

REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Virtual meeting, 8–9, 11–12 February 2021

PART B

A virtual meeting of the OIE Biological Standards Commission was held from 8 to 9 and 11 to 12 February 2021. The list of participants can be found at [Annex 1](#).

Considering the ongoing COVID-19 pandemic, the 88th Annual General Session will be held virtually from Monday 24 to Friday 28 May 2021. During the 88th General Session new and revised chapters of the OIE International standards (the *Aquatic Animal Health Code*, the *Terrestrial Animal Health Code*, the *Manual of Diagnostic Tests for Aquatic Animals* and the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*) will be proposed for adoption.

To facilitate this process, the **February 2021 meeting report of the Biological Standards Commission will be distributed in two parts: Part A** provides information about the new and revised texts for the *Terrestrial Manual* that will be proposed for adoption at the 88th General Session; and **Part B** (herewith), will provide information about other topics discussed at the Commission's February 2021 meeting including the following items to be proposed for adoption: new applications for Reference Centre status and the OIE Register of diagnostic kits, as well as other topics for information.

In preparation for the 88th General Session, the OIE will organise a series of information webinars to ensure that Members are well aware of the background and key aspects of the standards being presented for adoption. Attendance to these webinars will be by invitation only. Please note that Delegates will soon receive detailed information about the virtual 88th General Session, and in particular the process for commenting and adoption of standards.

3.2. Request to include instructional training videos in *Terrestrial Manual* chapters

An expert currently updating one of the *Terrestrial Manual* chapters requested permission to include in it an instructional training video on a diagnostic technique. The Commission considered that while the inclusion of such videos could be a useful way of conveying important information, difficulties would arise in evaluating and peer-reviewing the videos, editing them or making them available in multiple languages. As such videos could be perceived as being officially endorsed by the OIE, the Commission agreed to postpone the discussion to its next meeting in September 2021 when the request could be analysed along with the training video in question.

3.3. Review of the instructions for authors

Following the Commission's decision to remove recommendations for conducting target animal batch safety tests from the vaccine batch release testing sections of individual disease-specific chapters in the *Terrestrial Manual*, when feasible, the Commission approved text for inclusion in the instructions for authors reflecting this decision and providing guidance to authors on this new instruction.

3.4. Update from February 2018 meeting: review of a validation dossier for a quantitative real-time PCR method for detection of *Taylorella equigenitalis* directly from swabs

The OIE Reference Laboratory experts had completed their review of a validation dossier for a quantitative real-time PCR method for detection of *Taylorella equigenitalis* directly from swabs. The experts evaluated the reproducibility of this method and another quantitative real-time PCR and recommended their inclusion in the *Terrestrial Manual* chapter. The Commission would review the data at its next meeting in September 2021 before a final decision can be made.

3.5. *Terrestrial Manual* status: update on chapters selected for the 2021/2022 review cycle

The Commission examined the status of chapters that had previously been identified for update in the 2021/2022 review cycle (see September 2020 report). The Commission identified alternative expert reviewers for some of the chapters where the current expert is not available.

