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

Virtual meeting, 15–18 September 2020

A virtual meeting of the OIE Biological Standards Commission was held from 15 to 18 September 2020.

1. Welcome

Dr Matthew Stone, Deputy Director General (International Standards and Science) welcomed the Biological Standards Commission (the Commission) and thanked the members for taking time from their busy schedules to support the work of the OIE, extending this thanks to their employers and national governments. He thanked the Commission for its support during the organisation's response, including the reports prepared to ensure OIE Members remain well briefed on the activities of the Specialist Commissions following the cancellation of the General Session for 2020. Dr Stone noted the OIE's ongoing adaptation of its work programmes to the restrictions imposed as a result of the COVID-19 pandemic, with many successful virtual expert meetings now having been held ensuring that the OIE's productive output has continued thanks to the hard work of staff and the understanding and dedication of our expert community. Although the impacts of the global pandemic continue, and the scientific understanding of its root causes, mitigating and exacerbating factors is yet incomplete, the OIE continues its internal reflection on our role to support our members in the face of new priorities around emerging disease risk mitigation, resilience and preparedness. Concrete proposals in this respect will soon emerge, and we will look to the expert networks of our members and partners for implementation support, and funding support from our resource partners. These activities will also engage the Specialist Commissions, and therefore need to be considered in work programme prioritisation. Dr Stone noted the currently open call for nominations for the elections in 2021 for Specialist Commissions. He also provided the Commission with a summary of the performance evaluation process that all experts of Specialist Commissions would be participating in, as the concluding phase of the new Specialist Commission performance management system. This would result in a confidential report to OIE Council in February 2021.

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 comments received on chapters that would have been proposed for adoption in May 2020

As a result of the COVID-19 pandemic, the OIE Council decided, in agreement with the Director General, that the OIE 88th General Session for May 2020 would be postponed until 2021 and that alternative procedures to address key institutional and administrative matters would be instigated. As a consequence, no new or amended chapters for the *Terrestrial Manual* were proposed for adoption in 2020. Chapters that were to be proposed for adoption in 2020 will be proposed for adoption in May 2021. All relevant texts that were to be proposed for adoption in May 2020, which had been circulated in the February 2020 report, were open for one additional round of comments. Only substantial comments that had not been submitted before were considered. As stated in the February 2020 report, texts (incorporating any revisions resulting from this process) will be circulated with the February 2021 report as the versions to be proposed for adoption in May 2021.

Comments had been received from: China (People's Rep. of), Chinese Taipei, European Union, India, New Zealand, Switzerland.

The Commission reviewed the comments and approved the chapters for proposal for adoption at the 88th General Session in May 2021. A brief summary of the main amendments are:

2.1.2. Biotechnology in the diagnosis of infectious diseases: the advantages and strengths of isothermal amplification were deleted from Section A.3 as they are described in the previous two paragraphs; the Commission agreed that the techniques described in Section A.4. *Diagnosis by restriction fragment length polymorphisms* (*RFLP*) *and related DNA-based approaches* are not front-line diagnostic tools and so changed the title to "*Analysis by restriction fragment length polymorphisms* (*RFLP*) *and related DNA-based approaches*". In Section C.5.1 *Coxiella burnetii* was added as the causative agent of Q fever.

3.1.7. Epizootic haemorrhagic disease (infection with epizootic haemorrhagic disease virus): in the summary, the number of non-structural proteins coded for by the EHD virus was changed from "five" to "at least four", and the time period post-exposure for antibodies to be detectable was changed from "between 10 and 14 days" to "from 8 days"; still in the summary a request to change serogroup-specific "RT-PCR[1]" to "real-time RT-PCR" as one of the assays for detection of EHD virus was rejected as "RT-PCR" covers both conventional and real-time assays and the Commission did not want to limit the list to real-time RT-PCR; in Sections B.1.2.1 and B.1.2.2, the target genes of the PCR methods described were corrected; a sentence in Section C *Requirements for vaccines* was deleted as it referred to bluetongue and not EHD.

3.1.8. Foot and mouth disease (infection with foot and mouth disease virus) (Method of [vaccine] manufacture only): no comments received.

3.1.10. Japanese encephalitis (vaccine section): one Member requested reinstatement of the mouse inoculation test, but the Commission reconfirmed its removal as effective *in-vitro* methods exist and the absence of a method from the *Terrestrial Manual* does not mean that it cannot be used rather that it is not recommended by the OIE.

1 RT-PCR: reverse-transcription polymerase chain reaction

3.1.11. Leishmaniosis: minor editorial amendments to improve clarity; included a sentence and a reference to LAMP[2] as an alternative method for genetic analysis; added text and a reference to cross reactions found in dogs with *Trypanosoma* spp. using ELISA[3].

3.1.15. Paratuberculosis (Johne's disease): in the summary reinstated microscopy as one of the methods for confirming a diagnosis of paratuberculosis as faecal Ziehl–Neelsen staining is included in Table 1 *Test methods available for diagnosis of paratuberculosis and their purpose*; removed mention of the complement fixation test from the summary, and kept mention of the agar gel immunodiffusion test clarifying that it remains a valuable test for the detection of paratuberculosis in sheep; maintained deletion of the CFT from Table 1 but added text to Section 2.2. explicitly stating that the CFT works well on clinically suspect animals, but does not have sufficient specificity to enable its use in the general population for control purposes. Thus, the CFT is not recommended for control purposes nor for individual animal testing prior to international movement.

3.1.21. *Trypanosoma evansi* infection (surra in all species): added deer to the list of susceptible species; added a sentence and a reference stating that *Trypanosoma evansi* was considered a malignancy of *T. brucei* as this is an important characteristic of *T. evansi*; a proposal to delete the formol gel test was not accepted as it is the method of choice for camels.

3.3.3. Avian infectious laryngotracheitis: one comment received regarding a typo.

3.3.4. Avian influenza (infection with high pathogenicity avian influenza viruses): amended in line with a proposed revision to the definition of high pathogenicity avian influenza in the *Terrestrial Animal Health Code* (*Terrestrial Code*)*;* as proposal for adoption was postponed, a thoroughly updated version of this chapter has been prepared and endorsed for circulation for first-round comment (see item 3.3).

3.3.5. Avian mycoplasmosis (*M. gallisepticum*, *M. synoviae*): In Section B. 1.3.2. *16s-rDNA-PCR and denaturing gradient gel electrophoresis* a sentence regarding the method's suitability for use on DNA extracts from clinical specimens has been reinstated.

3.4.2. Bovine babesiosis: minor editorial amendments to improve clarity; a request to add more up-to-date molecular methods for detection of *B. bovis* and *B. bigemina* was put on hold as these methods are not sufficiently validated.

3.4.4. Bovine genital campylobacteriosis (vaccine section): no comments received on the vaccine section; as proposal for adoption was postponed, a further updated version of this chapter has been prepared and endorsed for circulation for first-round comment (see item 3.3).

3.4.5. Bovine spongiform encephalopathy: amended text reference to EU legislation and included a hyperlink.

3.4.8. Contagious bovine pleuropneumonia (infection with *Mycoplasma mycoides* subsp. *mycoides*): a suggestion to consult OIE WAHIS interface[4] for latest disease situation was included as the *Terrestrial Manual* is not appropriate place to list the countries that are recognised by the OIE as officially free of CBPP through adoption of an annual resolution.

3.4.10. Haemorrhagic septicaemia (*Pasteurella multocida* serotypes 6:b and 6:e): deleted Section B.1.2.7 because antimicrobial sensitivity testing is not a serotyping method and is not used to identify HS strains; made minor amendments to the PCR protocols.

2 LAMP: loop-mediated isothermal amplification
3 ELISA: enzyme-linked immunosorbent assay
4 http://www.oie.int/en/animal-health-in-the-world/the-world-animal-health-information-system/the-world-animal-health-information-system/

3.4.12. Lumpy skin disease (LSD): a request to delete electron microscopy from Table 1 was not accepted as the text reflect its deficiencies; deleted text in Section B.1.31 referring to PCR-based methods to distinguish between field and vaccine strains because emerging recombinant vaccine strains may not be recognised using these methods.

3.4.16. Animal trypanosomes of African origin (excluding infection with *Trypanosoma evansi* and *T. equiperdum*): the Commission noted that the taxonomy of Trypanosomes of African origin remains controversial and acknowledged that some studies considered that *T. evansi* and *T. equiperdum* evolved separately and therefore did not accept the proposal to consider *T. evansi* and *T. equiperdum* as a subspecies of *T. brucei*; a request to add a sentence on the high sensitivity and specificity of PCR methods was rejected as it applies to all PCRs and does not need to be restated here; added text and a reference to an FAO publication regarding the occurrence of *T. ingens* in domestic animals; did not agree to the proposal to state that *Trypanosoma lewisi* can be found in *Rattus* rodents as it is a parasite of other rodents.

3.5.8. Equine piroplasmosis: no comments received.

3.6.2. Rabbit haemorrhagic disease: text was added to the introduction to specify the susceptible host species in North America; a description was added to Section B.1.5 *Immunostaining* on findings in bone marrow and one reference was reinstated as it includes a description of renal mesangial cell positivity.

3.7.4. Contagious caprine pleuropneumonia: no comments received.

3.7.8. Ovine pulmonary adenomatosis (adenocarcinoma): no comments received.

3.7.9. Peste des petits ruminants (infection with small ruminant morbillivirus) (vaccine section only): no comments received.

3.8.1. African swine fever (infection with African swine fever virus): a sentence that had been inserted to recognise the existence of moderately virulent strains was modified to remove mention of the chronic form of the disease; the Commission did not agree to reinstate text on the role of the carrier and persistently infected wild pigs in eradication programmes as deletion of this text had been proposed in consultation with the Scientific Commission in September 2019 and no Member had commented on it then; as stated in the paragraph, the biological basis for the persistence of ASFV is still not well understood, nor it is clear what role persistence plays in the epidemiology of the disease; and finally the issue of disease control is not covered in the *Terrestrial Manual*.

