WORLD ORGANISATION FOR ANIMAL HEALTH
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REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Virtual meeting, 6–10 September 2021

A virtual meeting of the OIE Biological Standards Commission was held from 6 to 10 September 2021.

1. Welcome and Commission Induction

Dr Stone, Deputy Director General (International Standards and Science) together with Dr Gillian Mylrea, Head Standards Department, conducted an induction session at the start of the meeting. This was the final session of the Specialist Commission induction programme that had been implemented as part of the Performance Management System. In previous months induction sessions had been conducted for new Commission members, Presidents and all Commission members and secretariats, to meet each other and share information relevant to this new term.

During this induction session, Dr Stone presented for the consideration of members a discussion on managing the workload, roles and responsibilities, process innovation, and the performance management system.

Dr Stone recalled that the February 2021 Commission reports had been produced in two parts, A (texts for adoption) and B (texts for comments and information) to ensure early publication of texts that were to be proposed for adoption ahead of the virtual General Session. He noted that the OIE will continue with this approach in 2022. Dr Stone also recalled that Pre-General Session webinars hosted by Commission members to explain the standards being proposed for adoption were well received and will be repeated in the future. Dr Stone also encouraged Commission members to conduct webinars in their respective regions for Delegates and relevant Focal Points after the September meeting to explain decisions made. He acknowledged that these webinars would also provide a good way for members to build their constituency.

Dr Stone emphasised some key points on: managing a heavy workload through collaborative and prioritised work programming and the roles and responsibilities of Specialist Commission Bureaus, experts and Secretariats; emphasis was placed on the importance of the partnership between the Specialist Commissions and the OIE Headquarters Secretariat. Dr Stone recognised the contribution of the three main activities that were specific to this Commission namely the update of international standards in the OIE *Terrestrial Manual*, the management of the OIE Reference Centres and the international standardisation of reagents for use in diagnostic tests.

Dr Mylrea facilitated a short session on agreed ways of working in which members discussed expectations around behaviour and how they would like to work as a group in the coming 3 years. The President also shared with the members his expectations for the new term.

2. Adoption of Agenda

The proposed agenda was presented and adopted.

The Agenda and List of Participants are given at Annexes 1 and 2, respectively.

3. *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*).

3.1. Review of draft chapters received and their endorsement for circulation for first-round Member comment

Given that the lists of OIE Reference Laboratories[1] and Collaborating Centres[2] are available online, where they are kept up to date, the Commission agreed to remove the lists in Part 4 of the *Terrestrial Manual*; these lists rapidly become out of date following publication of each new edition when new Reference Centres are adopted or change of experts are approved.

The Commission reviewed 19 draft chapters and approved 17 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 2022. The 17 chapters and a brief summary of the main amendments are:

1.1.8. Principles of veterinary vaccine production: minor amendments to take account of VICH[3] guidelines on harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use.

2.3.4. Minimum requirements for the production and quality control of vaccines: minor amendments to take account of VICH guidelines on harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use.

3.1.4. Brucellosis (infection *Brucella abortus, B. melitensis, B. suis*): updated technical aspects of some of the diagnostic tests; included some information on the disease in camels and wildlife species; removed commercial names from test methods.

3.1.6. Echinococcosis (infection with *Echinococcus granulosus* and with *E. multilocularis*): had been sent for Member comment in September 2020 and was put on hold while the vaccine section was expanded. Also made minor editorial amendments to the introduction and the diagnostic test sections in response to comments, including information on diagnosis of alveolar echinococcosis in dogs.

3.1.x. Mammalian tuberculosis (infection with *Mycobacterium tuberculosis* complex): thoroughly updated by an *ad hoc* Group. The revision is so extensive that the changes have not been marked in the interest of clarity. Broadened the scope from bovine to mammalian tuberculosis, including specific information on cattle, goats and camelids. Updated and expanded the diagnostic tests section including nucleic acid recognition methods such as

1 List available on the OIE website at: https://www.oie.int/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-3
2 List available on the OIE website at: https://www.oie.int/en/what-we-offer/expertise-network/collaborating-centres/#ui-id-3
3 VICH: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products

PCR[4] and the delayed hypersensitivity test and interpretation of its results in different species; added some information on vaccines and updated the section on production of tuberculin.

Reviewed a separate Section on production of molecularly-defined antigen for use in skin tests. Molecularly-defined antigens are likely to play an important role in the future, for example as reagents in laboratory tests such as the interferon-gamma release assay, and eventually as skin test antigens to replace tuberculin PPD[5], with the possibility of use in a DIVA[6] strategy. The Commission agreed that this is an important advance in the diagnosis and control of tuberculosis, but felt it is too soon to include in the *Terrestrial Manual.* The Commission would reconsider inclusion of this text once the technology has been fully validated (see also agenda item 10.4).

3.1.14. Nipah and Hendra virus diseases: added statements on the zoonotic potential of these viruses and the subsequent need to undertake a biological risk assessment, which may lead to a decision to avoid serological tests using live virus; updated the tests included in Table 1 *Test methods available for the diagnosis of henipaviruses and their purpose* and their scores; clarified that molecular methods for agent detection are preferable as front-line tests as they carry less risk to the laboratory worker than virus isolation; updated the information on the real-time RT-PCR, including primer sequences; added protocol for an indirect ELISA and blocking ELISA using antigen derived from the Hendra G protein; added a sentence stating that a HeV DIVA assay is currently undergoing validation by the OIE Reference Laboratory; removed names of commercial reagents, test kits and equipment; updated information on candidate experimental vaccines for Nipah virus as well as on the soluble G henipavirus vaccine.

3.1.22. Tularemia: minor updates to clarify the text; in Table 1 *Test methods available for the diagnosis of tularemia and their purpose*, changed the score of bacterial isolation for the purpose "confirmation of clinical cases" from "+++" to "++" because the organism is highly fastidious and will only grow on certain media; also in Table 1 added a new row for the conventional PCR as described by Barns *et al.* (2005)[7] and indicated that the real-time PCR is that of Versage *et al.* (2003)[8]; updated the references.

3.2.1. Acarapisosis of honey bees (infestation of honey bees with *Acarapis woodi*): thorough update as the chapter was last adopted in 2008: added new diagrams and Table 1 *Test methods available and their purpose*; fully updated the diagnostic tests section including the addition of a new section on PCR, both conventional and real-time, and deleted the section on the ELISA[9].

3.3.9. Fowl cholera: updated the diagnostic tests section, in particular by adding molecular methods, deleting somatic typing and clarifying that animal inoculation is no longer recommended; in the vaccine section clarified that it is now known that a killed vaccine

4 PCR: polymerase chain reaction
5 PPD: purified protein derivative
6 DIVA: Detection of infection in vaccinated animals
7 BARNS S.M., GROW C.C., OKINAKA R.T., KEIM P. & KUSKE C.R. (2005). Detection of diverse new *Francisella*-like bacteria in environmental samples. *Appl. Environ. Microbiol.*, **71**, 5494–5500.
8 VERSAGE J.L., SEVERIN D.D.M., CHU M.C. & PETERSEN J.M. (2003). Development of a multitarget real-time TaqMan PCR assay for enhanced detection of *Francisella tularensis* in complex specimens. *J. Clin. Microbiol.*, **41**, 5492-5499.
9 ELISA: enzyme-linked immunosorbent assay

provides protection only against isolates with the identical or near to identical LPS[10] structure; updated the references.

3.3.15. Turkey rhinotracheitis (avian metapneumovirus): updated virus taxonomy, strain classification and host range; clarified that avian metapneumovirus (aMPV) does not cause infection in humans; added Table 1 *Test methods available and their purpose*; thoroughly updated and reformatted Section C on requirements for vaccines.

3.8.11. Scrapie: clarified the information on classical and atypical scrapie throughout the chapter; expanded the information on the influence of PrP genotype on disease susceptibility in goats; stressed that the medulla oblongata is appropriate for detection of classical scrapie but for detection of atypical scrapie the cerebellum should also be sampled; clarified that histological examination should not be used as a primary screening or confirmatory test, but that it is a valuable research tool; pointed out that some ELISA-based rapid tests have limited sensitivity when applied to goat samples and have not been validated for this species and that PrP polymorphisms may also affect the performance of immunoassays; updated the links to the protocols available from the OIE Reference Laboratories.

3.8.13. Theileriosis in sheep and goats (infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi*): This is a new chapter in anticipation of the listing of these agents by the OIE. The Commission agreed to amend the title of chapter 3.4.15. to Theileriosis in cattle (infection with *Theileria annulata* and *T. parva*).

3.9.3. Classical swine fever (infection with classical swine fever virus) (diagnostic section only): added text to the summary and introduction on the existence of and difficulties caused by persistent infections; included technical updates to the virus isolation test procedure and the reverse-transcription PCR; further emphasised the existence of other ruminant pestiviruses and the need for reliable differentiation of classical swine fever virus from other pestiviruses; updated the section on the ELISA; updated the references.

3.10.1. Bunyaviral diseases of animals (excluding Rift Valley fever and Crimean–Congo haemorrhagic fever): updated the taxonomy of these viruses; updated the information in the introduction to Schmallenberg virus (SBV) and Nairobi sheep disease virus (NSDV); included more recent references to the diagnostic section on Cache Valley virus (CCV), Akabane virus (AKAV), SBV and NSDV; updated the vaccine section on SBV.

3.10.4. Cryptosporidiosis: updated the information on differences among species within the genus *Cryptosporidium*; revised the description and impact of the disease and its human health risk and zoonotic potential; updated the information on transmission, biosafety and biosecurity requirements; updated the references.

3.10.6. Mange: minor updates, including addition of preliminary information on molecular methods and serology.

3.10.7. Salmonellosis: revised the Sections on the nature and classification of the pathogen, the description and impact of the disease, and its zoonotic potential and biosafety and biosecurity requirements; in the Section on detection of the agent – culture – updated the information on pre-enrichment, selective enrichment and selective plating media; revised the example test procedures for isolation of *Salmonella* from food, feedstuffs, faecal and environmental samples and on immunological and nucleic acid recognition methods; stressed that attenuation of live vaccines is essential to limit intestinal replication and persistence in the animals and environment, but such attenuation is unlikely to have no impact on the vaccinal response; updated the references.

10 LPS: lipopolysaccharide

The batch of draft chapters will also include three other chapters: contagious equine metritis (see agenda item 3.5), glanders and melioidosis (see agenda item 3.6), and foot and mouth disease (see agenda item 9.2.1) and the glossary (see agenda items 3.2 and 9.1.1i).

The chapters can be downloaded from the following address:
http://web.oie.int/downld/Terr_Manual/MAILING_OCT_2021.zip

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. Comments should be submitted to the Commission's Secretariat: bsc.secretariat@oie.int The deadline for comments is **15 December 2021.**

3.2. Follow-up from pre-General Session webinars

In preparation for the 88th General Session in May 2021, the Commission had organised three webinars to present to interested parties the *Terrestrial Manual* chapters that would be presented for adoption. During one of the webinars, a Member noted that the draft chapter on avian influenza mentioned SPF (specific pathogen free) eggs, defined in the glossary, and SAN (specific antibody negative) eggs, not defined. To address this omission, the Commission proposes that the following definition of SAN be added to the glossary:

- **Specific antibody negative (SAN) eggs**

Used in relation to animals that have been shown by the use of appropriate tests to be free from antibodies to specific avian pathogenic microorganisms, and also eggs derived from these birds.

