implementation of the SOPs for case definitions	On-going