3.9.2. Camelpox: no comments received.

3.9.5. Cysticercosis (including infection with *Taenia solium*): proposals to add text and references to genus-specific assays, along with the suggestion to add a new section on detection of taeniid eggs in environmental samples, food and water were deferred to the next update.

3.x.xx Middle East respiratory syndrome (infection of dromedary camels with Middle East respiratory syndrome coronavirus): deleted text from the summary referring to notification as this issue is not covered in the *Terrestrial Manual*; also in the summary deleted speculative text on the risk of spill-over transmission to humans; deleted the text in Section C. *Requirements for vaccines* as it is speculative and replaced with text on available candidate vaccines; nomenclature: the Commission agreed to leave the title of the chapter unchanged as *Terrestrial Manual* chapters are titled by disease name (Middle East respiratory syndrome) and in parenthesis the title of the corresponding chapter in the *Terrestrial Code*, which is the name of the infection.

NB: All amendments made in response to Member comments are highlighted in yellow in the chapters.

These chapters will be circulated with the February 2021 report.

3.2. Definition of peste des petits ruminants virus-containing material: proposal from the Code Commission that this definition be included in the *Terrestrial Manual*

The Commission suggested modifications to the definition of peste des petits ruminants virus (PPRV)-containing material proposed by the *ad hoc* Group on the Evaluation of PPR status of Members and endorsed by the Scientific Commission for Animal Diseases. On the question of including it in the *Terrestrial Manual*, the Biological Standards Commission agreed that a clear definition of PPRV-containing material is required for operational management of laboratories. However, noting that the definition of rinderpest virus-containing material is currently in the *Terrestrial Code*, the Commission felt that the PPRV definition should also be in the *Terrestrial Code* once the disease has been eradicated. For both rinderpest virus-containing material and PPRV-containing material, cross references to the *Terrestrial Code* chapter should be added to the corresponding *Terrestrial Manual* chapter so that those working in the diagnostic area can handle these materials appropriately, meet regulations relating to movement of samples and assess biosafety risks.

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

The Commission made one amendment to Table 1. *Test methods available and their purpose:* the title for tests in the first section of the Table has been changed from [tests for] "Agent identification" to [tests for] "Detection of the agent" as "detection" is a more appropriate word meaning detecting the presence of the agent in the specimen taken from the animal. This change will be applied to all the current draft chapters and to each chapter as it comes up for review.

The Commission reviewed 15 draft chapters and approved 15 for circulation, some subject to clarification of certain points by the experts, for first-round Member comment and eventual proposal for adoption by the Assembly in May 2021. The 15 chapters and a brief summary of the main amendments are:

1.1.1. Management of veterinary diagnostic laboratories: updated Section A.6.1 *Health and safety* by including information on hazards, risk assessments and responsibilities; expanded Section A.6.2 *Biosecurity* to include considerations of laboratories investigating new and emerging diseases; included in Section A.6.4 *Gene regulation* text on ethical behaviours in genetic manipulation; added a new section: B.4 *Disease surveillance*; expanded Section C.1. *Internal governance: policies and procedures* by referring to compliance with national legislation; and included in Section C.4. *Engineering and maintenance* text on the benefits of having a robust reliability programme.

3.1.3. Bluetongue (infection with bluetongue virus): extensively updated by the Reference Laboratory experts – improved the section on the description and impact of the disease; updated the classification of the pathogen; added a section on differential diagnosis; reviewed the ratings of tests in Table 1. *Test methods available and their purpose*; updated the section on identification of the bluetongue virus agent and deleted the subsection on isolation in sheep as alternative methods exist; included a new section on nucleic acid sequencing; deleted the complement fixation test as since 1982 it has been largely replaced by the agar gel immunodiffusion test; updated the vaccine section to include information on the advantages and disadvantages of live attenuated and inactivated vaccines.

3.1.6. Echinococcosis (infection with *Echinococcus granulosus* and with *E. multilocularis*): updated Section C. *Requirements for vaccines*.

3.1.12. Leptospirosis: updated by the Reference Laboratory experts – clarified the classification of the causal pathogen and the zoonotic risk and biosafety requirements; reviewed the ratings of tests in Table 1. *Test methods available and their purpose*; amended the test procedure for the microscopic agglutination test; kept vaccine efficacy test using challenge in hamsters as no *in-vitro* alternative exists; added a statement that target animal batch release safety tests or laboratory animal batch release safety tests should be avoided wherever possible; reduced the number of references.

3.1.23. Vesicular stomatitis: updated the test procedure for virus isolation in cell culture and the protocol for the virus neutralisation test; expanded the section on molecular test methods; added a statement that target animal batch release safety tests or laboratory animal batch release safety tests should be avoided wherever possible.

3.2.7. Varroosis of honey disease (infestation of honey bees with *Varroa* spp.): thoroughly updated by the Reference Laboratories. The revision is so extensive that the changes have not been marked in the interest of clarity.

3.3.4. Avian influenza (including infection with highly pathogenic avian influenza viruses): thoroughly updated based on the latest scientific information. The revision is so extensive that the changes have not been marked in the interest of clarity.

3.3.14. Newcastle disease (infection with Newcastle disease virus): updated nomenclature; aligned the diagnostic tests with the chapter on avian influenza; addresses the first-round Member comments received in 2019.

3.4.4. Bovine genital campylobacteriosis: updated the section on taxonomy of the pathogen; deleted some tests from Table 1. *Test methods available and their purpose* and amended the text accordingly; added information on a new culture medium; largely deleted the vaccine section.

3.5.3. Infection with *Trypanosoma equiperdum* (dourine in horses): added information on taxonomy of the pathogen; reviewed the ratings of tests in Table 1. *Test methods available and their purpose* and added the immunochromatographic test; updated information on detection of trypanosomal DNA and differential diagnosis; added a new section on the *in-vitro* method for antigen preparation and updated the *in-vivo* method; updated the text on confirmation of dourine cases.

3.5.5. Equine encephalomyelitis (Eastern, Western and Venezuelan): the important distinctions between Venezuelan equine encephalomyelitis (VEE) and Eastern and Western equine encephalomyelitis (EEE and WEE) are explicitly described; reference to inoculation of experimental animals and birds has been deleted from the summary and from the section on identification of the agent as alternatives exist; the intracerebral challenge has been deleted from the batch potency test.

3.6.1. Myxomatosis: minor amendments; updated the description of the disease, host species and taxonomy; reviewed the ratings of tests in Table 1. *Test methods available and their purpose*;

3.8.6. Porcine reproductive and respiratory syndrome: updated the taxonomy of the pathogen; included example conventional and real-time reverse-transcription PCR protocols; added an ELISA protocol; added a statement that target animal batch release safety tests or laboratory animal batch release safety tests should be avoided wherever possible.

3.9.6. *Listeria monocytogenes:* updated the introduction to include more information on the main sources of contamination; included Table 1. *Test methods available and their purpose*; updated the section on bacterial isolation methods, culture-based methods, rapid identification methods, PCR methods, antimicrobial susceptibility testing and subtyping methods, including the addition of new information on whole genome sequencing typing methods; deleted information on ways to reduce the risk of listeriosis in humans.

3.9.11. Zoonoses transmissible from non-human primates: on request from the OIE Working Group on Wildlife, deleted a sentence that implied a risk to humans of transmission of hepatitis B from non-human primates.

The chapters can be downloaded from the following address:
http://web.oie.int/downld/Terr_Manual/MAILING_OCT_2020.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. The deadline for comments is **11 December 2020**.

3.4. Review of *Terrestrial Manual* status: selection of chapters for update in 2021/2022 review cycle

The Commission examined the status of chapters that had previously been identified for update in the 2021/2022 review cycle. The Commission decided to add to the list chapters that had last been updated in 2016. The following chapters have thus been identified:

1.1.2. Collection, submission and storage of diagnostic specimens

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

1.1.5. Quality management in veterinary testing laboratories

1.1.6. Principles and methods of validation of diagnostic assays for infectious diseases

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

1.1.10. Vaccine banks

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

2.2.1. Development and optimisation of antibody detection assays

2.2.2. Development and optimisation of antigen detection assays

2.2.3. Development and optimisation of nucleic acid detection assays

2.2.4. Measurement uncertainty

2.2.5. Statistical approaches to validation

2.2.6. Selection and use of reference samples and panels

2.2.7. Principles and methods for the validation of diagnostic tests for infectious diseases applicable to wildlife

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

2.3.1. The application of biotechnology to the development of veterinary vaccines

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

2.3.5. Minimum requirements for aseptic production in vaccine manufacture

3.1.4. Brucellosis (*Brucella abortus, B. melitensis, B. suis*) (infection with *B. abortus, B. melitensis, B. suis*)

3.1.5. Crimean–Congo haemorrhagic fever

3.1.14. Nipah and Hendra virus diseases

3.1.18. Rift Valley fever (infection with Rift Valley fever virus)

3.1.22. Tularemia

3.2.1. Acarapisosis of honey bees (infestation of honey bees with *Acarapis woodi*)

3.2.2. American foulbrood of honey bees (infection of honey bees with *Paenibacillus larvae*)

3.2.3. European foulbrood of honey bees (infection of honey bees with *Melissococcus plutonius*)

3.2.4 Nosemosis of honey bees

3.3.6. Avian tuberculosis

3.3.9. Fowl cholera

3.3.10. Fowl pox

3.3.12. Infectious bursal disease (Gumboro disease)

3.3.15 Turkey rhinotracheitis (avian metapneumovirus)

3.4.1. Bovine anaplasmosis

3.4.6. Bovine tuberculosis

3.4.7. Bovine viral diarrhoea

3.5.10. Equine viral arteritis (infection with equine arteritis virus)

3.7.11. Scrapie

3.7.13. Theileriosis in sheep and goats (infection with *Theileria lestoquardi, T. luwenshuni* and *T. uilenbergi*)

3.8.3. Classical swine fever (infection with classical swine fever virus)

3.8.7. Influenza A virus of swine

3.8.10. Transmissible gastroenteritis

3.9.1. Bunyaviral diseases of animals (excluding Rift Valley fever and Crimean–Congo haemorrhagic fever)

3.9.4. Cryptosporidiosis

3.9.7. Mange

3.9.8. Salmonellosis

3.9.10. Verocytotoxogenic *Escherichia coli*

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 African swine fever*
National Surveillance and Research Center for Exotic Animal Diseases (National Reference Laboratory for African Swine Fever), China Animal Health and Epidemiology Center,
No. 369 Nanjing Road, Qingdao 266032, CHINA (PEOPLE'S REP. OF)
Tel.: (+86-532) 87.83.91.88
E-mail: zlwang111@163.com; wangzhiliang@cahec.cn
Designated Reference Expert: Dr Zhiliang Wang.