3.3. Follow-up from the General Session

3.3.1. Chapter 3.5.8 *Equine piroplasmosis*

At the General Session in May 2021, Chapter 3.5.8. *Equine piroplasmosis* had been adopted with one abstention from a Member that did not agree with the change in the scoring of the IFAT[11] and the C-ELISA[12] given in column 4 (confirmation of clinical cases) of Table 1 *Test methods available for the diagnosis of equine piroplasmosis and their purpose* from "recommended" to "not appropriate for this purpose".

The Member did not believe that concerns raised about inconsistencies in the text of this chapter and Table 1 had been addressed. The Member noted that in Table 1 microscopic examination and PCR are recommended for confirmation of clinical cases of equine piroplasmosis, while both serological tests (IFAT and C-ELISA) are not appropriate. The reliability of PCR and microscopic examination as diagnostic tests depends on the level of parasitaemia. That level is highly dynamic and variable, and can even be low in clinical cases when sampling is performed. The Member emphasised that a number of studies have highlighted a disparity in results between C-ELISA, microscopy and PCR for detection of equine piroplasmosis in both subclinical and acutely infected horses. The Member maintained that, due to the epidemiology of equine piroplasmosis, a combination of PCR and serological testing is essential to most accurately determine an animal's piroplasmosis status, even in clinical cases. The Member therefore did not support that serological tests for equine piroplasmosis are listed as "not appropriate" for confirmation of clinical cases.

The Commission reviewed the comments and the references provided and found that they did not substantiate the Member's arguments. The Commission reiterated that serological assays, which are recommended for detecting carrier animals, are not suitable for confirming clinical

11 IFAT: indirect fluorescent antibody test
12 C-ELISA: competitive enzyme-linked immunosorbent assay

disease as they cannot differentiate between an active infection and a past infection A combination of PCR and serological tests is essential to determine whether an animal is free from infection.

The Commission is not proposing any further changes to the chapter but invites the Member to submit more references to support their position. The Commission would review any new information provided.

3.3.2. Chapter 3.4.12 *Lumpy skin disease*

Also at the General Session, concerns had been raised about the DIVA PCR methods used to distinguish vaccine strains from field strains of LSDV[13], and the challenges encountered in recent years with correctly identifying new recombinant field strains that have emerged in certain parts of the world. Correct identification of LSDV strains has wide implications for disease notification, country status and international trade.

The Commission reconfirmed its commitment to addressing as a priority the issue of emerging recombinant LSDV strains, their correct diagnosis and notification. To this end, the advice of the OIE Reference Laboratories would be sought on how best to address the issue. The Biological Standards Commission would also collaborate with the Scientific and Code Commissions to best resolve this important problem.

3.4. Conclusions and recommendations from the OIE *Scientific and Technical Review* issue on diagnostic test validation science

The Commission reviewed the conclusions and recommendations from the recently published volume of the OIE *Scientific and Technical Review* on diagnostic test validation science. Those recommendations that concern the OIE Procedure for the Registration of Diagnostic Kits are discussed below (see agenda item 6.1.2).

For those concerning the *Terrestrial Manual*, the Commission agreed:

i) To review and update all the OIE validation chapters and glossary of terms, including Chapter 1.1.6 *Principles and methods of validation of diagnostic assays for infectious diseases* (see agenda item 3.9).

ii) That a list of OIE validated tests should be published on the OIE Website for end-users similar to the list of *Currently available OIE-approved International Standard Reagents*[14]. To advance this project, members of the Commission were identified who would develop a template for the validation data that would be requested of applicants wishing to add their test to the list. It would need to be agreed how far a test needs to advance in the OIE validation pathway to be considered as validated to the OIE standard. The Commission would review the template at its next meeting in February 2022.

iii) That a new section would be added to all disease chapters as they are revised to describe the rationale behind the selection of tests for different purposes given in Table 1 *Test methods available and their purpose*. Eventually, links could be provided to the validation reports for those tests validated to the OIE standard mentioned in point ii above. Members of the Commission were identified who would develop a template for this new section. The Commission would review the template at its next meeting in February 2022.

13 LSDV: lumpy skin disease virus
14 https://www.oie.int/en/what-we-offer/veterinary-products/#ui-id-4

3.5. Review of a validation dossier for a real-time PCR method for detection of *Taylorella equigenitalis* directly from swabs, and proposed text for Chapter 3.6.2 *Contagious equine metritis*

In September 2017, a validation dossier had been submitted for a real-time PCR method for detection of *Taylorella equigenitalis* directly from swabs. The Commission requested the OIE Reference Laboratories for contagious equine metritis to evaluate the dossier. While reviewing the dossier, the experts agreed that before approving a PCR as a recommended test, its reproducibility in laboratories other than the one of origin must be assured. They decided to investigate the reproducibility of the submitted test along with another real-time PCR that was already in the *Terrestrial Manual* (Wakeley *et al.*, 2006[15]), and to compare both PCRs with culture techniques.

For this meeting, the experts submitted a metanalysis of the published data directly comparing culture and PCR in field samples, and a summary of PCR and culture ring trial results in a number of laboratories, including specifically designed ring trial studies on the use of the two named real-time PCRs in a number of laboratories using a panel of DNA extracts derived from swabs of field cases of contagious equine metritis and a panel of swabs prepared in the laboratory to mimic field swabs.

The Commission reviewed the documents and agreed with the experts recommendation to include the two real-time PCR methods in the *Terrestrial Manual* chapter. The revised chapter is included in the batch of chapters that have been approved to be circulated for first-round Member comment (see agenda item 3.1).

3.6. Request to update Chapter 3.6.11 *Glanders and melioidosis* to include a new recombinant double antigen-based ELISA

The OIE Reference Laboratory in Germany had submitted a request to include a recombinant double antigen-based ELISA for the detection of antibodies specific for *Burkholderia mallei* in the *Terrestrial Manual* chapter on glanders and melioidosis. The request included a published reference to the validation study for this assay (Elschner *et al.*, 2021[16]). The experts believe that considering the comparable sensitivities of CFT[17] (96.5%) and this ELISA (98.1%), the ELISA is a suitable confirmatory test and a realistic alternative for serological testing of horses for trade or movement.

The Commission reviewed the reference and accepted the experts' request. It is proposed to add the assay to Table 1 *Test methods available for the diagnosis of glanders and their purpose*, and to section B.3.2 *Enzyme-linked immunosorbent assays* of the chapter. The revised chapter is included in the batch of chapters that have been approved to be circulated for first-round Member comment (see agenda item 3.1).

3.7. Request to update Chapter 3.1.1 *Anthrax* to include a new easier to produce *Bacillus anthracis* capsule stain

The Commission had received a request to include a new capsule stain in the *Terrestrial Manual* chapter on anthrax as it is quicker to make and thus more readily available and convenient. The request and supporting references would be submitted to the OIE Reference Laboratories for their opinion. Should the method be validated it could be included in the next revision of the chapter.

15 WAKELEY P.R., ERRINGTON J., HANNON S., ROEST H.I.J., CARSON T. HUNT B. & HEATH P. (2006). Development of a real time PCR for the detection of *Taylorella equigenitalis* directly for the genital swabs and discrimination from *Taylorella asinigenitialis. Vet. Microbiol*., **118**, 247–254.

16 ELSCHNER M.C., MELZER F., SINGHA H., MUHAMMAD S., GARDNER I. & NEUBAUER H. (2021). Validation of a Commercial Glanders ELISA as an Alternative to the CFT in International Trade of Equidae. *Front. Vet. Sci.,* **8**, 628389. doi:10.3389/fvets.2021.628389

17 CFT: complement fixation test

3.8. Including OIE *Terrestrial Manual* chapters in national regulations: requirement to mention the most recently adopted version of the OIE Standard

The OIE had received a request from a vaccine manufacturer for the 2012 edition of the *Terrestrial Manual* chapter on biosafety and biosecurity. The reason given was that the 2012 edition is specifically mentioned in national adopted GMP[18] regulations. The OIE and the Commission would like to reiterate that only the most recently adopted version of an OIE standard is the version in vigour. When referencing OIE Standards in national regulations, rather than giving a specific year, the regulations should refer to "the most recently adopted version of the OIE standard". This is all the more important for the chapter on biosafety and biosecurity as the OIE recommendations have moved on from defining risk groups (2012 edition) to a risk analysis approach (current edition).

3.9. Review of *Terrestrial Manual* status: selection of chapters for update in 2022/2023 review cycle

The Commission examined the status of chapters that had previously been identified for update in the 2021/2022 review cycle but had not been received. The Commission decided to add to the list chapters that had last been updated in 2017. The following chapters have been identified for update in 2022/2023:

1.1.2. Collection, submission and storage of diagnostic specimens (last adopted May 2013)
1.1.4. Biosafety and biosecurity: Standard for managing biological risk in the veterinary laboratory and animal facilities (last adopted May 2015)
1.1.5. Quality management in veterinary testing laboratories (last adopted May 2017)
1.1.6. Principles and methods of validation of diagnostic assays for infectious diseases (last adopted May 2013)
1.1.7. Standards for high throughput sequencing, bioinformatics and computational genomics (last adopted May 2016)
1.1.9. Tests for sterility and freedom from contamination of biological materials intended for veterinary use (last adopted May 2017)
1.1.10. Vaccine banks (last adopted May 2016)
2.1.3. Managing biorisk: examples of aligning risk management strategies with assessed biorisks (last adopted May 2014)
2.2.1. Development and optimisation of antibody detection assays (last adopted May 2014)
2.2.2. Development and optimisation of antigen detection assays (last adopted May 2014)
2.2.3. Development and optimisation of nucleic acid detection assays (last adopted May 2014)
2.2.4. Measurement uncertainty (last adopted May 2014)
2.2.5. Statistical approaches to validation (last adopted May 2014)
2.2.6. Selection and use of reference samples and panels (last adopted May 2014)
2.2.7. Principles and methods for the validation of diagnostic tests for infectious diseases applicable to wildlife (last adopted May 2014)
2.2.8. Comparability of assays after minor changes in a validated test method (last adopted May 2016)
2.3.1. The application of biotechnology to the development of veterinary vaccines (last adopted May 2010)
2.3.3. Minimum requirements for the organisation and management of a vaccine manufacturing facility (last adopted May 2016)
2.3.5. Minimum requirements for aseptic production in vaccine manufacture (last adopted May 2016)

18 GMP: good manufacturing practices

3.1.5. Crimean–Congo haemorrhagic fever (last adopted May 2014)
3.1.18. Rift Valley fever (infection with Rift Valley fever virus) (last adopted May 2016)
3.1.21. Trichinellosis (infection with *Trichinella* spp.) (last adopted May 2017)
3.2.2. American foulbrood of honey bees (infection of honey bees with *Paenibacillus larvae*) (last adopted May 2016)
3.2.3. European foulbrood of honey bees (infection of honey bees with *Melissococcus plutonius*) (last adopted May 2016)
3.2.4 Nosemosis of honey bees (last adopted May 2013)
3.3.6. Avian tuberculosis (last adopted May 2014)
3.3.8. Duck virus hepatitis (last adopted May 2017)
3.3.13. Marek's disease (last adopted May 2017)
3.4.1. Bovine anaplasmosis (last adopted May 2015)
3.4.7. Bovine viral diarrhoea (last adopted May 2015)
3.4.11. Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (last adopted May 2017)
3.6.9. Equine rhinopneumonitis (infection with equid herpesvirus-1 and -4) (last adopted May 2017)
3.6.10. Equine viral arteritis (infection with equine arteritis virus) (last adopted May 2013)
3.8.1. Border disease (last adopted May 2017)
3.8.2. Caprine arthritis/encephalitis and Maedi-visna (last adopted May 2017)
3.8.12. Sheep pox and goat pox (last adopted May 2017)
3.9.7. Influenza A virus of swine (last adopted May 2015)
3.9.9. Teschovirus encephalomyelitis (last adopted May 2017)
3.9.10. Transmissible gastroenteritis (last adopted May 2008)
3.10.4. Infection with *Campylobacter jejuni* and *C. coli* (last adopted May 2017)
3.10.8. Toxoplasmosis (last adopted May 2017)
3.10.10. Verocytotoxogenic *Escherichia coli* (last adopted May 2008)

The OIE Reference Laboratory or other experts, where necessary, would be asked to undertake the revisions.