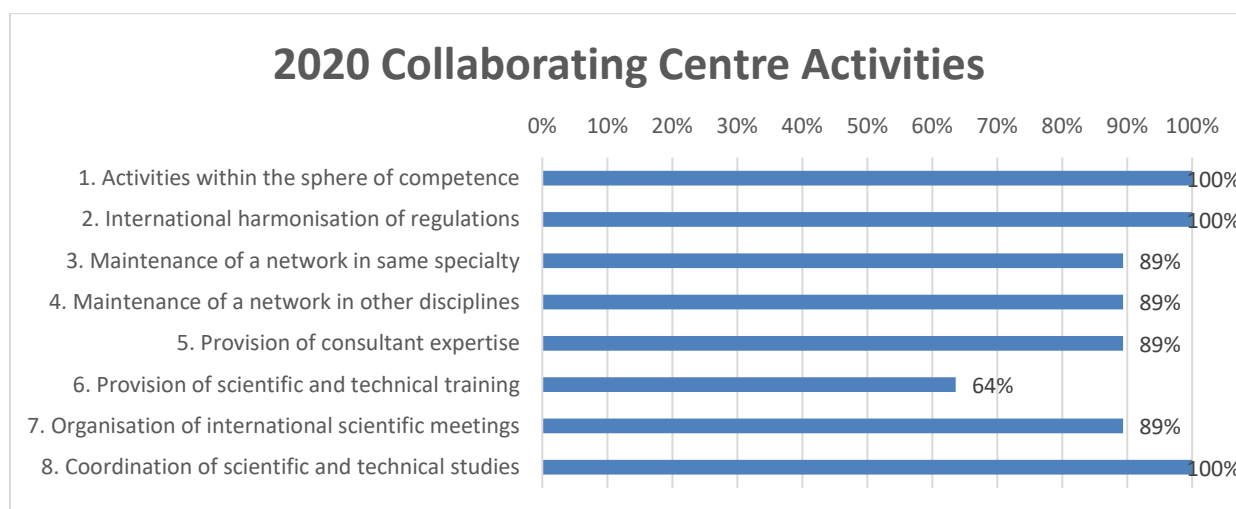
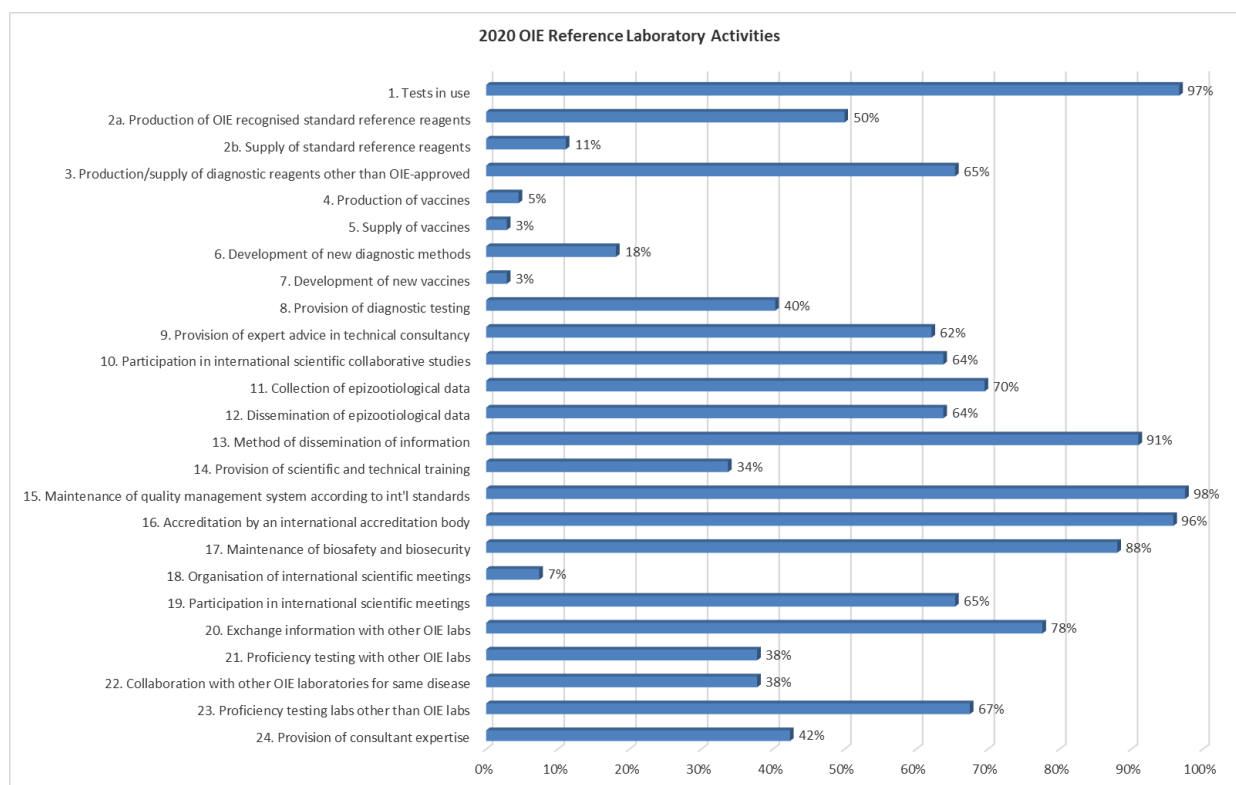
4. OIE Reference Centres