An application had been received for an OIE Collaborating Centre for Veterinary Medicinal Products. The Commission found that the application was very broad covering four main focus areas and six specialties. The applicants would be asked to revise and resubmit their application with a narrowed down focus on one main area with specific issues of relevance to the region.

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:

Cysticercosis
Dr Xuenong Luo to replace Prof. Xuepeng Cai at the Helminthosis Laboratory, Lanzhou Veterinary Research Institute, Chinese Academy of Agricultural Sciences, CHINA (PEOPLE'S REP. OF)

Brucellosis (*Brucella abortus*)
Dr Jin-Ju Lee to replace Dr Moon Her at the Animal and Plant Quarantine Agency (QIA)
Ministry of Agriculture, Food and Rural Affairs (MAFRA), Gimcheon-si, Gyeongsangbuk-do, KOREA (REP. OF)

Bluetongue
Dr Carrie Batten to replace Prof. Peter Mertens at The Pirbright Institute, Pirbright, Surrey, UNITED KINGDOM

The Commission reviewed two additional nominations for changes of experts at OIE Reference Laboratories and felt that neither 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.

4.3. Review of new and pending applications for laboratory twinning

As of September 2020, 62 projects have been completed, 30 projects are underway and 7 are awaiting funding before beginning.

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

i) ***France – Senegal*** for PPR: the Commission supported the technical contents of this project.

ii) ***United Kingdom– Philippines*** for ASF: the Commission supported the technical contents of this project.

iii) ***France – Mauritania*** for viral haemorrhagic fevers: the Commission supported the technical contents of this project.

iv) ***France – Benin*** for viral haemorrhagic fevers: the Commission supported the technical contents of this project.

v) ***South Africa – Ethiopia*** for viral haemorrhagic fevers: the Commission supported the technical contents of this project.

vi) ***Poland – Kazakhstan*** for Enzootic bovine leukosis: the Commission supported the technical contents of this project.

4.4. Follow-up February meeting: concerns about an OIE Reference Laboratory

The Commission reviewed the detailed technical feedback on the quality and safety issues at an OIE Reference Laboratory that had been brought to its attention at the last meeting in February. The Commission found that the information provided did not answer the questions asked and overall was not satisfied with the response. Three areas of concern were identified: the level of expertise – the laboratory does not currently have a designated OIE expert, and the proposed expert recently nominated by the Delegate of the Member hosting the Reference Laboratory to replace the previously recently retired expert was rejected by the Commission as not fulfilling the expectations of a Reference Laboratory expert (refer to item 4.2 above); lack of trust in the choice and efficacy of the tests undertaken by the laboratory and in the safety of the reagents it produces and supplies to other laboratories; and concern about the inadequate biosafety level of the temporary facilities the laboratory will occupy while new facilities are being built, and lack of information on a risk assessment or how staff intend to manage the risks of handling pathogens at a reduced biosafety level during the transition period.

The Commission believes that the best way forward to restore the reputation of the laboratory and confidence in it in the region would be through an ongoing performance monitoring scheme with other independent OIE Reference Laboratories. The scheme would include benchwork evaluation of test protocols and procedures, choice of tests, safety of reagent production, proficiency testing, risk assessment and risk management.

- **Reference Laboratories – implementation of the SOPs[5]**

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

The Commission reviewed the feedback received from Reference Laboratories that were not complying with key performance criteria according to their 2018 annual reports. The Commission accepted the explanation and detailed work plan provided by one laboratory to improve performance and decided to review the laboratory's annual report for the current year when received in January 2021.

One laboratory requested that its OIE Reference Laboratory status be revoked citing lack of national and international requests and low occurrence of a disease. The request was accepted in accordance with Article 9 of the Internal rules for OIE Reference Centres. The same laboratory, which is also designated for another related disease of low prevalence, asked to retain that designation with the aim of transferring expertise and capacity to a laboratory in Asia, where the disease is important, through a twinning project. The Commission accepted this proposal.

No response had been received from a laboratory that stated that it was no longer permitted to work on the disease in question as the country was free from this disease. A reminder letter will be sent to the Delegate of the country with the laboratory in copy. Should the situation be confirmed, or no response received by the next meeting, the laboratory's designation could be revoked in accordance with Article 9 of the Internal rules for OIE Reference Centres.

One laboratory asked for a further 6-month extension to the deadline to submit the certificate of accreditation to ISO 17025 or equivalent quality management system due to delays caused by the Covid-19 pandemic. The Commission agreed to this extension. Should the laboratory not achieve accreditation within this timeframe, the Reference Laboratory status will be reviewed at the next Commission meeting in February 2021.

Finally, given its continued lack of activities, one laboratory confirmed its agreement to revoke its designation and the laboratory was removed from the list of OIE Reference Laboratories.

4.6. Review of in-depth analysis of all annual reports for activities in 2019

The Commission reviewed the performance of all the Reference Laboratories by an in-depth analysis of all the annual reports submitted in 2019 to ensure that each laboratory is fulfilling the Terms of Reference (ToRs) to the benefit of OIE Members and performance criterion iii) of the *Procedures for Designation of OIE Reference Laboratories* (the SOPs).

The Commission identified 11 Reference Laboratories that were not complying with the key ToRs. The OIE Reference Laboratories concerned would be informed of the outcome of the review and asked to provide feedback and an explanation of their situation and possible reasons for the lack of activity; the Delegate will be in copy of all correspondence. The Commission also identified 19 Reference Laboratories that have low level of activities and placed them under watch list for follow up review in the next annual report review process.

One expert responsible for two laboratories that had not submitted annual reports will be sent a letter reminding him that the laboratory was not complying with the performance criteria, which could lead to the delisting procedure being initiated.

5 SOPs: Standard Operating Procedure

4.7. Annual report template for Reference Laboratories for Rinderpest

At the February 2020 meeting, the Commission suggested approaching the OIE Reference Laboratories for rinderpest to ask for their suggestions on how the annual reporting mechanism could be improved to demonstrate their ongoing expertise, competence and laboratory systems in spite of the disease being eradicated. To this end, the Secretariat organised a conference call with the Reference Laboratories to get their input. The laboratories confirmed both the need to maintain capability for the disease and that the current template is not suitable for reporting an eradicated disease. They asked if they could submit a joint report coving the OIE reporting obligation and including the report they submit to the JAC[6] as recognised rinderpest holding facilities.

At the September 2020 meeting, the Commission considered the feedback received from the laboratories and noted that the questions in the JAC report template related to rinderpest holding facilities are much narrower in scope than the OIE Reference Laboratory reporting needs, and thus a joint report would not achieve the level of assurance required by the Commission for evaluation. The Commission further identified various key elements that would facilitate the reporting of activities by laboratories designated for eradicated diseases. These include:

i) Competence – ongoing maintenance of scientific and technical skills for the designated expert and laboratory staff;

ii) Laboratory systems – quality assurance, biosafety/biocontainment, security, financial support and laboratory infrastructure;

iii) Scientific capability – an agreed process is in place to respond to a suspected case, valid testing capability is readily available, vaccine development capability, how the laboratory is active in relation to other similar diseases;

iv) Networks – established and ongoing connections to other laboratories for concerned and other similar diseases;

v) Safety and security – secure storage of infectious material and related information, regularly reviewed assessment of risks and associated mitigations, emergency response in place, inventory and biosecurity plans in place; and

vi) Research – ongoing research programme for the eradicated disease or a closely related disease/pathogen, regular reviews of research options and priorities with others in the network.

Based on the above key criteria, the Commission will develop a new reporting template for the annual reports for OIE Reference Laboratories designated for eradicated diseases for discussion at the next meeting.

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

4.8. Follow-up February meeting: feedback from the Centres that are not complying with the key ToRs according to their 2018 annual report

The Commission reviewed the feedback received from one Collaborating Centre that had been identified previously as having activities that fall into two distinct focus areas. The Commission approved the Centre's agreement to split into two separate Collaborating Centres for the identified specialties.

4.9. Review of in-depth analysis of all annual reports for activities in 2019

As for the Reference Laboratories, the Commission also undertook an in-depth analysis of all the annual reports of the Collaborating Centres submitted in 2019 to ensure fulfilment of the ToRs.

6 JAC: FAO-OIE Joint Advisory Committee

The Commission identified two 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 feedback and an explanation of their situation and possible reasons for the lack of activity; the Delegate will be in copy of all correspondence. The Commission also identified two Collaborating Centres that have low level of activities and placed them under watch list for follow up review in the next annual report review process.

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

4.10. Feedback on the review of the OIE Collaborating Centres' 5-year work plans

In accordance with the SOPs, all the OIE Collaborating Centres were sent a template to submit 5-year work plans for the years 2020–2024. The template focused on six areas: administrative details, strategic summary, Collaborating Centre profile, networks and affiliations, work plan for the next 5 years and authorisation.