4. OIE Reference Centres

4.1. Applications for OIE Reference Centre status

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

OIE *Reference Laboratory for Paratuberculosis*
National Reference Centre for Paratuberculosis, Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna, Sede Territoriale di Piacenza, Strada della Faggiola 1, 29027 Gariga di Podenzano (PC), ITALY
Tel.: (+39-0523) 52.42.53
E-mail: matteo.ricchi@izsler.it; piacenza@izsler.it Website: www.izsler.it
Designated Reference Expert: Dr Matteo Ricchi.

OIE *Reference Laboratory for Rift Valley fever*
CIRAD, Campus international de Baillarguet, TA A15/E, 34398 Montpellier Cedex 5, FRANCE
Tel.: (+33-4) 67.59.38.34
E-mail: catherine.cetre-sossah@cirad.fr website: https://www.cirad.fr
Designated Reference Expert: Dr Catherine Cetre-Sossah.

OIE *Reference Laboratory for avian mycoplasmosis* (Mycoplasma gallisepticum, M. synoviae)
Avian Medicine Laboratory, Istituto Zooprofilattico Sperimentale delle Venezie, Via Bovolino 1/C, 37060 Buttapietra (VR) ITALY
Tel.: (+39-045) 50.02.85

E-mail: scatania@izsvenezie.it website: www.izsvenezie.com
Designated Reference Expert: Dr Salvatore Catania.

OIE *Collaborating Centre for Camel Diseases*
Abu Dhabi Agriculture and Food Safety Authority, P.O. Box: 52150, Mohammed Bin Zayed City, Capital Mall, Abu Dhabi, UNITED ARAB EMIRATES
Tel.: (+971-2) 818.10.08
E-mail: vld.office@adafsa.gov.ae Website: https://www.adafsa.ae
Contact Point: Dr Salama Suhail Mohammed Al Muhairi.

OIE *Collaborating Centre for Veterinary Medicinal Products for Eastern Europe, Central Asia and Transcaucasia*
Federal State Budgetary Institution "The Russian State Center for Animal Feed and Drug Standardization and Quality", Zvenigorodskoye shosse, 5, 123022, Moscow, RUSSIA
Tel.: (+7-499) 941.01.51 ext. 643
E-mail: intcoopdiv@vgnki.ru; kanc@vgnki.ru website: http://en.vgnki.ru/
Contact Point: Dr Vasinina Gryciuk.

The Commission is aware that there is an existing OIE Collaborating Centre for the same topic in the Europe region, but proposed that for linguistic and cultural reasons, the circumstances justified an exceptional designation as a stand-alone Centre in the sub-region.

In February 2021, an application had been received for an OIE Reference Laboratory for African horse sickness. Amongst other information, the applicant had been asked to provide more detailed information on their experience in standardisation and validation of diagnostic tests. The Commission found that the response received did not provide convincing evidence of established experience in standardisation and validation of diagnostic tests for African horse sickness and thus did not accept the application at this time.

Finally, an application had been received for an OIE Reference Laboratory for Crimean–Congo haemorrhagic fever. Although the application was of very high quality, the Commission noted that it included only two publications. Before a decision can be taken the applicant would be asked to submit a complete publications list for review at the February 2022 meeting.

4.2. Changes of experts at OIE Reference Centres

The Delegate of the Member concerned had submitted to the OIE the following nomination for changes of experts at OIE Reference Laboratories. The Commission recommended their acceptance:

Babesiosis
Dr Valeria Blanda to replace Dr Santo Caracappa at the Istituto Zooprofilattico Sperimentale della Sicilia (IZSSi), Palermo, ITALY

Bovine tuberculosis
Dr Jason Sawyer to replace Prof. Glyn Hewinson at the Animal and Plant Health Agency, Weybridge, UNITED KINGDOM

Infestation with Aethina tumida (*small hive beetle*); *Infestation of honey bees with* Tropilaelaps *spp*.
Dr Stéphanie Franco to replace Dr Marie-Pierre Chauzat at Anses, Laboratoire de Sophia Antipolis, FRANCE

Foot and mouth disease
Dr Livio Heath to replace Dr François Maree at the Onderstepoort Veterinary Institute, SOUTH AFRICA

The Commission reviewed seven additional nominations for changes of experts at OIE Reference Laboratories and based on the information provided felt that none could fulfil the expectations of an OIE Expert. The Commission reiterated that OIE designated experts must be a leading and active researcher,

must have experience in the application of diagnostic techniques for the disease in question and must be able to provide adequate evidence of expertise (e.g. a body of published papers in peer-reviewed journals) so as to be able to provide sound scientific advice on all aspects of the disease to Members. The Reference Laboratories would be asked to either resubmit a strengthened curriculum vitae or to propose a different expert.

4.3. Review of new and pending applications for laboratory twinning

As of September 2021, 66 projects have been completed, 32 projects are underway and 1 is awaiting funding before beginning.

One Laboratory Twinning project proposal was presented for the Commission's review:

i) ***United Kingdom – Georgia*** for Mycoplasmosis: the Commission supported the technical contents of this project.

4.4. Inconsistencies among OIE Reference Laboratories in results obtained using the real-time RT-PCR for African horse sickness

The Commission reviewed a request from an OIE Reference Laboratory for AHS[19] to facilitate a discussion among laboratories regarding inconsistencies in the detection of AHS virus positive animals in a quarantine station by the real-time RT-PCR method and the implications this has for trade or free status. The Reference Laboratory raised concerns that inconsistencies in laboratory results may lead to confusion among countries in terms of import status, unpredictable responses to finding unexpectedly positive samples in pre- or post-import testing and unnecessary delays in the movement of horses.

The Commission considered it to be a serious issue: laboratories need to have a harmonised diagnostic approach. The Commission therefore recommended that the OIE facilitate a discussion between all the interested parties including all three OIE Reference Laboratories for AHS, the concerned quarantine station, and a representative of the Commission.

• Reference Laboratories – implementation of the SOPs[20]

4.5. Follow-up February meeting: further feedback from the Laboratories that are not complying with the key ToR according to their 2018 annual report

The Commission reviewed the feedback received from two Reference Laboratories that were not complying with key performance criteria according to their 2018 annual reports.

One Reference Laboratory was no longer permitted to work on the disease in question as the country was free from it responded that it is working closely with the national Veterinary Services to resolve this issue and to continue performing its function as an OIE Reference Laboratory. However due to the COVID-19 pandemic, the discussion could not move forward in a timely manner. The Reference Laboratory therefore requested an extension to solve this issue. The Commission accepted this request: the Reference Laboratory would be asked to submit evidence that it had resolved the problem for review at the next meeting in February 2022, failing this the Reference Laboratory's designation could be revoked in accordance with Article 9 of the Internal rules for OIE Reference Centres.

The second Reference Laboratory had again failed to submit a certificate of accreditation to ISO 17025 or equivalent quality management system. The Reference Laboratory reported that the institution's accreditation assessment process was complete. The accreditation body had requested some corrections, which has been supplied but because of the Covid-19 pandemic situation there would be a delay before

19 AHS: African horse sickness
20 SOPs: Standard Operating Procedure

the accreditation body could assess the Reference Laboratory's response. The Commission proposed that the Reference Laboratory be contacted regularly over the coming months for an update on its accreditation status. If the Reference Laboratory fails to submit an accreditation certificate by the next meeting in February 2022, it's designation will be revoked in accordance with Article 9 of the Internal rules for OIE Reference Centres.

4.6. Feedback from the Laboratories that are not complying with the key ToR according to 2019 annual report

The Commission accepted the explanations provided by one Reference Laboratory and noted the efforts taken to slightly increase the level of activity in 2020. The Commission expected the Reference Laboratory to further increase its diagnostic activities in 2021 by contacting other national laboratories in the region to offer diagnostic services.

4.7. In-depth review of all annual reports for activities in 2020

The Commission reviewed the performance of all the OIE Reference Laboratories by an in-depth analysis of the annual reports submitted in 2020 to ensure that each laboratory is fulfilling the ToRs[21] to the benefit of OIE Members and performance criterion iii) of the *Procedures for Designation of OIE Reference Laboratories* (the SOPs).

The Commission identified 53 Reference Laboratories that had a low level of activities: many cited the impact of the Covid-19 pandemic situation that had led to the disruption of the laboratory's activities. The Commission agreed that the pandemic has negatively impacted the performance of OIE Reference Laboratories in 2020 and placed all of the low performance laboratories in a watch list for follow up at the next annual report review cycle.

Three OIE Reference Laboratories had not submitted annual reports for 2020: the laboratories for Crimean–Congo haemorrhagic fever and Rift Valley fever had withdrawn their designations and the Member in question had submitted new applications (see agenda item 4.1). The OIE Reference Laboratory for babesiosis did not have a designated expert in 2020, but had submitted a nomination for a replacement expert for review at this meeting (see agenda item 4.2).

- **Collaborating Centres – implementation of the SOPs**

4.8. Follow-up February meeting: feedback on the mapping exercise for the existing Centres against the list of main focus area and specialties

At the February 2021 meeting, one Centre in the Americas region that had been categorised under focus area 'Training and education' but was reporting a broad range of activities under all focus areas had been asked to consider dividing up into separate Centres for each focus area. The Centre understood this requirement and preferred to remain as one OIE Collaborating Centre. To this end the Centre proposed to change its focus area to 'Animal Health Management' and to report only relevant activities. The Centre also provided a rationale for retaining its title. The Commission accepted the Centre's new focus area and retention of its title.

In the Europe region, two Centres in the same country with similar titles and core activities had been asked to consider joining together to form one Collaborating Centre consortium. Rather than forming one joint Centre, the Centres proposed that they remain separate with one focusing on viral diseases and the other on bacterial diseases. The Commission accepted this proposal, and the title of the Centres will be adjusted accordingly. One of these two Centres also had the focus area 'food safety' in its title and

21 ToRs: Terms of Reference

remit. The Centre will be invited to establish a separate stand-alone Collaborating Centre on Food Safety under the focus area 'Animal production and food safety'. The Commission is aware that there is an existing OIE Collaborating Centre for the same topic in the Europe region, but proposed that for linguistic and cultural reasons, the circumstances justified an exceptional designation as a stand-alone Centre in the sub-region.

4.9. Follow-up February meeting: feedback from the Centres that are not complying with the key ToR according to 2019 annual report

One Centre that had shown a low level of activity in its 2019 annual report had reassured the Commission at that time that it would improve its performance in 2020. However, the Centre had not submitted a report for activities in 2020. Furthermore, the Centre had not submitted a 5-year work plan for activities in 2020–2024. The Centre will be sent a letter requesting that it submit the 5-year work plan as soon as possible. The Centre will also be reminded that non-submission of its annual report means that it was not complying with the performance criteria, which could lead to the delisting procedures being initiated.

4.10. Follow-up September: feedback on the review of the 5-year work plans received from Collaborating Centres:

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

One Centre clarified that the activities planned for the first half of 2020 and delayed due to Covid-19 pandemic situation will be re-programmed later when the situation improves; the Commission accepted this explanation. One Centre that had submitted an incomplete 5-year work plan was asked to correct and update the information and include authorisation signature. The Commission reviewed the re-submitted work plan and noted that the information provided in Section 5.1 *Planned activities* covered what had already been achieved not what the Centre intends to accomplish over the next 5 years. The Centre will be asked to provide more details listing specific activities they intend to carry out in the future.