4.1. Annual reports of Reference Centre activities in 2020

As of 10 March 2021, 217 out of 224 (97%) Reference Laboratories and 58 out of 59 (97%) Collaborating Centres had submitted annual reports for 2020 to the OIE. In accordance with the adopted *Procedures for designation of OIE Reference Laboratories* (the SOPs) (<https://www.oie.int/en/scientific-expertise/reference-laboratories/sops/>) and the *Procedures for designation of OIE Collaborating Centres* (<http://www.oie.int/en/scientific-expertise/collaborating-centres/sops/>), the Commission agreed to review all the reports, noting in particular the performance of each Reference Centre with regard to fulfilling the Terms of Reference (ToR) to the benefit of OIE Member. The Commission expressed its appreciation for the continued support and expert advice given to the OIE by the Reference Centres.

In accordance with the SOPs, those Reference Centres that were not complying with the performance criteria will be asked to provide an explanation of their situation; the Delegate will be in copy of all correspondence.

The activities relevant to the Terms of Reference of OIE Reference Centres for terrestrial animals are summarised in the following graphics:



4.2. Applications for OIE Reference Centre status

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

OIE Reference Laboratory for avian influenza

Reference Laboratory for Veterinary Quality Control on Poultry Production, Animal Health Research Institute, Agriculture research Centre, Ministry of Agriculture and Land Reclamation, 7 Nadi el Seidst.Dokki, Giza, EGYPT
 Tel.: (+202) 33.37.09.57 / 33.35.28.97 / 33.38.01.21
 E-mail: araby85@hotmail.com
 Web site: www.ahri.gov.eg
 Designated Reference Expert: Dr Abdelsatar Arafa.

OIE Reference Laboratory for *brucellosis* (*Brucella abortus*, *B. melitensis*)
Department of Brucellosis Research, Animal Health Research Institute, Agricultural Research Center, Ministry of Agriculture and Land Reclamation, 7 Nadi El-Said Street, P.O. Box 12618, Dokki, Giza, EGYPT
Tel.: (+201) 222.28.14.76
E-mail: merhamdy@ahri.gov.eg; merhamdy@hotmail.com
Web site: www.ahri.gov.eg
Designated Reference Expert: Dr Mahmoud Hamdy.

OIE Reference Laboratory for *contagious equine metritis*
ANSES, Laboratory for Animal Health, Normandy site, Physiopathology and Epidemiology of Equine Diseases (PhEED) Unit, RD675, 14430 Dozulé, FRANCE
Tel.: (+33-[0]2) 31.79.22.76
E-mail: sandrine.petry@anses.fr
Designated Reference Expert: Dr Sandrine Petry.

OIE Reference Laboratory for *bovine viral diarrhoea*
National Reference Laboratory for Bovine viral diarrhoea/Mucosal Disease, Friedrich-Loeffler-Institut, Federal Research Institute for Animal Health, Institute of Diagnostic Virology, Südufer 10, 17493 Greifswald – Insel Riems, GERMANY
Tel.: (+49-38351) 7-1212
E-mail: kerstin.wernike@fli.de
Web site: <https://www.fli.de/en/institutes/institute-of-diagnostic-virology-ivd/reference-laboratories/nrl-for-bvdmd/>
Designated Reference Expert: Dr Kerstin Wernike.

OIE Reference Laboratory for *equine influenza*
Equine Research Institute, Japan Racing Association, 1400-4 Shiba, Shimotsuke, Tochigi 329-0412, JAPAN
Tel.: (+81-285) 44.0090
E-mail: manabu_nemoto@jra.go.jp; nemoto_manabu@equinst.go.jp
Web site: http://japanracing.jp/en/about/jra_organization/jeri.html
Designated Reference Expert: Dr Manabu Nemoto.

OIE Collaborating Centre for *Economics of Animal Health*
University of Liverpool, Centre of Excellence for Sustainable Food Systems, Global Burden of Animal Diseases Programme, Institute of Infection, Veterinary and Ecological Sciences, Liverpool, UNITED KINGDOM
Tel.: (+44-151) 794.61.13
E-mail: j.rushton@liverpool.ac.uk
Web site: www.liverpool.ac.uk
Designated Contact Point: Prof. Jonathan Rushton.

This multi-national OIE Collaborating Centre will include participation from the following institutions:

Norwegian Veterinary Institute, P.O. Box 750 Sentrum, 0106 Oslo, NORWAY
Tel: (+47-91) 61.85.87
E-mail: edgar.brun@vetinst.no
Web site: www.vetinst.no
Designated Contact Point: Dr Edgar Brun.