Of a total of 58 Collaborating Centres for terrestrial animal health issues, 53 had submitted the 5-year work plan; those that were yet to submit would be sent a reminder. The Commission reviewed the 5-year work plans received and approved the range of activities proposed by various Centres and their relevance to the identified main focus areas and specialties. Eleven work plans were found to be incomplete and the Centres concerned would be asked to provide more information on profile, networks, international collaboration, specific details in the work plan including time frames for activities or missing authorisation signatures. Two work plans were duplications of each other and the Centres would be asked to submit individual workplans or consider merging the Centres into one. Replies would be reviewed at the next meeting in February 2021.

- **Reference Centre networks**

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

The leaders (coordinators) of three identified new Reference Laboratory networks, namely African swine fever (South Africa), PPR (France) and rabies (Germany and USA) joined the meeting to present the final network concept documents summarising the goals, objectives, planned activities, criteria for membership and proposed laboratories for each network. The leader of the existing network on FMD (UK) also participated in the discussion to share his experience of the successful implementation of that network's activities.

The Commission approved all three concept notes and agreed to launch the networks and initiate the defined activities. The Commission recognised that these networks have a key role to play in the existing global strategies for these animal diseases and advised the network leaders to admit those sustainable national laboratories that have participated in the OIE laboratory twinning programmes into their respective networks.

4.12. Update on Guidance for the Management of OIE Reference Centre Networks

It had been brought to the attention of the Commission that the current Guidance for the Management of OIE Reference Centre Networks had the same text for both Reference Laboratories and Collaborating Centres, though it fits more with Reference Laboratories. The Commission reviewed and amended the text to provide separate guidance for Reference Laboratories[7] and Collaborating Centres[8] and to include recommendations on managing conflicts of interest and confidentiality undertakings. The new texts were uploaded to the OIE website.

7 https://www.oie.int/en/scientific-expertise/reference-laboratories/reference-centre-networks/
8 https://www.oie.int/en/scientific-expertise/collaborating-centres/reference-centre-networks/

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) and revision of the OIE *Terrestrial Manual* chapter 3.4.6 Bovine tuberculosis

This *ad hoc* Group has been meeting for the past 5 years, with the primary task to develop a new international standard for bovine tuberculin (ISBT). This was in recognition that the present bovine international standard (BIS), developed and maintained by WHO[9], was running out and deteriorating. WHO agreed that it would be appropriate for OIE to develop the new standard.

Membership of the Group has varied over the years. It has included representatives of OIE Reference Laboratories for bovine tuberculosis, other experts in the disease and members with specialist knowledge of the production and calibration of tuberculin.

At a video conference in July 2020 the Group decided that further laboratory work was needed before it could make a final recommendation to the OIE.

More recently the Group was asked to review, revise and update the chapter in the OIE *Terrestrial Manual.* At the request of the Biological Standards Commission this was to include a broadening of scope to "Mammalian Tuberculosis" rather than restricting it to the bovine disease. Although useful exchanges of views have taken place on the chapter revision, a final draft text has not yet been achieved. The Group also noted that many scientific advances are expected imminently in diagnostic procedures such as replacement of PPD[10] tuberculin by defined antigens, and new approaches to vaccination with the possibility of DIVA[11] strategies.

The Group therefore decided not to proceed with the chapter revision this year but will hopefully be able to work on it in 2021 with the aim of having a draft that could be proposed for adoption in May 2022.

5.2. *Ad hoc* Group on Sustainable Laboratories, 27, 29, 30 April and 27 May 2020 by video conference

The OIE convened the second meeting of the *ad hoc* Group on Sustainable Laboratories virtually in April and May 2020. Experts from seven Members, AU-PANVAC[12], Chatham House, FAO[13], and WHO focused on the enhancement and improvement of the PVS[14] Sustainable Laboratories Tool.

As main outcomes, the Group:

- Finalised the streamlined mission report outline for review by the economist team to examine impact from an economic perspective and highlight commercial and societal benefits in addition to costs;
- Reviewed the accuracy and completion analysis of the Supply Tool variables;
- Sorted and ranked the existing Supply Tool (data collection tool) variables for further development of timeline and tools needing to be developed for data collection;
- Convened subcommittees to examine specific areas of the model and evaluate unit costs and values;
- Established a need for a focus on training, especially pre-mission for those who fill out the Supply Tool, on data needed, and how to collect it.

9 WHO: World Health Organization
10 PPD: Purified protein derivative
11 DIVA: Detection of infection in vaccinated animals
12 AU-PANVAC: Pan-African Veterinary Vaccine Centre of the African Union
13 FAO: Food and Agriculture Organization of the United Nations.
14 PVS: Performance of Veterinary Services

Subcommittees began meeting virtually in June 2020 and will continue to convene virtually through the fourth quarter of 2020. The next full *ad hoc* Group virtual meeting is tentatively targeted for October 2020. During the next meeting, the experts will discuss the progress of work on the enhanced tools (improvements made, testing, etc.), provide feedback on the economist team's work and recommendations, finalise values and unit costs for the models, and endorse the streamlined data collection and visualisation tools.

The *ad hoc* Group report 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

At present, there are 14 registered kits; four new applications (2019 and 2020) are in various stages of review. Two diagnostic kits renewals are going to be started in 2020: Pourquier IIF *Taylorella equigenitalis* (IDEXX) and Rapid MERS-CoV Ag Test (BioNote Inc).

7. Resolutions adopted in June 2020 by the Assembly using the adapted procedure replacing the General Session

The Commission noted that the following resolutions had been adopted in June 2020 by the Assembly using the adapted procedure replacing the General Session:

- Resolution No. 18 Designation of OIE Reference Laboratories for terrestrial animal diseases;
- Resolution No. 19 Designation of OIE Collaborating Centres;
- Resolution No. 20 Register of diagnostic kits validated and certified by the OIE.

8. Conferences, Workshops, Meetings

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

8.1. WAVLD[15] International Symposium, Lyon, France 2021

The 20th International Symposium of the WAVLD will be held in Lyon, France in 2021. Traditionally, the Biological Standards Commission organises a 1-day seminar held during the WAVLD Symposium. The Commission will work between meetings to agree on topics for the seminar and to develop a programme and proposed speakers. The proposals will be finalised at the February meeting.

9. Liaison with other Commissions

9.1. Horizontal issues among the Specialist Commissions

9.1.1. Update on case definitions

In February 2020, the OIE Secretariat drafted a concept note on case definitions to inform the Specialist Commissions of the need to revise or develop case definitions of OIE-listed terrestrial animal diseases for inclusion in disease-specific chapters of the *Terrestrial Code*. The Commissions endorsed the approach presented in the note, which involves three steps to be implemented in a stepwise fashion: (i) the collection of information on case definitions currently provided in the disease-specific chapters of the *Terrestrial Code*; (ii) the ranking of diseases according to the severity of notification issue linked to case definitions[16] by WAHIAD; and (iii) the prioritisation of diseases by combining the information collected in steps (i) and (ii) with considerations of whether a disease-specific chapter in the *Terrestrial Code* was under development/revision or on the work plan of the Code Commission.

15 WAVLD: World Association of Veterinary Laboratory Diagnosticians

16 Notification issue linked to case definitions means the under-notification of disease events by Members that is due to the absence of a case definition in the *Terrestrial Code* or the presence of a case definition that does not provide sufficient guidance for reporting cases.

The OIE Secretariat implemented step (i) and (ii) and presented the results in a two-way contingency table (i.e. case definition status in the *Terrestrial Code* against the severity of notification issues). With step (iii), diseases were classified in three priority groups.

The first tranche of diseases proposed for attention to the Commissions consists of all priority group 1 diseases (namely, equine influenza, theileriosis, Crimean–Congo haemorrhagic fever and surra [*Trypansoma evansi*]), along with the WAHIAD high priority items from Priority group 2 (namely, leishmaniosis, Nipah virus encephalitis, Q fever, and tularemia).

The Commission was informed that the development or revision of case definitions for the first tranche of diseases will begin following the meeting, and that the resulting case definitions will be presented for their consideration at the next meeting in February 2021.

9.1.2. Guidance for the application of the criteria for listing terrestrial animal diseases

The Commission noted the finalised guidance document that was developed by the Secretariat and is intended to be used when undertaking an assessment of a pathogenic agent against the criteria for listing a terrestrial animal disease, infection or infestation as described in Chapter 1.2. of the *Terrestrial Code*. The aim of this guidance document is to support consistency and objectivity in the interpretation of the criteria, and it is part of the SOPs for listing pathogens for terrestrial animals.

9.2. Scientific Commission for Animal Diseases

Definition of PPR virus-containing material: (see Item 3.2).

9.3. Terrestrial Animal Health Standards Commission

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

The Biological Standards Commission was updated by the Secretariat on the current topics under review by the Code Commission, and provided the Secretariat of the Code Commission with an update of the *Terrestrial Manual* chapters under review.

9.4. Aquatic Animal Health Standards Commission

None at this meeting.

10. Matters of Interest for Information

10.1. Update on OFFLU

The Commission was briefed on the OFFLU[17] contribution of avian influenza (AI) data for the period October 2019 to February 2020 to the WHO Consultation on the Composition of Influenza Virus Vaccines. During this period, 235 H5, H7 or H9 AI events were reported from 30 countries/territories. Significant amount of genetic and antigenic data on zoonotic AI was shared with WHO at the February 2020 vaccine composition meeting. Animal health laboratories in countries representing Africa, Asia, Oceania, Americas and Europe contributed sequence data for 89 H5, 3 H7 and 139 H9 and antigenic data for selected AI viruses. Additionally, a summary of H1 and H3 global swine influenza A virus events with genetic 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.

17 OFFLU: Joint OIE-FAO Network of Expertise on Animal Influenza.

The Australian Centre for Disease Preparedness (formerly Australian Animal Health Laboratory) in Geelong coordinated the OFFLU proficiency test by engaging with the OIE-FAO Reference Centres on avian influenza. The proficiency test panel was designed to assess the capability of the laboratories to detect and characterise isolates of AI from different regions and helped in reviewing or updating the diagnostic methods as required based on the results.