The Commission reviewed three newly submitted 5-year work plans and approved the range of activities proposed by two of the Centres and their relevance to the identified main focus areas and specialties. The third Centre had not provided any information for Section 5.1 *Planned activities* or for Section 5.2 *Measurement of benefits*, both of which are critical and mandatory for the work plan. The Centre will be asked to re-submit the work plan to include these necessary details.

Two Collaborating Centres that had still not submitted a 5-year work plan would be sent reminders; the Centres would be advised that a 5-year work plan is mandatory to comply with the SOPs, and non-submission could lead to the delisting procedures being initiated.

4.11. In-depth review of all annual reports for activities in 2020

As for the Reference Laboratories, the Commission also undertook an in-depth analysis of all the annual reports of the Collaborating Centres submitted in 2020 to ensure fulfilment of the ToRs.

The Commission identified six Collaborating Centres that were not complying with the performance criteria. The Centres concerned would be informed of the outcome of the review and asked to provide an explanation of their situation and possible reasons for the lack of activities; the Delegate will be in copy of all correspondence. The Commission was particularly concerned with some of the Centres where the activities are minimum, nationally driven without international collaboration, quite narrowly focused and not covering a broad range of activities as described in the ToR.

The Commission expressed its appreciation for the continued support and expert advice given to the OIE by the Reference Centres.

- **Reference Centre networks**

4.12. Update on the three identified Reference Laboratory networks (Rabies, PPR and ASF)

The Commission was briefed on the progress of the recently launched three OIE Reference Laboratory networks for rabies, PPR[22] and ASF[23]. All three networks are up and running and have held regular virtual meetings to initiate each network's activities.

The rabies Reference Laboratories network (RABLAB) conducted a survey to identify the core activities and capacities of the participating laboratories along with a gap analysis. The network's logo was agreed on and finalised. A technical discussion was held among network members on a proposal to reduce the post-titre waiting period for imported dog from 90 days to 30 days. The network's advice will be provided to the appropriate Specialist Commissions for further follow up.

The PPR Reference Laboratories network developed the activities plan for 2021. The network discussed a list of potential key national laboratories from all the regions of the world that could be invited as additional members. These members were asked to provide more information on their PPR work and to agree to participate in the network activities. The logo of the network was drafted. The detailed structure of the network website was finalised after various consultations on design, content and responsibilities. The network provided expertise for the call for tender to the OIE PPR vaccine bank. The network's first workshop bringing together PPR Reference Laboratories along with selected national laboratories will be held in November 2021.

The ASF Reference Laboratories network met to gain an understanding of the impact of the low virulent strains circulating in China (People's Rep. of), their consequences for Asia and other regions and how the network could support the Members to address any changing risk. As a follow up action, the network agreed on the need to develop an 'ASF laboratory diagnosis protocol' that would be valuable for Members. Subsequently the experts held meetings to discuss and collect various laboratory protocols with the aim of developing a summary of diagnostic tools for the detection of ASF infection in different scenarios that will be finalised by the end of the year for publication in coordination with the FAO[24]. The network is also working on developing a concept note for a centralised ASF virus genetic sequence database detailing the needs, expectations and requirements for deposit of sequences. The network shared experiences and participated in the discussion to curb the ongoing spread of ASF in the Americas.

The Commission appreciated the efforts of all the three network Reference Laboratories in establishing the networks to carry out a variety of activities intended to accelerate progress towards global strategic control and eradication programmes through scientific collaboration.

5. *Ad hoc* Groups

- **Update on activities of *ad hoc* Groups**

5.1. *Ad hoc* Group on Replacement of the International Standard Bovine Tuberculin (ISBT): update on the replacement ISBT

This *ad hoc* Group has been meeting for the past 6 years, with the primary task to develop a new international standard for bovine tuberculin (ISBT). This was in recognition that the present bovine

22 PPR: peste des petits ruminants
23 ASF: African swine fever
24 FAO: Food and Agriculture Organization of the United Nations

international standard (BIS), developed and maintained by WHO[25], was running out and deteriorating. WHO agreed that it would be appropriate for OIE to develop the new standard.

The Commission was informed that the Group would meet virtually in October to discuss new data on the candidate tuberculin following further research that had been undertaken. The Group is confident that it will be in a position to finalise the report by December in time to present it to the Commission at its next meeting in February 2022. The project is still on target for presentation of the replacement ISBT for adoption by resolution in May 2022.

5.2. *Ad hoc* Group on the revision of *Terrestrial Code* chapters regarding the collection and processing of semen of animals, 9 November 2020 to 15 January 2021

The Commission was updated on the work of the *ad hoc* Group on the revision of *Terrestrial Code* chapters regarding the collection and processing of semen of animals, which convened for the second time between May and July 2021 and developed draft text for Chapter 4.6. *General hygiene in semen collection and processing centres*.

Further information on the work of the *ad hoc* Group as well as the next steps may be found in the September 2021 report of the Code Commission.

5.3. *Ad hoc* Group on Sustainable Laboratories

The OIE convened a meeting of the *ad hoc* Group on Sustainable Laboratories virtually in June 2021. In 2019, the Group established a working definition of a sustainable laboratory network as "a network of laboratories that can maintain appropriate safety, security, and quality on a path towards compliance with OIE International Standards, taking into account social, environmental, and economic factors in its day to day operations for the benefit of the health system." The Group took stock of the work done to date in three key areas – economic indicators for laboratory sustainability, mission methodology, and data – and agreed on next steps for each area.

The report of the virtual meeting of the *ad hoc* Group on Sustainable Laboratories, held in June 2021, was endorsed and is attached as Annex 3.

6. International Standardisation/Harmonisation

6.1. OIE Register of diagnostic kits

6.1.1. Update on new or renewed applications

The Secretariat for Registration of Diagnostic Kits (OIE SRDK) informed the Commission of the current status of the OIE Register of diagnostic kits. At present, there are 14 registered kits. There are seven active applications that are being managed by the OIE SRDK:

- Four new applications (submitted in 2019 and 2020) are under evaluation, of which two are suspended with extended clock stops.
- One application for extension of claim of a registered kit is under evaluation.
- Two new applications for registration of aquatic kits were received in 2021, but are not yet under evaluation.

25 WHO: World Health Organization

The renewal process for one kit (the Rapid MERS-CoV[26] Ag Test [BioNote Inc.]) is ongoing. The applicant has engaged with the OIE Reference Laboratory for MERS for assistance and expects to submit their additional data by the end of 2021 or in January 2022.

6.1.2. Conclusions from the OIE *Scientific and Technical Review* issue on diagnostic test validation science

As reported in agenda item 3.4, the Commission reviewed the conclusions and recommendations from the recently published volume of the OIE *Scientific and Technical Review* on diagnostic test validation science. Some of the recommendations concern the OIE Procedure for the Registration of Diagnostic Kits. The Commission agreed to discuss these recommendations with the SRDK at the next meeting in February 2022.

6.2. Standardisation programme

6.2.1. AFNOR[27]: creation of a European Technical committee for diagnostic standardisation

The Commission was briefed on a proposal received from AFNOR for the creation of 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 will ensure that it does not duplicate the OIE standards in the *Terrestrial* and *Aquatic Manuals* but rather complement them. The project, based on available OIE 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 goal of this project is to harmonise European standards and contribute to the animal health control chain in collaboration with the OIE and relevant European institutions.

The Commission noted that the intention of this project is not to conflict or duplicate OIE 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 kick-off meeting of this Technical Committee in September 2021.

7. Follow-up from the General Session

See Agenda Items 3.3 And 9.2.2

8. Conferences, Workshops, Meetings

- ***Future Conferences, Workshops, Meetings***

8.1. ISWAVLD[28], Lyon, France, 2023

The 20th ISWAVLD was to be held in Lyon, France in June 2021. Traditionally, the Biological Standards Commission organises a 1-day seminar held during the Symposium. The OIE is a member of the Scientific Committee of the ISWAVLD 2021.

Due to the COVID-19 pandemic and travel restrictions and difficulties around visa, air travel and requirements, the WAVLD Executive board has decided that:

26 MERS-CoV: Middle East respiratory syndrome coronavirus
27 AFNOR: Association française de normalisation
28 ISWAVLD: International Symposium of the World Association of Veterinary Laboratory Diagnosticians

- the typical face-to-face symposium should not be held as a virtual event
- the symposium should be postponed to June 2023 in Lyon, France.

The One Health concept will be a major theme of the symposium, and given the COVID-19 pandemic, the spotlight on laboratory diagnosis, and significant work at the OIE related to laboratory sustainability, emergency preparedness, and resilience, the theme of the OIE seminar is currently proposed to be "The Veterinary Laboratory Function and COVID-19: How can we apply lessons learnt for better preparedness and resilience?" Given the postponement of the event, the finalisation of the agenda and list of speakers for the OIE seminar will be postponed until February 2022.

9. Liaison with other Commissions

9.1. Horizontal issues among the Specialist Commissions

9.1.1. Review of case definitions

i) Bovine viral diarrhoea

Referring to the description of infection with FMDV[29] (see agenda item 9.2.1), the Biological Standards Commission recommended that the same principle be applied to the case definition for infection with Bovine viral diarrhoea; specifically, that the identity of the virus (option 1) be confirmed by the detection of viral antigen or nucleic acid.

The Biological Standards Commission found that the reference to "excluding vaccine strains" in option 1 might suggest that the virus has been appropriately identified, and suggested that this be made explicit. To this end, the Commission proposed that options 1 and 2 be combined.

The Commission noted the importance of providing recommendations for Members on how to identify and thus exclude vaccine strains. The members of the Commission considered that such details should not be included in the case definition itself; rather, this information should be available in the OIE *Terrestrial Manual.*

ii) Nipah virus encephalitis

Again referring to the description of infection with FMDV (see agenda item 9.2.1), the Commission recommended that the same principle be applied to the case definition for infection with Nipah virus; specifically, that the identity of Nipah virus (option 1) be confirmed by the detection of viral antigen or nucleic acid.

The Commission questioned the use of serology as stated in option 3. The Commission also questioned whether the presence of antibodies (with the epidemiological link) would indicate active infection with Nipah virus, and proposed revising the text to ensure that option 3 captures active infections. The Commission suggested referring the proposed text back to the expert group to ensure that it is appropriate, given the serological tests currently used in animals. In addition, the experts may be able to advise whether active infection may be present (or persist) in the presence of an antibody response.

In the course of this discussion, Biological Standards Commission noted that the term 'seroconversion' should be defined and included in the glossary of the *Terrestrial Manual*. The following definition was proposed and would be circulated for Member comment (see agenda item 3.1).

29 FMDV: foot and mouth disease virus

• Seroconversion

i) Demonstration of a change from a seronegative to a seropositive condition using a serological assay specific for the antigen

OR

ii) Demonstration of a four-fold or more rise in antibody titre between an acute and convalescent serum using an ordinal test specific for the antigen

The full reports of the development of the case definition for infection with bovine viral diarrhoea viruses (bovine viral diarrhoea) and for infection with Nipah virus (Nipah virus encephalitis) can be found at annexes 10 and 11 of the September 2021 report of the meeting of the Scientific Commission for Animal Diseases. The final versions of the case definitions will be made available on the OIE website.