Utrecht University, Department of Population Health Services, Utrecht, NETHERLANDS
Tel.: (+31-30) 253.10.91
E-mail: j.a.stegeman@uu.nl
Web site: www.uu.nl
Designated Contact Point: Prof. Arjan Stegeman.

Reminder: The Commission reviewed the following OIE Reference Centre applications and recommended their acceptance in February 2020 and September 2020, respectively:

OIE Collaborating Centre for Good Beekeeping Management Practices and Biosecurity Measures in the Apiculture Sector

Istituto Zooprofilattico Sperimentale delle Regioni Lazio e Toscana “M. Aleandri”, via Appia Nuova, 1411 - 00178 Rome, ITALY
Tel.: (+39) 06.79.09.91
Email: izslt@legalmail.it
Website: <http://www.izslt.it/>
Designated Contact Point: Dr Giovanni Formato.

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.

Both Reference Centres will also be included in the resolutions proposed for adoption in May 2021.

An application had been received for an OIE Reference Laboratory for African horse sickness. Before a final decision can be made, the applicant would be asked to provide more detailed information on their experience in standardisation and validation of diagnostic tests, and to confirm that the laboratory can receive samples from other Members. The Commission noted that the proposed expert is currently listed as an expert for four OIE Reference Laboratories, which represents a significant workload and a broad range of expertise. The Commission also agreed to seek further information about how the expert proposes to manage the broad scope of subjects, about what support there is from the other scientific staff at the institution and about a succession plan.

Another application had been received for an OIE Reference Laboratory for foot and mouth disease. The applicant laboratory had completed a twinning project a number of years ago and the Commission was impressed with its activities and competencies. The Commission felt however, that it was too soon to endorse the application, that the laboratory needed to acquire more experience, for example of validating tests, and producing and distributing reference reagents. The Commission also questioned whether the laboratory operated under the containment level required for the work it would need to perform with FMD virus. The Commission would welcome a future re-submission after the laboratory has developed and strengthened its post-twinning activities.

Finally an application had been received for an OIE Reference Laboratory for avian mycoplasmosis (*Mycoplasma gallisepticum*, *M. synoviae*). The Commission found that the application lacked details on the provision of international training and consultations, along with organisation of and participation in scientific meetings. The applicant would be asked to review these aspects and resubmit the application.

4.3. Changes of experts at OIE Reference Centres

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

Contagious bovine pleuropneumonia and contagious caprine pleuropneumonia

Dr Lucia Manso-Silvan to replace Dr François Thiaucourt at the Centre international en recherche agronomique pour le développement (CIRAD), Campus International de Baillarguet, Montpellier, FRANCE

Heartwater

Dr Valérie Rodrigues to replace Dr Nathalie Vachieri at the Centre international en recherche agronomique pour le développement (CIRAD), Campus International de Baillarguet, Montferriez-sur-Lez, Montpellier, FRANCE

Surra (*Trypanosoma evansi*)

Dr Nick Van Reet to replace Prof. Philippe Büscher at Institute of Tropical Medicine, Department of Parasitology, Antwerp, BELGIUM

The Commission reviewed an additional nomination for a change of expert at an OIE Reference Laboratory and felt that the nominee, being an epidemiologist rather than a laboratory-based expert on disease diagnosis and control, would not fulfil the expectations of an OIE Expert. In accordance with the proposal to amend the *Guidelines for applicants for OIE Reference Laboratory status* (see Item 4.5), the Commission agreed to request information about the multidisciplinary team to which the nominee belongs to determine that all aspects of disease diagnosis and control will be covered and that the required level of expertise is available within the Reference Laboratory.

4.4. Review of new and pending applications for laboratory twinning

As of February 2021, 66 projects have been completed, 29 projects are underway and 11 are awaiting funding before beginning.

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

- *United Kingdom – Sierra Leone* for rabies: the Commission supported the technical contents of this project.

4.5. Follow-up on the consultation with the Council

In February 2020, the Commission had sought the opinion of the Council on three issues. The following is a summary of the issues and the proposed way forward.