OFFLU experts updated the guidance document on Influenza A cleavage sites taking into account the recent highly pathogenic AI outbreaks.

The Expert Surveillance Panel of equine influenza (EI) comprising OFFLU and WHO influenza experts met at the OIE Headquarters in April 2019 and reviewed the EI virus activity, characteristics of the viruses isolated and vaccine performance and issued recommendations for vaccines for the international market.

The swine influenza experts drafted a position statement about the emergence of 'G4' of swine influenza A(H1N1) viruses in Chinese pigs with evidence of zoonotic transmission for pandemic risk and preparedness.

10.2. Biosafety research road map

The OIE is working with WHO and Chatham House on a Biosafety Research Roadmap. The ultimate objective of the Biosafety Research Roadmap project is to support the application of laboratory biological risk management and sustainability by providing access to an evidence base to inform biosafety procedures, and options for low resource settings, which will inform strategic decisions on global health security and investments in laboratory systems.

Specifically, the project aims to: 1) perform a gap analysis on the current evidence base to inform laboratory biological risk management for selected pathogens and procedures; 2) highlight research priorities to fill the gaps; 3) develop and communicate solutions to improve the application of evidence based laboratory biological risk management (particularly for low resource settings).

The project aims to support implementation of *Chapter 1.1.4 Biosafety and biosecurity: Standard for managing biological risk in the veterinary laboratory and animal facilities of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals and the update version of the WHO Biosafety Manual.* In 2015 the approach to the OIE's Chapter was updated to take a risk-based approach. Previously the Chapter had taken a more prescriptive approach based on biosafety levels. The risk-based approach requires access to evidence to inform risk assessment and risk management measures it also requires expert competencies in risk assessment/risk management.

The project is being supported through a grant to the OIE from Global Affairs Canada and will be implemented by a Technical Working Group, supported by a consultant. The Biological Standards Commission will be represented in the Technical Working Group.

10.3. Update on the Grand Challenge for sustainable laboratories

The OIE has been exploring options for holding a Grand Challenge to find solutions to improve the sustainability of laboratories. The first step, to develop a concept note, has involved extensive discussion with numerous stakeholders including laboratory experts, open innovation consultants, potential funding partners, biohackers, and laboratory constructors. The proposed approach was summarised in a concept note and policy brief (see Annex 4 for information). A Grand Challenge will stand a greater chance of success if it meets the needs of several sectors (public health, animal health, security, development) and if a few partners (a consortium) are involved in running it. The OIE is currently socialising the idea with potential partners, including the Bill and Melinda Gates Foundation, the World Bank, Global Affairs Canada, UK Department for International Development (Dfid). This project is being supported through a grant from Global Affairs Canada.

10.4. Update on rinderpest – debrief of the 15th meeting of the Joint Advisory Committee

The Commission was informed that the *ad hoc* Group on Rinderpest had met via Zoom from 24 to 26 March 2020. The Group, which had been charged with revising the OIE *Terrestrial Code* chapter on infection with rinderpest virus, worked in accordance with its Terms of Reference and provided a draft chapter that will be reviewed by the Code Commission. The points under lengthiest discussion were the definitions of case and suspected case, and the introduction of a definition of "potential case", which allows for gradation in alert levels as suspected cases of rinderpest are notifiable, as well as the provisions for recovery of freedom, which no longer refer back to previous editions of the *Terrestrial Code*, in the new draft versions. The zoning, trade, and surveillance provisions were revised without much contention.

There were no meetings of the FAO-OIE Joint Advisory Committee (JAC) for Rinderpest since the last update to the Specialist Commissions. However, the FAO-OIE Rinderpest Secretariat contacted the JAC on numerous occasions to provide updates and to ask for the review of applications for research using rinderpest virus containing materials (RVCM). In the last 6 months the FAO-OIE Rinderpest Secretariat received applications from NIAH, Japan, for the production of 200,000 doses of LA-AKO rinderpest vaccine and a stock of bulk antigen equivalent to 300,000 doses, and from The Pirbright Institute, UK, for testing archived sera for the presence of anti-rinderpest virus antibodies. The sera tested by Pirbright was to be shipped to Japan to allow for the continuation of the ongoing research project concerning the assessment of the cross-reactivity of neutralising antibodies raised against LA-AKO and RBOK vaccines.

In relation to destruction of RVCM outside rinderpest holding facilities (RHF), Korea (Rep. of) has notified the FAO-OIE Rinderpest Secretariat of the destruction of their holdings in March 2020. Currently there are seven countries holding RVCM outside RHF. There has been no progress in applications from institutes to become RHF in this reporting period.

10.5. Update on COVID-19

The Commission was updated on the activities related to coronavirus disease (COVID-19) caused by SARS-CoV-2. Since the previous meeting of the Commission, the OIE has been active in supporting Veterinary Services to contribute to the public health response to COVID-19 through a number of initiatives such as developing relevant guidance, sharing SARS-COV-2 events in animals reported by OIE Members, responding to requests from Members and collaboration with WHO and FAO and other international organisations.

Through the support of expert groups, the OIE has developed *Guidance on veterinary laboratory support to the public health response for COVID-19*, *Considerations for sampling, testing and reporting of SARS-CoV-2 in animals*, and *Considerations on the application of sanitary measures for international trade related to COVID-19*. Support has included developing the questions and answers page on the OIE website[18] and a technical factsheet on infection with SARS-CoV-2 in animals. The OIE aims to ensure that all the guidance and recommendations are updated regularly based on the latest scientific evidence.

The OIE is grateful for the role played by Members of the Commission in the COVID-19 Advisory Group on Animal Health Laboratories in developing the veterinary laboratory support guidance which has been widely shared with OIE Members and partners. The OIE is planning to hold a webinar for Laboratory Focal Points in November 2020 with the purpose to share experiences of veterinary laboratories supporting the public health response to COVID-19 through the testing of human specimens. The webinar will specifically determine the impact of the guidance, share success stories and the challenges and lessons identified including effects on business continuity of animal health laboratory work, and identify areas of innovation. The outputs of this webinar will inform future work of the Advisory Group, the Sustainable Laboratories Initiative, other capacity building activities and lastly be used by the OIE to continue to advocate for Veterinary Services to be included in whole of government frameworks for public health emergencies.

18 https://www.oie.int/en/scientific-expertise/specific-information-and-recommendations/questions-and-answers-on-2019novel-coronavirus/oies-response/

10.6 IAEA[19] Zodiac[20] Project

The Zoonotic Disease Integrated Action (ZODIAC) project is an IAEA initiative to establish a comprehensive, multisectoral and multidisciplinary approach to the timely detection of zoonotic diseases and prevention of their spread. The aim is to strengthen the ability of the IAEA and key partner organisations to support Member States in preparing for, and responding to, outbreaks of zoonotic diseases.

The Commission reviewed the concept note and noted that the proposal includes a number of areas where there is overlap with OIE activities and other international players. The Commission recommended that significant consultation be undertaken at the strategic level to better understand and develop the scope of the project so that at the operational and technical levels further discussions can be held to avoid duplication, maximise the efficiency of resource management and ensure sustainability.

10.7. EuFMD[21]: Draft pre-qualification procedure for vaccines for FMD and similar transboundary diseases

The programme of the EuFMD aims to counter the threat of FMD and Similar Transboundary animal Diseases (FAST). The EuFMD works with member nations on their preparedness, with European neighbours, to put in place sustainable control programmes, and to support and promote the progressive control of FMD in all regions under the Global FMD Control Strategy of FAO and OIE. An assured supply of high quality vaccines forms an important part of this programme.

To date, EuFMD has obtained vaccines through specific procurement procedures run by FAO, as and when the need arises. Having in place a system to assure the quality of vaccines in advance of need would improve vaccine security. EuFMD is now proposing an approach to establishing a pre-qualification system for vaccines FAST diseases. In the first instance, a pre-qualification system would be established and run by the EuFMD to assure the quality of vaccines against FMD on behalf of Member Countries. In future, on the basis of a suitable mandate, the scope and scale of the pre-qualification system could be expanded to include vaccines against other FAST diseases and for other animal disease control programmes operated by FAO.

The aim of establishing a pre-qualification procedure is to ensure that vaccines supplied to EuFMD meet minimal internationally accepted criteria for quality, safety and efficacy and can be produced and controlled consistently in manufacturing facilities that operate according to the principles of good manufacturing practice.

The Commission reviewed the draft document and provided comments for the EuFMD.

10.8 Revision of PVS lab tool, *Global Laboratory Leadership Programme* (*GLLP*)

To help ensure that laboratories can continue to effectively play their critical role in the prevention, detection, and control of diseases, laboratory directors and senior laboratory managers worldwide need specialised training in leadership and management. Towards this end, The OIE is engaged with WHO, FAO, the ECDC[22], the CDC[23], and the APHL[24] to develop GLLP[25] targeting human and animal health laboratories, as well as laboratories with public health impact (e.g. environmental, agricultural, food, or chemical laboratories).

The GLLP partners are committed to the Programme's vision and mission:

Vision: Laboratory leaders empowering national laboratory systems across the globe using a One Health approach to strengthen health security.

19 IAEA: International Atomic Energy Agency
20 ZODIAC: Zoonotic Disease Integrated Action
21 EUFMD: European Commission for the Control of Foot-and-Mouth Disease
22 ECDC: European Centre for Disease Prevention and Control
23 CDC: US Centers for Disease Control and Prevention
24 APHL: Association of Public Health Laboratories
25 GLLP: the Global Laboratory Leadership Programme

Mission: To provide laboratory professionals with the tools to develop their laboratory leadership competencies and advance effective national laboratory systems for improved health security using a One Health approach.