9.2. Scientific Commission for Animal Diseases

9.2.1. Proposed amendments to the *Terrestrial Code* and *Terrestrial Manual* chapters on FMD to harmonise the description of infection with FMDV

While reviewing the technical disease card, two FMD experts had noticed a difference in the description of infection with FMDV between the *Terrestrial Code* and *Terrestrial Manual*. In the *Terrestrial Code*, confirmation of infection with FMDV by virus isolation is considered definitive whereas confirmation by other laboratory tests is provisional on other supporting evidence. In the *Terrestrial Manual*, diagnosis of FMD is by virus isolation or by the demonstration of FMD viral antigen or nucleic acid in samples of tissue or fluid.

The experts proposed that the text in the *Terrestrial Manual* be amended to clarify that it is essential to confirm the presence of FMDV by antigen or nucleic acid detection test. The Biological Standards Commission fully supported this proposal. Furthermore, the Commission proposed that a footnote should be added to Table 1 *Test methods available for the diagnosis of FMD and their purpose*, row "Virus isolation" column "*Confirmation of clinical cases"*, clarifying the need to confirm virus isolation by an antigen or nucleic acid detection test. Furthermore, the Commission agreed that depending on the agent in question, confirmation of a clinical case can involve agent isolation followed by an agent identification test. The Commission would review Table 1 of the virus chapters, on a case by case basis, to ensure that this point is clarified where appropriate.

The Scientific Commission also agreed with the FMD experts' proposal. Noting that there is no information about virus characterisation in the section of virus isolation of the *Terrestrial Manual* chapter, the Scientific Commission recommended that the experts review that section of the chapter too.

The revised chapter is included in the batch of chapters that have been approved to be circulated for first-round Member comment (see agenda item 3.1).

The Biological Standards Commission also agreed that the *Terrestrial Code* Article 8.8.1 needed to be amended as proposed by the experts to include a requirement to characterise the virus, and would advise the Code Commission to consider this comment.

9.2.2. Follow-up General Session: emerging recombinant LSDV strains, their correct diagnosis and notification)

See agenda item 3.3.2.

9.2.3. Review of assessments of two diseases against the listing criterion 3

The Biological Standards Commission reviewed with the experts assessment of West Nile fever and paratuberculosis against listing criterion 3[30] and agreed with their acceptance that both diseases fulfil this criterion.

9.3. Terrestrial Animal Health Standards Commission

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

9.3.1. Updates from the February 2021 Code Commission meeting

The Biological Standards Commission was updated by the Secretariat on the current topics under review by the Code Commission.

9.3.2. Technical questions on Chapter 11.10 *Infection with* Theileria annulata, T. orientalis *and* T. parva – reply for the Code Commission

The Biological Standards Commission's advice had been sought on comments from a Member regarding point 4) of Article 11.10.5. *Recommendations for importation from countries or zones not free from infection with* Theileria.

The Member questioned the need to subject animals to both serological and agent detection tests with negative results on samples taken on entry to the *establishment* given that the IFAT and microscopic examination are both recommended in the *Terrestrial Manual* for individual animal movement. The Biological Standards Commission stressed that the tests are not very sensitive and thus both are necessary: the Commission determined therefore that the word "and" is correct in the sentence rather than "or".

Still in point 4) of Article 11.10.5. the Member believed that it is impractical to have testing 5 days prior to shipment and recommended the same testing schedule that is used in the *Terrestrial Code* chapter on African horse sickness, where testing is conducted at least 25 days after entry to the isolation establishment.

The Biological Standards Commission agreed that 5 days is too short a time to undertake the tests and agreed to change it to "at least 25" days. The Commission proposed the following amendments to the Article:

4. were subjected to serological and agent detection tests with negative results on samples taken immediately prior to ~~on~~ entry and ~~five~~ at least 25 days after entry into the isolation *establishment* ~~before shipment~~.

9.4. Aquatic Animal Health Standards Commission

None at this meeting.

30 Criterion 3: Reliable means of detection and diagnosis exist and a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections or infestations

10. Matters of Interest for Information

10.1. Update on OFFLU

The Commission was briefed on OFFLU[31]'s contribution to the WHO Consultation on the Composition of Influenza Virus Vaccines on avian influenza and swine influenza for the period September 2020 to February 2021. Data for 43 H5 and 13 H9 genetic sequences were contributed by animal health laboratories in countries representing Africa, the Americas, Asia, Europe and Oceania to which 150 H5 and 3 H9 sequences from online resources were also added. Additionally, 504 swine H1 and 174 swine H3 global swine influenza A virus sequences from the reporting period were analysed along with 32 genetic clades of H1 and H3 and antigenic analyses was submitted. These data were used by WHO to update the candidate vaccine viruses for production of human vaccines against zoonotic viruses of concern. The data collection for the September 2021 WHO meeting is currently underway.

The OFFLU Steering and Executive Committees met virtually in July 2021 to review the progress in the work plan of OFFLU technical activities. The Committees received updates from avian, swine, equine, wildlife, epidemiology and socioeconomics technical activity leaders and future course of action points identified.

In July 2021, the equine influenza experts participated in the virtual meeting of the OIE expert surveillance panel on equine influenza vaccine composition to update the vaccine recommendations for the equine industry in 2021.

The OFFLU annual report 2020 was published on the website and disseminated widely.

10.2. Update on rinderpest

The Commission was informed that the inspections of the laboratories in India and Ethiopia related to designation as an FAO-OIE rinderpest holding facility (RHF) and a rinderpest vaccine production facility, respectively, are still on hold while awaiting the lifting of COVID-19 related travel restrictions. The seven designated RHF, or those for which designation was extended in 2019, would need to be reassessed for extension of their designations in 2022, as the term of the RHF's mandate is 3 years. Kazakhstan had destroyed their rinderpest virus containing materials (RVCM) in 2021, leaving only six OIE Members holding RVCM. Finally, the Commission was informed that as a result of an open call for proposals, the OIE had awarded the Institute for Infectious Animal Diseases, Texas A&M AgriLife Research, United States of America, and the Royal Veterinary College, United Kingdom, acting as a consortium of OIE Collaborating Centres, the contract for undertaking a risk assessment of rinderpest re-introduction 10 years after its eradication, considering the current distribution of RVCM and emerging technologies. This work, which would include a review of progress done in sequestration and destruction over the past 10 years, would be ready by the end of the year.

10.3 Update on Global Laboratory Leadership Programme

The GLLP[32] Partnership will enable the OIE to provide more comprehensive laboratory systems workforce development to Veterinary Services' stakeholders and to expand access for Veterinary Services staff. GLLP will complement existing face-to-face training and provide access to virtual training through the OIE's Training Portal. The aim of the OIE's involvement in this partnership is to ensure that animal health laboratory leaders can benefit from laboratory leadership training, that their context and

31 OFFLU: Joint OIE-FAO Network of Expertise on Animal Influenza.
32 GLLP: the Global Laboratory Leadership Programme

needs are included and addressed, and that they have access to training materials, both through the OIE Training Portal and through WHO's Health Security Learning Platform.

To support the application of the GLLP's Laboratory Leaders Competency Framework, the OIE worked with its GLLP partners to finalise the first version of the GLLP Learning Package materials (three Sections: Laboratory Management; Laboratory Leadership; and Laboratory Systems; nine units and 42 modules). All materials have been adapted to have a strong One Health focus, although environmental health expertise is still needed. This version is currently available for GLLP partners' access only on the WHO Health Security Learning Platform for piloting and testing. 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.

Next steps include incorporating additional modifications from testing and piloting experience in order to publish open-source versions of all GLLP Learning materials by mid-2022.

10.4. The potential role for BCG vaccination in global efforts to control and eradicate bovine tuberculosis

The OIE Reference Laboratory for bovine tuberculosis in the United Kingdom had submitted a technical discussion paper on the potential role for BCG[33] vaccination in global efforts to control and eradicate bovine tuberculosis. The Reference Laboratory is developing a new approach to the control of bovine tuberculosis based on vaccination by subcutaneous injection of BCG and complementary use of an associated DIVA skin test to identify infected animals within a vaccinated population instead of the conventional tuberculin skin test. The approach is aimed at replacing the current control method of testing and slaughtering infected animals.

The Commission agreed that the BCG vaccination and DIVA skin test approach looks very promising and could provide an alternative to bovine tuberculosis control that could be used in certain countries in certain situations. The Commission felt however, that it is premature to include it in the *Terrestrial Manual* at present. The Commission encourages the Reference Laboratory to continue with the validation of the DIVA approach and would welcome regular progress reports. Before considering its inclusion, the Commission would expect to receive strong evidence that this new methodology and control strategy is appropriate and safe and has been fully validated to the OIE standard (see also agenda item 3.1).

The Commission is aware that the inclusion of this approach in the *Terrestrial Manual* will have an impact on the *Terrestrial Code* in particular how the *Code* defines freedom from tuberculosis for trade purposes – currently defined by measuring reaction to tuberculin. The DIVA approach would be a complete shift in the current tuberculosis control strategy that would need to be clearly explained and presented to the Members, many of which do not currently allow vaccination. The Reference Laboratory's validation data will also assist the OIE to better present this new approach to Members.

10.5. Update on COVID-19

The Commission was updated on the activities of the OIE in response to COVID-19. The OIE remains mobilised and is working with its network of experts and partners, including WHO and FAO, to support its Members in responding to this One Health crisis by taking a multi-sectoral approach. With the support of the *ad hoc* Group on COVID-19 and the human–animal interface, the OIE is regularly assessing the reports of both natural and experimental infection in animals to inform the development of risk-based guidance and to adapt risk communication messages. The OIE regularly updates its Questions and

33 BCG: Bacille Calmette-Guérin

Answers Page on the COVID-19 portal, as well as the list of events reported by OIE Members of natural infection of animals with SARS-CoV-2 and the OIE Technical Factsheet on Infection of animals with SARS-CoV-2. The joint OIE and FAO advisory group on viral evolution of SARS-CoV-2 in animals continues to inform and advise the organisations on the on risks related to the evolution of SARS-CoV-2 (through mutation or recombination) in animal populations.

10.6. Update on Global Burden of Animal Diseases programme

The objective of GBADs[34] is to assess the economic burden of animal diseases in standardised terms of production loss, expenditure, and trade impacts. The accumulated data and analytical output will support evidence-based decision-making on investments in the livestock and aquatic animal sectors by various actors such as policy makers, the private sector, and donors. GBADs is currently developing methodologies and a prototype analytics platform. The GBADs methodology development will focus on populations, biomass and value of livestock and aquatic animals, on animal health ontologies, and on animal health loss envelope. A peer review of the programme's methodology following OIE processes is planned for the second half of 2022. The newly designated OIE Collaborating Centre for the Economics of Animal Health will operate in the European region while also supporting the development of similar consortia in other regions notably in Africa and the Asia-Pacific linking with GBADs case study implementation partners in Ethiopia and Indonesia, respectively.

11. Any Other Business

11.1. Work plan

The updated work plan was agreed and can be found at Annex 4.

11.2. Dates of the next Biological Standards Commission meeting

The Commission noted the dates for its next meeting: 7–11 February 2022.