4.5.1. Appointment of OIE Reference Laboratory experts

The Commission has observed a diversity in the nominations received for OIE Reference Laboratory experts. Some Delegates appoint subject-matter experts (technical profile) while others appoint the Head of the institution to which the laboratory is associated (management profile). The Commission asked if the designation of an OIE Reference Laboratory expert who has responsibility for the management of the laboratory, but who is not necessarily a subject-matter expert, a contravention of the ToR¹?

Given that it is understood that the designated expert works within a team, the Council agreed a management profile for the nominated expert was acceptable if the expertise available within the laboratory team provided the required technical aspects. The Council agreed that the Commission should amend the *Guidelines for applicants for OIE Reference Laboratory status* and the CV template to include a request for information about the team to determine that all aspects of disease diagnosis and control are covered and that the required level of expertise is available within the Reference Laboratory.

4.5.2. Applications from private companies for Reference Centre status

The Council informed the Commission that it had no objection, in principle, to applications for OIE Reference Centre status from the private sector, but the transparency of the OIE-related activities undertaken by such Reference Centres should not be compromised.

To ensure that the same transparency principles as those for public institutions are applied, applications from the private sector should provide information on: how the institute is integrated into the national Veterinary Services; how the applicant plans to differentiate OIE-related activities from private activities; and how the applicant plans to address the issue of transparency of its OIE-related activities. The applicant should also be reminded of the necessity to report conflicts of interest to the OIE annually through the Declaration of Interests form.

1 ToRs: Terms of Reference

If the applicant is officially designated, the Centre should be periodically monitored by responding to the questions on: the profitability of its activities as an OIE Reference Centre as opposed to its other activities; on the benefits of being an OIE Reference Centre to the rest of its commercial activities or to the Veterinary Services of the host country or to the region; on how any conflicts of interest that arise were managed; and on any other relevant matters specific to the Centre's ownership, management structures and work that could create a perception of conflict of interest.

The information provided when evaluating an application and when reviewing activities once designated should satisfy the Specialist Commission and the OIE that the Centre is complying with expectations regarding transparency and the management of conflicts of interest.

The Commission proposed that guidelines be developed on how to evaluate the declared conflicts of interest and the practicalities of implementing transparency principles when dealing with the private sector.

4.5.3. Lack of testing of international samples by OIE Reference Laboratories

On analysing the annual reports, the Commission has identified 51 OIE Reference Laboratories that did not report any international diagnostic testing on samples. As international testing is one of the core functions of an OIE Reference Laboratory, these laboratories were sent a short survey to identify the reasons for this lack of international diagnostic testing.

A total of 38 laboratories replied to the questionnaire giving the following reasons: no request was received from other countries (25); preference for other OIE Reference Laboratories for submission of samples (8); disease was absent in the region in the reporting period (3); and difficulty in transporting samples to the Reference Laboratory (2). Some respondents also mentioned that the national laboratories use the OIE Reference Laboratories to request reference materials, for test method development and validation, and for training and advising on the diagnosis of diseases in certain cases. Thus, the samples are mostly being tested at the national level, not requiring the testing services of the OIE Reference Laboratory.

To address this issue, it was agreed that the annual report template could be amended such that when a Reference Laboratory clicks "no" to the Question 1: *Did your laboratory perform diagnostic tests for the specified disease/topic for purposes such as disease diagnosis, screening of animals for export, surveillance, etc.?*, a follow-up question is asked as to the reason for this lack of testing. This way, the Biological Standards or Aquatic Animal Health Standards Commissions can understand the situation and decide if further action is needed.

- **Reference Laboratories – implementation of the SOPs²**

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

The Commission further reviewed the feedback received from Reference Laboratories that were not complying with key performance criteria according to their 2018 annual reports. 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. Several reminders were sent to the Delegate of the country with the laboratory in copy, but no response was received. Another laboratory had still not achieved accreditation to ISO 17025 or equivalent quality management system despite requesting two 6-month

2 SOPs: Standard Operating Procedure

extensions to the deadline. Both laboratories will be asked to submit an official letter requesting that their OIE Reference Laboratory designation be voluntarily revoked in accordance with Article 9 of the Internal rules for OIE Reference Centres, with consideration of further steps on the basis of response to this request.