Building global consensus on laboratory leadership competencies will help harmonise education and training programmes and speed their uptake by implementing agencies. International experts agree that laboratory leaders need certain core competencies to meet national, regional, and global disease prevention and control objectives. The GLLP encapsulates the following nine core competencies outlined in the Laboratory Leadership Competency Framework:

- Laboratory Systems
- Leadership
- Disease Surveillance and Outbreak Investigation
- Management
- Emergency Preparedness, Response and Recovery
- Communication
- Biosafety and Biosecurity
- Quality Management Systems
- Research

The core competencies guide the development of the forthcoming GLLP Learning Package, which will provide the materials necessary to implement programmes in any country or educational institution in the world, including core course materials, guidance for programme development, planning, implementation, and evaluation, and a flexible programme. GLLP may be adapted to meet country-specific workforce needs and may be presented in both face-to-face and/or virtual formats.

The ultimate 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 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 achieve this, the OIE is working with OIE Reference Centre experts as well as members of the BSC to review the materials for relevance to an animal health audience and draft additional materials as needed to address animal health perspectives and specificities. Development of the first draft of learning materials, including instructor's guides, participants' guides, and slide decks for each of the 36 modules is underway through end 2020. Additional review and testing will continue through 2021.

10.9 Report of the meeting of the OIE Working Group on Wildlife, Paris, France, 10–13 March 2020

The President of the Biological Standards Commission had proposed that the Commission review information in the technical disease cards for wildlife diseases developed by the Working Group on diagnostic methods recommended for the non-OIE listed wildlife diseases reportable to the OIE. The recommendation was accepted by the Working Group.

11. Any Other Business

11.1. Work plan

The updated work plan was agreed and can be found at Annex 5.

11.2. Dates of the next Biological Standards Commission meeting

The Commission noted the dates for its next meeting: 8–12 February 2021.

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.../Annexes

Annex 1

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 15–18 September 2020

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Agenda

1. Welcome

2. Adoption of Agenda

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

3.1. Review of comments received on chapters that would have been proposed for adoption in May 2020

3.2. Definition of PPR virus-containing material: proposal from the Code Commission that this definition be included in the *Terrestrial Manual*

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

3.4. Review of *Terrestrial Manual* status: selection of chapters for update in 2021/2022 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. Follow-up February meeting: concerns about an OIE Reference Laboratory

Reference Laboratories – Implementation of the SOPs

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

4.6. Review of in-depth analysis of all annual reports for activities in 2019

4.7. Annual report template for Reference Laboratories for Rinderpest

Collaborating Centres – Implementation of the SOPs

4.8. Follow-up February meeting: feedback from the Centres that are not complying with the key ToRs according to their 2018 annual report

4.9. Review of in-depth analysis of all annual reports for activities in 2019

4.10. Feedback on the review of the 5-year work plans received from Collaborating Centres

Reference Centre networks

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

4.12. Update on Guidance for the Management of OIE Reference Centre Networks

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) and revision of the OIE *Terrestrial Manual* Chapter 3.4.6 Bovine tuberculosis

5.2. *Ad hoc* Group on Sustainable Laboratories

6. International Standardisation/Harmonisation

6.1. OIE Register of diagnostic kits

6.1.1. Update on new or renewed applications

7. Resolutions adopted in June 2020 by the Assembly using the adapted procedure replacing the General Session

8. Conferences, Workshops, Meetings

Future Conferences, Workshops, Meetings

8.1. WAVLD International Symposium, Lyon, France 2021

9. Liaison with other Commissions

9.1. Horizontal issues among the Specialist Commissions

9.1.1. Update on case definitions

9.1.2. Guidance for the application of the criteria for listing terrestrial animal diseases

9.2. Scientific Commission for Animal Diseases

9.3. Terrestrial Animal Health Standards Commission

9.4. Aquatic Animal Health Standards Commission

10. Matters of Interest for Consideration or Information

10.1. Update on OFFLU

10.2. Biosafety research road map

10.3. Update on the Grand Challenge for sustainable laboratories

10.4. Update on rinderpest – debrief of the 15th meeting of the Joint Advisory Committee

10.5. Update on COVID-19

10.6 IAEA Zodiac Project

10.7. EuFMD: Draft pre-qualification procedure for vaccines for FMD and other diseases

10.8 Revision of PVS lab tool, *Global Laboratory Leadership Programme* (*GLLP*)

10.9 Report of the meeting of the Working Group on Wildlife, Paris, France, 10–13 March 2020

11 Any Other Business

11.1. Work plan

11.2. Dates of the next Biological Standards Commission meeting: 8–12 February 2021

Annex 2

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 11–14 February 2020

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List of participants

MEMBERS

Prof. Emmanuel Couacy-Hymann
(*President*)
Professor of Virology, Central Laboratory for Animal Diseases (LANADA/CLAD)
BP 206 Bingerville
CÔTE D'IVOIRE
chymann@gmail.com

Dr Franck Berthe
(*Vice-President*)
Senior Livestock Specialist, Food and Agriculture Global Practice, World Bank, 1818 H Street NW, Washington, DC 20433
UNITED STATES OF AMERICA
fberthe1@worldbank.org

Dr John Pasick
(*Vice-President*)
Formerly Canadian Food Inspection Agency, National Centre for Foreign Animal Disease, 1015 Arlington Street
Winnipeg, Manitoba R3E 3M4
CANADA
jmpasic55@gmail.com

Prof. Ann Cullinane
(*Member*)
Head of the Virology Unit
Irish Equine Centre
Johnstown
Naas
Co. Kildare
IRELAND
ACullinane@irishequinecentre.ie

Dra. Ana Maria Nicola
(*Member*)
Head, Brucellosis Department (OIE/FAO Laboratory/Reference Center), General Directorate of Laboratories and Technical Control, National Service of Agri-Food Health and Quality (SENASA), Talcahuano 1660, CP1640 Martínez, Buenos Aires
ARGENTINA
anicola@senasa.gob.ar
nicolaana@hotmail.com

Dr Joseph S. O'Keefe
(*Member*)
Head, Animal Health Laboratory, Ministry for Primary Industries,
P.O. Box 40-742
Upper Hutt, 5140
NEW ZEALAND
Joseph.O'Keefe@mpi.govt.nz
okeefej@mpi.govt.nz

CONSULTANT EDITOR OF THE *TERRESTRIAL MANUAL*

Prof. Steven Edwards
c/o OIE 12 rue de Prony
75017 Paris
FRANCE
steve-oie@cabanas.waitrose.com

OIE HEADQUARTERS

Dr Gregorio Torres
Head, OIE Science Department
g.torres@oie.int

Ms Sara Linnane
Scientific Secretariat Officer - BSC, OIE Science Department
s.linnane@oie.int

Dr Gounalan Pavade
Chargé de mission, OIE Science Department
g.pavade@oie.int

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Annex 3

Original: English
April 2020

MEETING OF THE OIE AD HOC GROUP ON SUSTAINABLE LABORATORIES

Video Conference Meeting, April and May 2020

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The OIE *ad hoc* Group on Sustainable Laboratories met for its second meeting in April and May 2020 (27, 29, 30 April and 27 May 2020). Due to COVID-19 severely limiting international travel, it was not possible to meet face to face, so Zoom video conference was the preferred option. Given the Group's membership and distribution across the globe, four two-hour meetings were held to cover the agenda items as originally proposed. Additional zoom meetings will be convened on a regular basis to further develop the action items of the meeting.

1. Welcoming remarks and background

Dr Keith Hamilton, Head of the Preparedness and Resilience Department of the OIE, welcomed the participants on behalf of the OIE and underlined the importance of ensuring that the outcomes of the meeting are focused on the end users—OIE Member Countries—and are user friendly, adaptable, not a burden to their everyday work, and help them to better manage their laboratory system.

New Group members introduced themselves and Dr Ana Maria Nicola resumed the chairperson role and Dr Andre do Oliveira Mendonça acted as vice 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 Annexes I and II of this report, respectively.

Presentations on the objectives, deliverables, and the advancements made since the last Group meeting, considerations were pre-recorded and provided one week prior to the meeting.

2. Meeting Objectives and Deliverables

Ms Jennifer Lasley, OIE Sustainable Laboratories Programme Manager, reviewed the objectives to brief on work done since last meeting on improving the PVS Laboratory tools, to review existing PVS Laboratory tools one-by-one and challenges encountered for each, and to take decisions on streamlining and enhancing each tool.

3. Advancements made since the previous meeting

Ms Lasley presented the advancements made since the last meeting of the Group.

- Design, development, and testing of a relational database model had been completed
- Legacy data from the past 16 PVS Laboratory Missions had been migrated into the relational database model for cleaning and analysis, in order to learn lessons from the data and inform the enhancement of the tools.
- New Data Analyst has begun work to advance the analysis of the legacy dataset.
- Streamlined Demand Tool was beta tested during the Uzbekistan Mission (Nov 2019) and used to visualize data for the closing meeting of the mission and for the Mission Report.
- Integration of the modified Demand Tool with the Calculation Tool.

- Call for proposals for "Economic expertise on investing in sustainable laboratory biosafety and biosecurity" launched. The team with the selected proposal will assist with the in-depth analysis of the financial data and advise on the integration of economic indicators into the documentation and outputs of the mission.

- The Biological Standards Commission was briefed on the progress of the Group's work, and a meeting with Chatham House was held on the linkages of the Group's work on the PVS Sustainable Laboratories Tool and the equipment management survey.

4. Impact of COVID 19 on the outcomes of the Group and the enhancement of the PVS Sustainable Laboratories Tool

The arrival of the COVID-19 pandemic in France, resulting in the lockdown of France and the European Union in mid-March 2020, heavily disrupted all work of the OIE with the closing of OIE's office in Paris and all staff working from home. A majority of OIE staff are still working from home, as of this report. Two PVS Sustainable Laboratories missions and future face-to-face Group meetings, and the PVS Sustainable Laboratories expert training are at risk of not being implemented. The Group brainstormed different delivery modalities to keep their work on track until the pandemic has passed.