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.../Annexes

34 GBADs: Global Burden of Animal Diseases programme

Annex 1

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Virtual meeting, 6–10 September 2021

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Agenda

1. Welcome and Commission Induction

2. Adoption of Agenda

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

3.1. Review of draft chapters received and their endorsement for circulation for first-round Member comment

3.2. Follow-up from pre-General Session webinars

3.3. Follow-up from the General Session

3.3.1. Chapter 3.5.8 *Equine piroplasmosis*

3.3.2. Chapter 3.4.12 *Lumpy skin disease*

3.4. Conclusions and recommendations from the OIE *Scientific and Technical Review* issue on diagnostic test validation science

3.5. Review of a validation dossier for a quantitative real-time PCR method for detection of *Taylorella equigenitalis* directly from swabs, and proposed text for Chapter 3.6.2 *Contagious equine metritis*

3.6. Request to update Chapter 3.6.11 *Glanders and melioidosis* to include a new recombinant antigen-based ELISA

3.7. Request to update Chapter 3.1.1 *Anthrax* to include a new easier to produce *Bacillus anthracis* capsule stain

3.8. Including OIE *Terrestrial Manual* chapters in national regulations: requirement to mention the most recently adopted version of the OIE Standard

3.9. Review of *Terrestrial Manual* status: selection of chapters for update in 2022/2023 review cycle

4. OIE Reference Centres

4.1. Applications for OIE Reference Centre status

4.2. Changes of experts at OIE Reference Centres

4.3. Review of new and pending applications for laboratory twinning

4.4. Inconsistencies among OIE Reference Laboratories in results obtained using the real-time RT-PCR for African horse sickness

Reference Laboratories – Implementation of the SOPs

4.5. Follow-up February meeting: further feedback from the Laboratories that are not complying with the key ToR according to their 2018 annual report

4.6. Feedback from the Laboratories that are not complying with the key ToR according to 2019 annual report

4.7. In-depth review of all annual reports for activities in 2020

Collaborating Centres – Implementation of the SOPs

4.8. Follow-up February meeting: feedback on the mapping exercise for the existing Centres against the list of main focus area and specialties

4.9. Follow-up February meeting: feedback from the Centres that are not complying with the key ToR according to 2019 annual report

4.10. Follow-up September: feedback on the review of the 5-year work plans received from Collaborating Centres

4.11. In-depth review of all annual reports for activities in 2020

Reference Centre networks

4.12. Update on the three Reference Laboratory networks (rabies, PPR and ASF)

5. *Ad hoc* Groups

Update on activities of past *ad hoc* Groups

5.1. *Ad hoc* Group on Replacement of the International Standard Bovine Tuberculin (ISBT): update on the replacement ISBT

5.2. *Ad hoc* Group on the revision of *Terrestrial Code* chapters regarding the collection and processing of semen of animals, 9 November 2020 to 15 January 2021

5.3. *Ad hoc* Group on Sustainable Laboratories

6. International Standardisation/Harmonisation

6.1. OIE Register of diagnostic kits:

6.1.1. Update and review of new or renewed applications

6.1.2. Conclusions from the OIE *Scientific and Technical Review* issue on diagnostic test validation science

6.2. Standardisation programme

6.2.1. AFNOR: creation of a European Technical committee for diagnostic standardisation

7. Follow-up from the General Session

8. Conferences, Workshops, Meetings

Future Conferences, Workshops, Meetings

8.1. ISWAVLD, Lyon, France, 2023

9. Liaison with other Commissions

9.1. Horizontal issues among the Specialist Commissions

9.1.1. Review of case definitions

9.2. Scientific Commission for Animal Diseases

9.2.1. Proposed amendments to the *Code* and *Manual* chapters on FMD to harmonise the description of infection with FMD virus

9.2.2. Follow-up General Session: emerging recombinant LSDV strains, their correct diagnosis and notification

9.2.3. Review of assessments of two diseases against the listing criterion 3

9.3. Terrestrial Animal Health Standards Commission

9.3.1. Updates from the February 2021 Code Commission meeting

9.3.2. Technical questions on Chapter 11.10 Infection with *Theileria annulata, T. orientalis* and *T. parva* – reply for the Code Commission

9.4. Aquatic Animal Health Standards Commission

9.4.1. Nothing for this meeting

10. Matters of Interest for consideration or information

10.1. Update on OFFLU

10.2. Update on rinderpest

10.3 Update on Global Laboratory Leadership Programme

10.4. The potential role for BCG vaccination in global efforts to control and eradicate bovine tuberculosis

10.5. Update on COVID-19

10.6. Update on Global Burden of Animal Diseases programme

11. Any other business

11.1. Workplan

11.2. Dates of the next Biological Standards Commission meeting: 7–11 February 2022

12. Meeting review

Annex 2

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Virtual meeting, 6–10 September 2021

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Annex 3

Original: English
June 2021

MEETING OF THE OIE *AD HOC* GROUP ON SUSTAINABLE LABORATORIES

1-4 June 2021

The OIE *ad hoc* Group on Sustainable Laboratories met for its third meeting 1-4 June 2021. Due to COVID-19, the Group was not able to meet face-to-face. Given the Group's membership and distribution across time zones, zoom meetings were held over four days to cover the agenda items and achieve the meeting's objectives. Additional zoom meetings will be convened on an *ad hoc* basis to further develop the action items of the meeting.

Welcome and Meeting Objectives

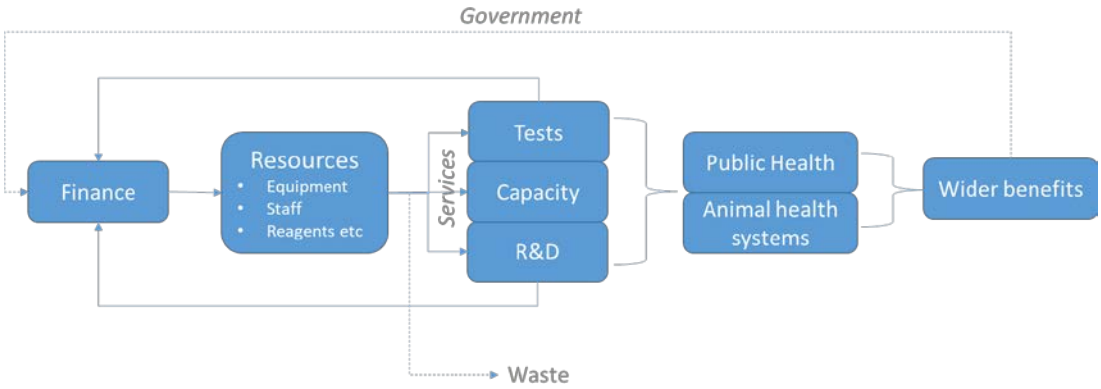
Ms Jennifer Lasley, OIE Sustainable Laboratories Programme Manager of the Preparedness and Resilience Department, welcomed the participants and underlined the importance of taking stock of the work done to date in three key areas—economic indicators for laboratory sustainability, mission methodology, and data—to consider proposed next steps for each area of work and agree on path forward, and to address specific objectives for each thematic session.

Dr Ana Maria Nicola resumed as Chairperson. Mrs Barbara Martin and Mr David Korcal, along with OIE staff, acted as rapporteurs. The adopted Agenda and List of Participants are presented in Appendices I and II of this report, respectively.

Economic Indicators of Sustainable Laboratories

Dr Nick Lyons presented an update on behalf of the Economics team[1] on the development of the economic indicators for laboratory sustainability. An Expert Opinion Elicitation (EOE) exercise was conducted with laboratory management experts to assess the importance and feasibility of proposed key performance indicators (KPI) for economic sustainability of a laboratory system network. The aims of the indicators are to capture information needed by managers to improve decision making, in a way that is easily understandable, and is based on economic sustainability-related outcomes for effective laboratory services.

Figure 1: Economic Sustainability cycle framework for laboratory systems.



1 Composed of J Rushton and N Lyons of University of Liverpool, and Jessica Cargill, Miguel Gonzales, and Terry McElwain of Institute for Infectious Animal Diseases (IIAD), OIE Collaborating Centre for Biological Threat Reduction.

Dr Lyons reviewed the methodology of the EOE, in which the Group participated. The participating experts categorised each indicator's importance and feasibility as Low, Medium, or High (with an option for no opinion). The exercise was completed by 38 respondents from 28 countries. The methods, results, and conclusions to recommend a list of economic indicators for laboratory sustainability will be detailed in their final report (due in fourth quarter 2021), at which point the Group will make contributions.

Dr Lyons also presented outputs under consideration: benchmarks, as reference points that could be used by Members to see how their performance compares with *peers*, and the development of levels (similar to the PVS Tool) in thematic areas—financial, services, and resources—to evaluate and identify areas in the laboratory network where economic sustainability may be compromised and can facilitate priority and target determination. Regarding benchmarks, Dr Lyons explained the importance of putting the tool and its outputs into context and considering geography, the importance of livestock sector, and the economic status of the country. The Group suggested a heat map or traffic light system visualisation of tool outputs instead of prescriptive targets, since this type of format will present the risks to laboratory sustainability in certain areas and for specific indicators.

The Group thanked the experts for their work and reiterated that the aim of the economic indicators for laboratory sustainability is to develop an open-source tool for Members to understand areas where resource sustainability can be improved in the laboratory system. The tool is being developed to be used in conjunction with the PVS Sustainable Laboratories mission and tools, before or after a planned mission, or as a first look at laboratory sustainability in the laboratory system, prior to a request for a PVS Sustainable Laboratories Mission.

The Group participated in an exercise to assess the availability and accuracy of data for each indicator within their own laboratory networks, and if they should be included in a "sustainability index", followed by a pairwise ranking of the indicators. The results of the Group's work will inform the final revisions of the proposed indicators, modelling, and testing. Some refinements of the KPI definitions are needed. Dr Lyons reported that preliminary results of the exercise reflect that "Service" KPIs are easily available and are of the highest quality, followed by the "Resource" KPIs, with the most uncertainty over "Financial" KPIs. At this stage, all KPIs could be included in a sustainability assessment subject to proposed changes by the Group.

The Group developed a working definition for economic sustainability of laboratory systems as "sufficient resources (public and/or private) for the provision of accurate and timely data, information, and laboratory services that continually responds to the demand of the laboratory network's respective animal and public health sectors" to assist continued work in this area and to complement the working definition developed by the Group of "sustainable laboratory system"[2]. The Group agreed that this definition is necessary for next steps, notably for advocacy development and the writing of the position paper on investment needs for sustainable laboratories.

Dr Lyons informed the Group on additional outputs of their work. Given the different types of economic analyses that could bring benefit to a laboratory system, the economic experts indicated that a full cost-benefit analysis (CBA) or cost-effectiveness analysis (CEA) can take several months to complete and therefore a "one-size fits all" tool is not well adapted to complement the PVS Sustainable Laboratories mission or tools approach at this time. They stated that the PVS Sustainable Laboratories support and the Economic Indicators for laboratory sustainability efforts towards appropriate data collection and analysis will provide needed good practices for countries towards conducting CBA and CEA, an excellent contribution towards sector-wide efforts like Global Burden of Animal Diseases (GBADs) to understand the benefits of Veterinary Services and its contributions to preparedness and prevention. The experts will produce guidance on how to do a cost-benefit analysis focussing on investments in biosafety and biosecurity, with considerations for how inputs/outputs of PVS Sustainable

2 A system/network of laboratories that can maintain appropriate safety, security, and quality on a path towards compliance with OIE International Standards, taking into account social, environmental, and economic factors in its day-to-day operations for the benefit of the health system

Laboratories tools can be leveraged for CBA and CEA, by including examples using data from previous missions. The Group supported this proposal and looks forward to the outcomes of this work.

Ms Cargill presented a proposed outline for the position paper on advocating for sustainable laboratories. Proposed topics to be discussed in the paper are:

- introduction on role of laboratories in surveillance systems, emergency management systems, and research and balance between public and private funding, national and external investment;
- defining "economic sustainability for laboratory systems", demonstrating economic sustainability as critical in securing investments into laboratory systems, the ability of laboratory systems to advocate for themselves, benefit streams, and the ability to provide timely, accurate, safe, and secure diagnosis;
- overview of the PVS Sustainable Laboratories missions, tools, and discussion of gaps in some economic indicators;
- working towards an economic basis for sustainability through description of economic dynamics for veterinary laboratory systems so that Members understand economics as well as scientific and management components of their work, CBA (and when it is needed and appropriate), and the need for other economic tools to understand sustainability;
- development of a Sustainability Index with KPIs, based on EOE and benchmarking exercises and testing;
- case studies from 1-3 countries in the cohort tested against the KPIs;
- future directions and recommendations.