The Group considered "virtual" PVS Sustainable Laboratories missions and testing transferring the PVS Sustainable Laboratories mission data entry, calculations, visualisations, and tools to an online delivery. This modality could allow improved access to the outputs of the missions and approach. A virtual tool increases access for end users in remote areas or in areas which were difficult access for security, geographical, physical, or health-related reasons, and would reduce cost related to travel and accommodation of experts, and overcome hurdles with visas etc.

This innovative delivery approach—where as much as possible is done through direct, online data entry and exchange between Members and PVS Laboratory experts—contributes to security objectives. Laboratories are often located in remote or dangerous areas, and "teleconsultation" to the extent possible allows for safer access to laboratories in such locations. This kind of adaptation offer a forward-thinking solution to interact with laboratories in countries where security, environmental, or sanitary concerns may limit travel and face to face interactions. The current COVID-19 pandemic has illustrated even more the need for such an approach.

5. Mission Outputs: Mission Report

Ms Martin and Ms Lasley presented the main mission output: The Mission Report. The Group discussed how modifications could be made to improve the impact of the PVS Laboratory reports. The Group reviewed, discussed, and finalized a new report outline (See Appendix 3). The report outline would directly inform the revision of the report template for use in upcoming missions. Key points and suggestions raised during the discussion included:

- The proposed outline, through data visualisation, will make the data more consumable and easier to interpret, which is a main objective of the streamlining exercise.

- The executive summary should include visualizations and should be able to stand alone for use by those stakeholders who need a synthesised summary of the mission outputs (secondary audience).

- The report outline will be provided to an economist team for their further inputs.

- Using visualizations in the right way will be more powerful than words and may not necessarily increase the length of the report.

- Standardized visualizations should be considered.

- The report should include major risks and threats to the operations of the laboratory. This should include service vulnerabilities as well as sustainability and resilience in responding to emergencies and crisis (at surge capacity) and any work disruptions.

- An explanation of key matrices should be included to allow Member Countries to follow progress of or impact of the transformation of the laboratory network.

- The Mission Report should not be the only output of the mission, although it is the main one right now. Other outputs should be produced for other audiences in other formats (outside of the mission report) to assist in the improved sustainability of laboratories.

- A searchable web-based dashboard of the material should be considered for the future.

- Interactive tables should be considered as a tool to show the impact of incremental increases and decreases of key performance indicators. This may be out of scope for the current timeframe but should be a future target.

- The Options (simulations) add value to the mission methodology and report and should be maintained. The status quo option demonstrates the consequences of no changes. The other options show potential gains related to changes. Other recommendations related to options included the following:
    - The Group will further discuss on how many scenarios are valuable to present in the report, and find other ways to present others that do not make it into the final mission report (online tools, appendices, etc.), with advice provided by the economist team.
    - The actions related to biosafety (and biosecurity) required according to the current and future demand should be included in the options.
    - It is important to consider options that optimize use of existing resources.
    - The Group will consider how to provide successful examples of how an option has been implemented in another laboratory.

6. Mission Outputs: Calculation and Demand Tools

Mr Korcal presented the Calculation Tool improvement process, and its streamlining and enhancement objectives. The Group's recommendations from the first meeting on data collection and management were implemented and integrated into a beta version of an integrated Demand/Calculation Tool which was demonstrated to the Group. The demonstration emphasized:

- A reduction of data entry and elimination of data manipulation
- Dropdown pick lists where possible
- Realtime visualization of laboratory data.

Following the presentation and demonstration, the Group discussed next steps and made the following recommendations:

- Internal and external validation of all calculations in the new integrated Demand/Calculation Tool is needed
- Function testing the tool with previous mission data, given no missions are planned in the foreseeable future
- Testing during a PVS Sustainable Laboratories mission, remotely if possible, in the short term
- Add unit costs and standard values for additional methods
- Form subcommittees to review current standard values
    - Budget alignment between the Calculation and Supply Tools
    - Unit Costs in the Demand Tool
    - Standardize values in the Calculation Tool
    - Point values in the Calculation Tool

7. Mission Inputs: Supply Tool

Observations on the completeness and quality of the Supply Tool data were presented by Mr Michael Jacobs and Mr Duncan Millard (CLODE Consultants) to the Group. The observations largely validated the decisions taken by the Group to train those providing data for the mission through various methods (videos, webinars, instructions, and videoconferences pre-mission) and to streamline and integrate the Demand/Calculation Tool. The Group was pleased to have a broader evidence base for these actions and looks forward to seeing further analysis of the legacy data that will continue to inform decision making on the enhancement of the Tools in the future.

The Group participated in a breakout session to rank variables in the Supply Tool. Variables were ranked based on importance to the performance of the mission and generation of the mission report. The small groups also were asked to consider how data collection could be improved, what variables could be added, and when and how could the data be collected.

Following the breakout session, the Group discussed the challenges faced in ranking the variables and their focus on the need to improve clarity and how data was collected. Following the breakout session, each group provided a short summary of what they had learned. The following feedback was received:

- Ensure data collection is straightforward.
- Clarify language to ensure understanding by those completing any of the tools.
- Examine the Supply Tool instructions and see how they can be integrated into the Supply Tool file itself.
- Variables that have an impact on cost are always important.
- PVS Laboratory missions aim to determine the real cost of laboratory analysis.
- Determine the level of granularity needed.
- Use the background documents to specify what data are needed and when so expectations are clear.
- Remove data that are collected during a mission from the Supply Tool.
- Develop effective data entry guide, interview guides, and templates.
- Develop the intake interview to set the tone, objectives, and scope of the mission.
- Ensure the laboratory/country is clear on when, where, why, how what, data are needed in the Supply Tool (laboratory providing data remotely to the extent possible was recommended).
- Ensure that data requests are for reasonable amounts of related data and that data entry modules include training and guidance.

As discussed in the first meeting, the Group reiterated the need to - improve documentation on the premise for improved sustainable laboratory biosafety and biosecurity, to provide training on how to complete the Supply Tool, and to develop mission evaluation and follow-up action components. In addition, the Group reiterated the importance to integrate where possible, streamline, and enhance existing tools and improve data visualization.

Ms Martin then provided a short presentation of the subcommittees that have been identified to review and propose a process for reviewing standard values which form the basis of critical calculations within the Calculation and Demand Tool including Calculation Tool budget, points and standardized values and Demand Tool unit values. Each subcommittee will utilise a spreadsheet which will help them evaluate changes made to the standard values. The product of each subcommittee will include:

- Proposed standard value changes
- Definition of process used to review values
- Proposed frequency of future review

The subcommittees will provide the results of their work to the Group for review and finalization.

The recommendations from the Group's first meeting determined the goals for continued work of the Group and are being implemented and manifested through the development of the beta version of the integrated Demand/Calculation Tool and the new data entry tools under development. Several of the recommendations require input from the economist team, that will commence its study of the tools in June 2020.

8. Next Steps

The next meeting of the *ad hoc* Group is targeted to be held in October 2020, if face-to-face meetings are feasible either at the OIE or another location at that time. If not, the zoom video conferencing will be used again to continue advancing the terms of reference of the Group.

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…/Appendices

Appendix I

MEETING OF THE OIE AD HOC GROUP ON SUSTAINABLE LABORATORIES

Video Conference Meeting, April and May 2020

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Agenda

27 April 2020: 14:00-16:00

- Questions about "Objectives and Deliverables" (Pre-recorded presentation)
- Questions about "Advancements made to date" (Pre-recorded presentation)
- Review of action items from last meeting (A Nicola)

Item 2 Mission Outputs: Report / report template

- Questions about "Mission report: Part 1" (Pre-recorded presentation)
- Presentation: Potential New Report Outline (Part 2)
- Discussion questions:
    - What questions should the Report answer?
    - Can « advantages and disadvantages » be changed to « risks and benefits » or should a separate section on « benefits » be added?
    - Proposed additions to the outline: Client Chapter; Reform of Options: Status Quo, Opportunity, Rationalised, Compromise, Other; Roadmap (from Part 1 slides)
    - What do the Options do in the report? How do they relate to the Roadmap? Could we do this mission without the Options? What value added do the Options bring?
    - What visualizations and tables are essential for the report?
    - How can we improve to the reporting process?
- Decisions/Outcomes
    - Revised report outline (decision to use revised report outline for next mission and comment back to AHG)
    - How can we represent a roadmap that would work for any scenario selected?
- Summary/Actions for 30/04/20

28 April 2020: 14:00-16:00

Item 3 Mission Outputs: Calculation Tool

- Questions about "Calculation Tool challenges encountered" (Pre-recorded presentation)
- Discussion
    - Standard relative values and budget renewal rates
    - Proportions of share of cost between equipment, reagents, & staff
    - FOB/CIF
    - Budget
    - How to make current/real vs simulated and prospective options?
    - What are we missing?
    - Data visualisations: which are needed?
- Calculation tool (Progress demo)

30 April 2020: 14:00-16:00

- Outcomes from previous calls
- Supply Tool discussion preparation
    - Data aggregation: high level observations to inform next AHG meeting call
    - Discussion and experts' impressions
- Next meetings (2-4 needed)
- Path forward and Action Items

Appendix II

MEETING OF THE OIE AD HOC GROUP ON SUSTAINABLE LABORATORIES

Video Conference Meeting, April and May 2020

List of Participants

MEMBERS

Dr Ana Maria Nicola (Chair)
SENASA
Talcahuano 1660
Código Postal 1640
Martinez
Buenos Aires
ARGENTINA
anicola@senasa.gob.ar

Dr Gemma Carlile
CSIRO Australian Animal Health Laboratory
PMB 24 Geelong 3220
AUSTRALIA
gemma.carlile@csiro.au

Dr Alfonso Clavijo
Director
National Bio and Agro-Defense Facility (NBAF)
USDA, Agricultural Research Service
1880 Kimball Ave, Suite 300
Manhattan, KS 66502
alfonso.clavijo@usda.gov

Prof David Harper
Senior Consulting Fellow
Centre on Global Health Security
Chatham House
david@harperpublichealth.com

Dr Andre de Oliveira Mendonça
Coordenador
Laboratório Federal de Defesa Agropecuária – LFDA/SP
Rua Raul Ferrari S/n, Jardim Santa Marcelina, Campinas-SP,
BRAZIL
andre.mendonca@agricultura.gov.br

Dr Salama Almuhairi
Director of Veterinary Laboratories Division
Animal Wealth Sector
Abu Dhabi Agriculture and Food Safety Authority
52150, AD
UNITED ARAB EMIRATES
salama.almuhairi@adafsa.gov.ae

Dr Nick Nwankpa
Director
Pan African Veterinary Vaccine Center - African Union Commission
P. O. Box 1746,
Debre Zeit
ETHIOPIA
NickN@Africa-union.org

Dr Heather Sheeley
Workplace Health and Safety Lead
Public Health England
UNITED KINGDOM
Heather.Sheeley@phe.gov.uk

OBSERVERS

Dr Virginie Dolmazon
Laboratory Strengthening & Surveillance
WHO Lyon Office / Bureau OMS de Lyon
Immeuble Tony Garnier
24 rue Jean Baldassini
69007 Lyon, France
dolmazonv@who.int

Ms Beatrice Mouillé
EMPRES Laboratory Unit Deputy Coordinator
Animal Health Services (AGAH)
Emergency Centre for Transboundary Animal Diseases (ECTAD)
Viale delle Terme di Caracalla
00153 Rome, ITALY
Beatrice.Mouille@fao.org

CONSULTANTS

Mrs Barbara Martin
Executive Director
World Association of Veterinary Laboratory Diagnosticians
2503 Eisenhower Ave Iowa 50010
Martin.barbara.m@gmail.com

Mr David Korcal
Quality and Risk Management Administrator
Michigan State University
Veterinary Diagnostic Laboratory
4125 Beaumont Rd.
Lansing, Michigan 48910
UNITED STATES OF AMERICA
korcal61@gmail.com

OIE STAFF

Ms Jennifer Lasley
Preparedness and Resilience Department
12 rue de Prony
75017 Paris
FRANCE
j.lasley@oie.int

Mr Emmanuel Appiah
Preparedness and Resilience Department
12 rue de Prony
75017 Paris
FRANCE
e.appiah@oie.int

Dr Valentyna Sharandak
Capacity Building Department
12 rue de Prony
75017 Paris
FRANCE
v.sharandak@oie.int

Appendix III

OUTLINE OF PVS SUSTAINABLE LABORATORIES MISSION REPORT

Executive Summary

Acknowledgements

Acronyms and Abbreviations

Report

I. **Introduction**
   1. Scope and objectives of the mission (Appendix 1 & 2)
   2. Context of the mission (Appendix 3, 4, 5)

II. **Current Demand for Laboratory Services**
   1. Market Analysis (Appendix 6)
   2. Analysis of Clients of the National Laboratory System
      i. Client profiles (existing and potential)
      ii. Services each client needs
      iii. Neglected areas of investment (determination of Roadmap)

III. **Analysis of the Supply of Veterinary Laboratory Analysis Appendix 7)**
   1. Current capacity (summary) of the national veterinary laboratory network
      i. Human, Physical, Financial resources
      ii. Testing conducted in the network
      iii. National budget: Capital and operational investments

IV. **Possible Options for improved sustainability of the National Veterinary Laboratory Network**
   1. Limitations/Constraints
   2. Options
   3. Risks (considerations, challenges, weaknesses, deficiencies, lack of confidence) and benefits (charts)
      i. Comparative budgeting of proposed Options (Appendix 8)

V. **Roadmap towards the sustainability of the national laboratory system**
   1. Strategy for investment in neglected areas
   2. Implement official Animal Health programmes
   3. Optimize quality management system
   4. Establish and maintain biosafety and biosecurity programs
   5. Ensure relevant data management
   6. Establish tariff processes and accounting of costs
   7. Analyse existing and new project opportunities
   8. Institute efficient human resources management programs

VI. **Conclusions**
   1. Take-away messages/Argument relating to Options
   2. Take-away messages/Argument for the immediate implementation of the roadmap

Appendices

Appendix 1: Mission Method

Appendix 2: Tools Used

Appendix 3: Country NVS with diagram, How the lab function within the VS, Farming systems, Animal populations, VS organization chart, Laboratory organization and reporting chains, Priority diseases, National animal health programs, Testing fee structure

Appendix 4: Extracts from previous PVS Pathway reports

Appendix 5: Mission Timetable and People Met

Appendix 6: Detailed Laboratory Management benchmarks/indicators by area of the Supply Tool (per tab) for National Lab network (systematic summary, same for all reports)

Appendix 7: Capacity of other laboratories/List of all labs in country (private and public)

Appendix 8: Options' details

WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

CHATHAM HOUSE
The Royal Institute of International Affairs

Canada

A Grand Challenge for Sustainable Laboratories

Supporting development, strengthening biosafety and biosecurity, improving health security

BACKGROUND

- Early detection of infectious disease in animals and humans allows timely intervention, minimizing health and economic impacts.
- Effective disease surveillance supports control of endemic diseases and early detection of exotic diseases and emerging diseases which may lead to major outbreaks if left unchecked. It also supports agricultural productivity, food security, food safety, livelihoods, animal and human health, and economic prosperity.
- Infectious disease diagnostic laboratories support routine disease surveillance and early detection of disease events. This capability is needed for rapid disease containment and control.
- Laboratories also store potentially hazardous pathogens. Storage of pathogens and samples creates safety and security risks. Laboratory accidents and deliberate releases of pathogens have severe health and economic impacts and can quickly wipe out progress made through investments in capacity building and development and hamper efforts to achieve the UN Sustainable Development Goals.
- Many laboratories around the world are faced with significant challenges to sustainability, including that over-engineered laboratories may not meet local needs and that operating budgets are low. Such problems undermine their performance, safety and security.

ADDRESSING THE PROBLEM THROUGH A GRAND CHALLENGE

- These individual problems interact with each other and multiply to create significant challenges to running the overall system. Solving one or two of these problems alone will not be enough to bring breakthrough solutions to the critical barriers in the current system. An 'open innovation approach', using a Grand Challenge, is therefore called for to generate creative yet pragmatic holistic solutions to the sustainability problem for laboratories in low-resource settings.
- Although there is no guarantee of 100% success, a Grand Challenge can provide a sharp focus, engage the best minds and bring fresh thinking. Although the complete problem may remain unsolved, owing to the breadth of the challenge, partial success is most likely. Good ideas can be extracted from proposals.
- A Grand Challenge for sustainable laboratories would aim to find truly transformative and innovative solutions that focus on sustaining the ***functions*** of an infectious disease diagnostic laboratory in a low-resource setting.
- Multidisciplinary consortia would be expected to apply to the Grand Challenge, however it would also be important to engage individuals who may have good ideas but who are not involved in a consortium.
- The solutions would be expected to address a public good and should not create a dependency or economic burden for the end user, and awards should be invested into further development and dissemination of the solutions. The most interesting proposals could get chance to move to a subsequent stage for prototyping and demonstrating in a real environment their approach.

APPROACH

- The possibility of a consortium of underwriters for a Grand Challenge for sustainable laboratories is being investigated as a first step in assessing the viability of applying the Grand Challenge approach to the problem of laboratory sustainability. OIE and Chatham House are currently exploring interest within the donor community in joining a funders consortium. Global Affairs Canada, which is supporting OIE's and Chatham House's exploration of the concept, has expressed interest in participating in such a consortium.
- The design and running of the Grand Challenge could be managed by a service provider or an existing network or platform with experience in running Grand Challenges. For instance, AgResults – a multilateral initiative of development partners that underwrites, designs and implements prize competitions to incentivize the private sector to invest in high-impact agricultural innovations to benefit smallholder farmers – has expressed preliminary interest in the idea.
- Technical oversight during development, submission, judging, awarding prizes could be provided by a Steering Committee with involvement of OIE and Chatham House and representatives of the funders consortium. In addition, the process could be supported by a technical advisory committee.
- Incentives for Grand Challenge entrants include addressing a global public good; visibility and recognition through winning prizes; the opportunity to develop a prototype or idea through funds offered by the award; and stimulating (local) innovation and business.

Annex 5

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 2020
	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) Continual communication with Working Group on Wildlife to identify needs for specific diagnosis of wildlife diseases	Ongoing
Collaborating Centres	1) Implementation of the adopted SOPs: a) identify "miscategorised" Collaborating Centres and write to them to resolve the situation.	February 2021
	b) review new "map" that has resulted from the mapping exercise	February 2021
	c) send feedback to those Centres that need to complete or submit their 5-year work plans	February 2021
	2) Send feedback to Centres re: review of annual reports	For February 2021
Reference Laboratories	1) Send feedback to labs re: review of annual reports	For February 2021
	2) Develop a template for the annual report for OIE Reference Labs for eradicated diseases	For February 2021
Reference Centre Networks	1) Launch of the three OIE networks	November 2020
	2) Continue communicating 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 two of the existing guidelines, and include the template as an annex for the data to be submitted with a request for approval to be added to the list of approved reagents	For February 2021
	3) Project to develop Replacement International Standard Bovine Tuberculin: finalise report and propose for adoption	February 2021
***Ad hoc* Groups**	1) None at present	
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	June/July 2020
	2) WAVLD OIE seminar: theme and programme and speakers	June 2021
Covid-19	Engage with changes associated with post-pandemic reviews	On-going
Performance	Engaging with the ongoing processes around performance issues with Reference Labs	On-going

Subject	Issue	Status and Action
Twinning Programme	Assess the status of the post-twinning labs: dashboard. Gather feedback from the labs, way forward. Review geographical distribution	February 2021
Develop laboratory standards for emerging diseases	1) Discuss the *Terrestrial Code* chapter once adopted in May 2021? with the aim of introducing a corresponding chapter for the *Terrestrial Manual*	After May 2021