The Group agreed for continued development in this direction and that multiple publications in different formats for advocacy tools, like policy briefs, peer-reviewed articles, and a white paper would be helpful to address the topics proposed and to reach different audiences. The Group brainstormed different options for presenting the work to the public, like an OIE Scientific and Technical Review special issue on laboratory sustainability, a special session during the OIE Seminar or in general session of WAVLD on economic sustainability. Members of the Group were invited to contribute to the documents as authors. The Group proposed that revisions integrating sustainability into existing standards in the Terrestrial *Manual* could be proposed, potentially with a new chapter on considerations for economic sustainability of laboratory systems. The Group noted that this work will contribute to the transformative agenda proposed for laboratory strengthening by the OIE Preparedness and Resilience Department and following the Resolution 31[3] and its Technical Item "Lessons Identified From Before And During The Pandemic: How The OIE Can Support Veterinary Services To Achieve One Health Resilience" and towards the OIE 7th Strategic Plan.

The Group also made additional comments to be taken into account the next steps:

- Gender and age are important factors in relation to access to training and are important to sustainability and succession planning.
- Relative contribution indicator should be retained.
- AMR studies with the World Bank and useful models for this can be leveraged.
- OECD linkages with OIE can be leveraged on this work.
- Binding commitments at highest governmental and multilateral organisations should be sought in recovery and preparedness phases.

3 Presented and adopted at GS88.

Mission Methodology

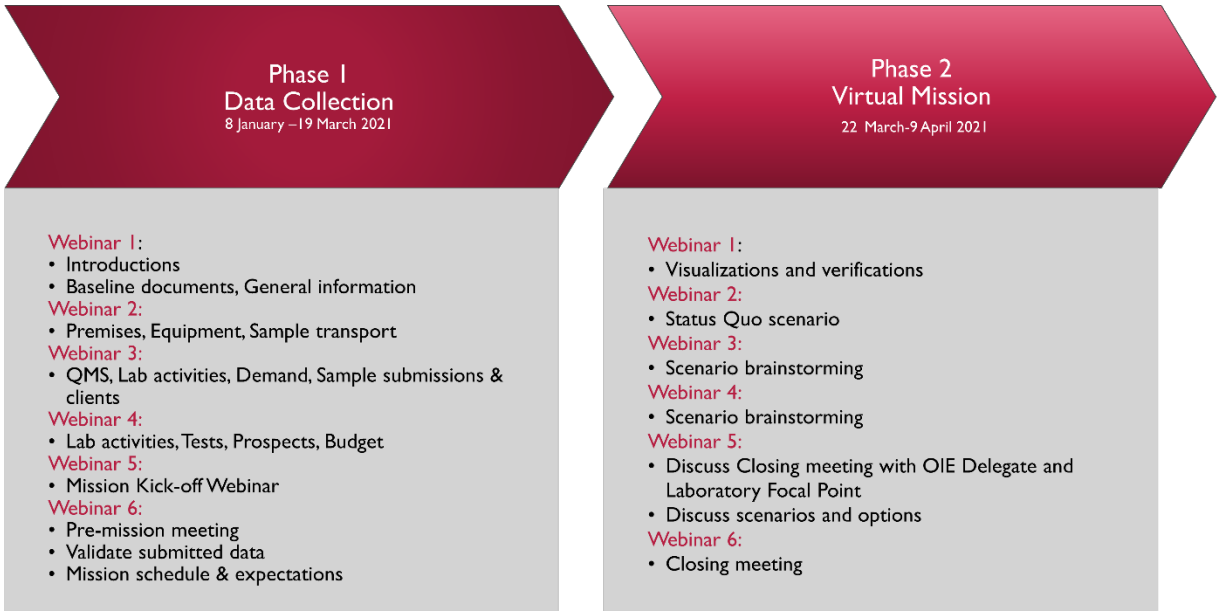
At its last meeting, the Group considered "virtual" PVS Sustainable Laboratories mission delivery and recommended piloting the approach and adapting the mission methodology to a virtual delivery. Since that time, the OIE decided to undertake a pilot remote PVS Sustainable Laboratories mission and proposed to Liberia, whose mission had been cancelled due to COVID-19 in March 2020. Liberia accepted to participate in this pilot in late 2020 and the mission occurred 22 March to 9 April 2021. Dr Ana Maria Nicola, Mr David Korcal, and Ms Barbara Martin served as the Expert team in conjunction with OIE Observers Ms Jennifer Lasley, Dr Valentyna Sharandak

and Mr Emmanuel Appiah. The Liberia Expert team presented their experience by mission phase, the lessons learned, and major innovations made. The advantages and disadvantages of a 100% remote mission delivery and recommendations were also presented.

The major innovations were presented to the Group:

- Developed the 1st full 100% remote mission approach;
- Developed and tested the data collection Phase 1;
- Developed and tested Phase 2 web-based approach, based on the previous Mission format;
- Developed Satisfaction Survey for mission participation by the country team;
- Developed and tested the New Data Entry Tool (Supply Tool replacement);
- Developed and provided videos to provide instruction on tool use;
- Utilized improved tool functionality to produce data visualisations for faster insight and feedback in Phase 1 and Phase 2;
- Provided clearer definition of the roles of country focal point;
- Conducted risk analysis for 100% remote mission delivery;
- Developed Mission supporting documents in early stages to increase understanding;
- Documented areas for improvement and additional work to be done for next missions;
- Developed templates for each meeting and stage to ensure more structure and quality control;
- Developed a Donor Questionnaire to be filled in by the OIE Delegate and Lab management to obtain relevant information about budget;
- Tested the report outline developed by AHG.

Figure 2: 100% Remote PVS Sustainable Laboratories mission: Liberia experience



The Liberia Expert team presented the results of the testing of the newly developed Satisfaction Survey (Microsoft Forms) for PVS Sustainable Laboratories Mission participants. Six participants in the mission (out of 9) filled in the survey. In general, the respondents agreed that the data entry tool was easy to use and navigate, the instructions were easy to understand, and that the data can be used to monitor their laboratory's level and performance over time. The amount of time required to fill in the tool still requires some effort in the respondent's opinion, but

automatic visualisations and dynamic dashboards are under development to add more value to this data collection phase and produce an additional output to complement the Mission Report for any PVS Sustainable Laboratories mission. The participants rated the overall success of the mission at 8.2 out of 10. The survey and results were reviewed, The Group suggested standardization of the response options for improved understanding and reporting of results.

Areas of improvement to be addressed in the next pilot missions include:

- Better define the Delegate's role in mission:
    - Develop Agenda for 1st webinar with Delegate & Country Contact Person.
    - Determine which data & documentation should be provided by Delegate (as opposed to Lab staff).
    - Request budget information from Delegate and donors.
    - Explain the need for baseline documentation and how to obtain it.
    - Standardise requests and timing for Delegate.
    - Determine with the Delegate which laboratories must participate.
- Address through methodology how to incorporate larger lab network;
- Further innovate and integrate Data Entry Tool and Integrated Demand/Calculation Tool;
- Continue work on compiling data from multiple laboratories in a network and migrating data to database;
- Continue work to streamline the data entry process and develop additional multimedia materials to support those providing information;
- Address access to information of the lab leadership by engaging the Delegate more and creating connections between the national laboratory and VS;
- Provide additional explanation of the importance of information requested;
- Develop "pre" Phase 1 webinars or training videos to explain purpose to Member Country;
- Provide more exposure to the virtual mission format prior to the actual mission along with opportunities for discussions to increase understanding and assist with the mission process. The webinars and training should be available in OIE languages and include the following:
    - Description and instruction of the tool.
    - Baseline documents video.
    - Mission overview.

During the next AHG meeting, the similarities and differences between face-to-face and remote pilot missions will be used to highlight the new advancements.

The Expert team reported that the revised report outline developed by the Group succeeded in reducing the report to a more accessible format and keep the detail in the appendices of the report.

The Group agreed that the next months should be spent to better develop the communication materials as additional remote missions occur. The time between remote missions should be used to advance on materials for the different Mission phases. Another option to consider is to provide mission related training to the OIE laboratory focal points at the next opportunity in the calendar.

The Group agreed that the effort to convert the face-to-face mission format to a 100% remote delivery was excellent and the experience was overall a positive one, given the challenges experienced. The current COVID-19 pandemic has illustrated even more the need for such an approach. The Group was encouraged by the high quality of the first pilot mission materials developed and encouraged experts that each mission will improve progressively. The Group congratulated the Experts for making the process more documented, standardized, and streamlined for future experts to implement, and was recognised as a step forward.

The Group recommended that a virtual delivery component in the data collection Phase 1 (through webinars) could be used in the future, even when face-to-face missions are possible again. The Expert teams suggested that once international travel is possible again, a blended model with involvement of regional experts should be considered where Phase 1 occurs remotely, and the remainder of the Mission occurs face-to-face.

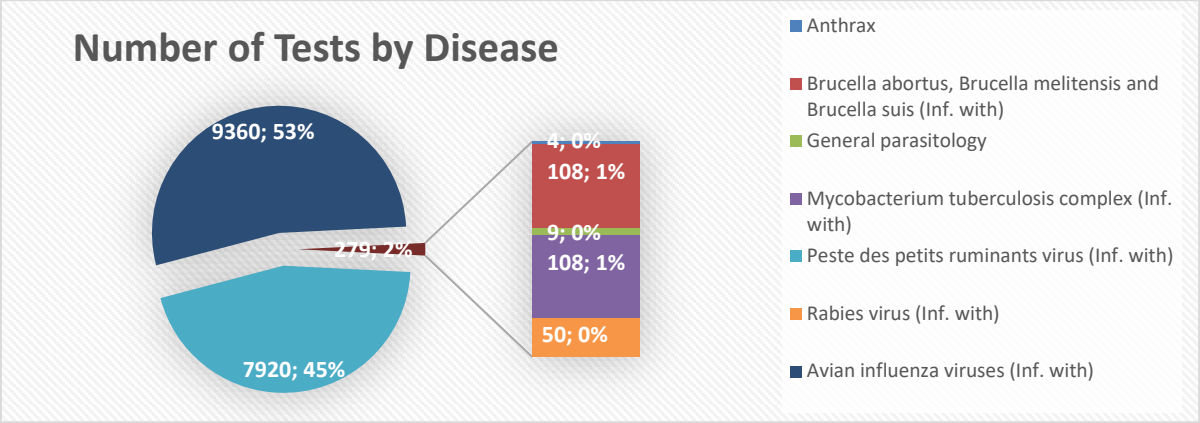
The Group agreed that it is fruitful to explore further connections and synergies between the OIE Twinning Programme and projects and PVS Sustainable Laboratories missions and how they can inform one another better and contribute to each other's outcomes. For example, sharing the report would be a great way to improve the connections.

Data Collection and Visualisation

At its last meeting, the Group considered testing transferring the PVS Sustainable Laboratories mission data entry, calculations, visualisations, and tools to an online platform, and Mr Appiah, Ms Lasley, and Mr Korcal presented the accomplishments to date and gave indications on the direction of future development towards this goal.

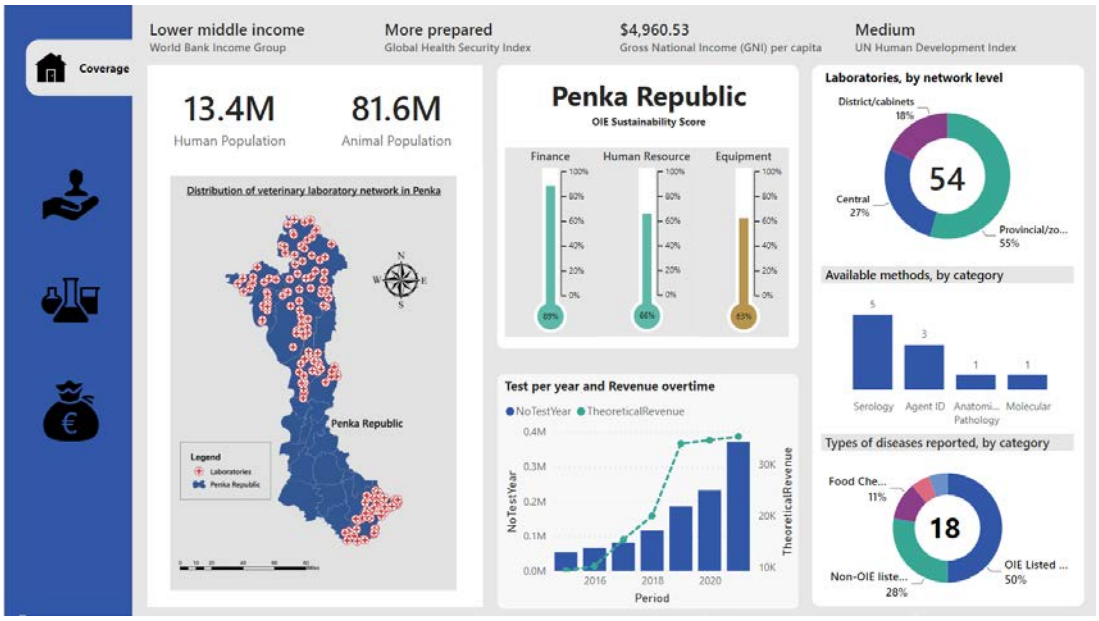
Mr. Korcal provided a demonstration of the Data Entry Tool (DET) and explained that the offline tool is still in MS Excel format since widely accessible. The Group's recommendations from the first and second meetings on data collection and management were implemented and integrated into a beta version which was demonstrated to the Group. The DET is markedly different as there has been much integration and improvement. The DET uses macros and has been tested for functionality on Macs and PCs. A dashboard lists all the data categories and provides navigation buttons and user forms for data entry. Instructions are available as well as summarized in a printable format. The process for securely uploading data to OIE SQL database has been developed and includes saving data as CSV and then exporting aggregated data to the OIE SQL database. The process can be used for either individual laboratories or a network of laboratories. Data from the Liberia virtual mission were used to demonstrate the data visualizations that were generated as data were entered. Next steps in tool refinement and development include a streamlined dashboard and the ability to navigate to separate dashboards (personnel, demand for services).

Figure 3: Example of a visualization from the DET, on test demand by disease



Mr. Appiah and Ms. Lasley provided an overview of the country dashboard mock-up (Figure 4). An overview of the IT high-level plan for online web portal development was provided with accomplishments to date. Phase 1 (data structure management) was completed December 2020 and included database structure development, data aggregation, data cleaning, database scripting, and data migration. Phase 2 (Data insights and dashboard) is currently underway and is scheduled to be completed July 2021. The PVS Lab dataset is from 16 member countries (2012-2019) with 168 laboratories and more than 193,000 pieces of data. The Equipment survey dataset includes data from 136 Member Countries with 223 laboratories providing information on over 68k+ pieces of equipment. Calculations are used in the background to visualize the cohort data in a dashboard format.

Figure 4: Country mock-up dashboard for PVS Sustainable Laboratories mission (all data is made for demonstration purposes only and once finalised, will be translated into Spanish and French)



Phase 3 (Portal and e-forms), scheduled to begin in 4th quarter 2021 and continue through 2023. The goal of Phase 3 is real-time data visualization and analysis and will involve going from offline MS Excel tools to a secure, online, integrated web portal with outputs that can be seen by different audiences (MC, PVS experts) with different levels of access. A country view dashboard mock-up was demonstrated (Figure 4). Buttons for separate dashboards for economic, laboratory management, and PVS Sustainable Laboratories Mission were presented with many functionalities and presentations possible according to the indicators that the AHG will decide over the coming months. Data will be able to be viewed by network (country), but there could also be an option to view by individual laboratory, which makes it an appealing tool for Delegates, Focal Points, and Laboratory Leaders to use as a management tool at the laboratory and network levels. Benchmarks and AHG input will be used to finalize mock-ups for different uses, and once consultations with Members occur, translation of content into Spanish and French will be possible. Following the presentation and demonstration, the Group discussed next steps and made detailed recommendations for immediate implementation.

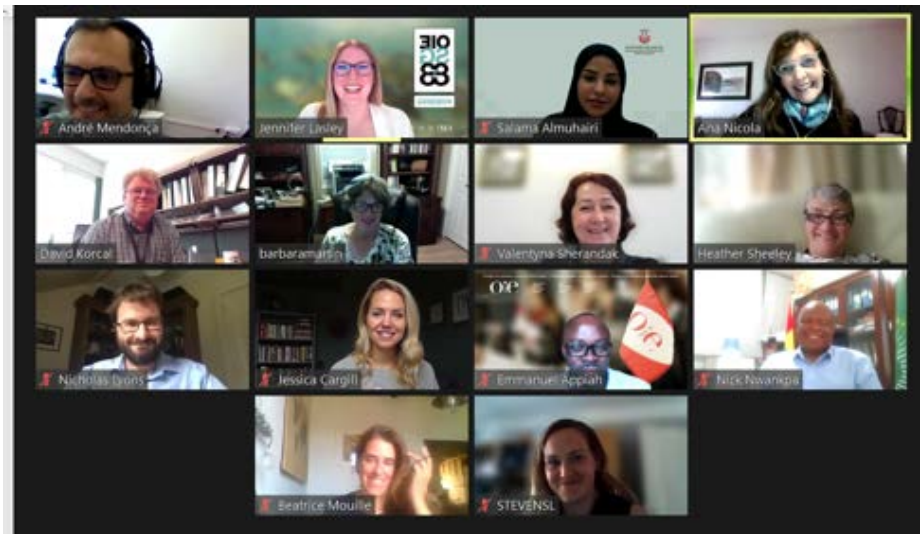
Additional considerations for next steps

The recommendations from the Group's first and second meetings determined the goals for continued work of the Group. The Group's input has been implemented throughout the remote mission approach, analysis of data and leveraging the data provided, the beta version of the Data Entry Tool, while also taking into account feedback from Experts who had used the tools in the past and data integrity best practices. Ms Lasley reiterated the achievements made since the last meeting of the Group to take stock of the Group's outputs and achievements to date.

The Group agreed that much progress had been made and agreed that the following need to be considered as the project progresses:

- Determine how to demonstrate economic sustainability at the country level and how it impacts the laboratory network;
- Follow up missions and impact evaluations can occur in parallel, to measure impact for all missions, not just those that request PVS Lab or other follow-up missions;
- The Web portal will also allow the follow up over time according to the Members interest in using the portal as a management information system;
- Follow Up missions can occur in virtual format;
- Prepare a survey for countries to determine progress;

- Determine how to encourage regional sharing and analysis to better understand transboundary challenges;
- Consider adding other fields of expertise to the Mission Expert team such as economists and epidemiologists;
- Form a subgroup to determine priorities for multimedia tool (video) development;
- A subgroup was formed to work on Country mission manual outline development;
- Develop a communication plan to inform stakeholders of progress and ensure impact on policy makers regarding guidance on investment in laboratory systems;
- Tools and documentation are not yet finalized and may impact activities;
- Develop pre-mission action plans that can be used as a template for future missions;



The Group expressed their satisfaction with the improvements presented at the meeting and congratulations were extended to those working on the project day to day.

The next meeting of the *ad hoc* Group is targeted to be held in mid-2022, date to be determined. *Ad hoc* meetings will be scheduled with subsets of the committee to advance on particular tasks.

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON SUSTAINABLE LABORATORIES

Paris, 1–4 June 2021

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Appendix II

MEETING OF THE OIE *AD HOC* GROUP ON SUSTAINABLE LABORTORIES

1-4 June 2021

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PROPOSED AGENDA

Day 1 (June 1): Economics Team outputs

- Objectives:
  - To share progress on EOE and to finalise the list of indicators
  - To demonstrate models developed to date
  - To discuss next steps proposed and the Group's perspectives
  - To examine impact of integration of new variables into Data Entry Tool
- Presentation on KPI development and results of EOE (30 minutes)
- Exercise on KPIs (30 minutes)
- Feedback from groups on KPI exercise (30 minutes)
- Presentation on the proposed advocacy paper (with discussion)

Day 2 (June 2): Liberia pilot mission outcomes

- Objectives:
  - To present the major innovations in mission methodology including remote delivery
  - To take stock of the work done to date
  - To discuss next steps proposed and the Group's perspectives
- Major innovations in mission methodology
- Recommendations in preparation for next mission and the future
- Discussion

Day 3 (June 3): Data Entry Tool and data visualisation development

- Objectives:
  - To demonstrate the Data Entry Tool and its major innovations
  - To demonstrate a country dashboard (mockup) and preliminary dashboards on the cohort analysis
  - To discuss next steps proposed and the Group's perspectives
- Data Entry Tool
- Power BI Dashboards
- Discussion

Day 4 (June 4): Conclusions

- Conclude any remaining agenda items
- Project changes
- Taking Stock: Accomplishments to date
- Next steps
- Discussion
- Closing

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Annex 4

Work Programme for the OIE Biological Standards Commission

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 2021
	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 list of OIE validated tests to be published on the OIE Website	
	a) Develop a template for the validation data that would be requested of applicants wishing to add their test to a future list	For February 2022
	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 link of validated tests mentioned above	
	a) Develop a template for this new section.	For February 2022
Collaborating Centres	1) Implementation of the adopted SOPs:	For February 2022
	a) review the final "map" that has resulted from the mapping exercise	February 2022
	b) review the remaining submitted or re-submitted 5-year work plans	February 2022
	2) Send feedback to Centres re: review of annual reports 2020	October 2021
Reference Laboratories	1) Put under-performing labs on watch list	October 2021
	2) Follow up of in-depth review of all annual reports for activities 2018 onwards: create document detailing past history of annual reports,	For February 2022
Reference Centre Networks	1) Follow up with the three newly launched Reference Laboratory networks (ASF, PPR and rabies)	On-going
Standardisation/ Harmonisation	1) Project to extend the list of OIE approved reference reagents	On-going
	2) Update the existing guidelines, and include a template as an annex for the data to be submitted with a request for approval to be added to the list of approved reagents	On-going
	3) Project to develop Replacement International Standard Bovine Tuberculin: finalise report and propose for adoption	For February 2022
	4) Review the conclusions from the OIE *Scientific and Technical Review* issue on diagnostic test validation science re: the OIE Procedure for the Registration of Diagnostic Kits	February 2022

Subject	Issue	Status and Action
***Ad hoc* Groups**	1) *Ad hoc* Group on Sustainable Laboratories	On-going
	2) *Ad hoc* Group on the revision of *Terrestrial Code* chapters regarding the collection and processing of semen of animals	On-going
Projects	1) Veterinary Biobanking (project)	Ongoing
	2) High Throughput Sequencing and Bioinformatics and Computational Genomics (HTS-BCG)	On hold awaiting funding
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	Engaging with the ongoing processes around performance issues with Reference Labs	On-going
Twinning Programme	Assess the status of the post-twinning labs: dashboard. Gather feedback from the labs, way forward. Review geographical distribution	For September 2022
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 2022