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

The Commission reviewed the feedback received from 11 Reference Laboratories that were not complying with key performance criteria according to their 2019 annual reports. The Commission also verified the performance of some of these laboratories as illustrated in their 2020 annual reports. The Commission accepted the explanations provided by ten laboratories and was satisfied with the efforts taken by those laboratories to address the lack of activity.

The reason given by one laboratory reporting a low level of activity was the low incidence of disease in question in the region. The laboratory will be advised to contact national laboratories in other regions where the disease is prevalent and organise proficiency testing with them.

One laboratory had made many mistakes in filling in the annual report template, which it then corrected following receipt of feedback from the Commission in September. The laboratory will be informed that reporting is a key part of the ToR and care should be taken when reporting activities to the OIE.

One laboratory stated that its underperformance in the area of international activities is primarily due to its success in expanding diagnostic capacity within the region. The laboratory gave assurances that there would be improvements in its performance in the coming years.

Two laboratories – for Crimean–Congo haemorrhagic fever (CCHF) and for Rift Valley fever (RVF) – had not submitted annual reports for 2019. The laboratories proposed submitting new applications for joint Reference Laboratory designations in partnership with other institutions. The Commission did not agree to this request as it no longer accepts applications for joint Reference Laboratory status. As they are unable to fulfil the ToR, the laboratories will be asked to consider revoking their OIE Reference Laboratory status in accordance with Article 9 of the Internal rules for OIE Reference Centres. This withdrawal will mean that there are no OIE Reference Laboratories for CCHF and only one for RVF. The Commission is aware of the importance of these two disease in the sub-Saharan Africa region, and of the existence of the required capacity in certain laboratories in this region and would encourage laboratories having the necessary capacity and expertise to submit applications for OIE Reference Laboratory status for these diseases.

One laboratory had not replied to the request for feedback despite several reminders. A final reminder letter will be sent to the Delegate of the country with the laboratory in copy. Should no response be 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.

4.8. Annual report for Reference Laboratories for Rinderpest: adapted template

As the September 2020 meeting the Commission identified various key elements that would facilitate the reporting of activities by laboratories designated for eradicated diseases, and developed a new reporting template for the OIE Reference Laboratories for Rinderpest. The new template and guidance document were sent to the four OIE Reference Laboratories to use for the annual report of activities in 2020.

The Commission reviewed the four annual reports submitted and noted some proposals for improving the template, in particular the terminology used.

4.9. Further develop the SOPs to include provisions for suspending laboratories and for laboratories temporarily with no expert

The *Procedures for the designation of OIE Reference Laboratories* (SOPs) were adopted in 2017 and have been implemented by this Commission and the Aquatic Animal Health Standards Commissions since then. More recently, it has become apparent that parts of the SOPs need to be updated, for example the time line for the achievement of accreditation to a quality management system can be deleted from the SOPs as the final deadline of 31 December 2019 is past. Implementation of the SOPs has also revealed the need for a procedure for temporary suspension of OIE Reference Laboratory status, for example because of temporary lack of diagnostic ability due to construction or restructuring of the laboratory's facilities. The need was also identified for a procedure to be followed when the nomination for a replacement expert is not endorsed by the Specialist Commission leaving a laboratory without a designated expert for a short period of time. The Commission reviewed and approved text proposed by the Secretariat to address these issues. The SOPs would now be reviewed by the Aquatic Animal Health Standards Commissions and presented to the Director General for endorsement. If endorsed, the amended SOPs would be appended to the report of the next meeting of the Biological Standards Commission and uploaded to the web page.

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

4.10. Postponed from September: feedback on the mapping exercise for the existing Centres against the list of main focus area and specialties

At the February 2020 meeting, the Commission noted that a Centre in the Americas region had been miscategorised based on an analysis of the annual report and proposed a new focus area and speciality that better match the Centre's activities. In accordance with its title, the Centre was asked to concentrate on activities related to emergency preparedness and response for animal health emergencies during natural disasters such as earthquakes, floods, tsunamis, etc., and contingency planning. The Centre agreed with the proposed new focus area and speciality, but informed the Commission that it would like to broaden the Centre's activities to include management of health emergencies caused by disasters using a multi-hazard approach. At the February 2021 meeting, the Commission accepted the Centre's explanations and proposals; the Centre will continue to be an independent Centre in the region.

Another Centre in the Americas region that was categorised under focus area 'Training and education' requested the Commission to consider allowing it to also work and report on activities under other focus areas including animal health management, animal production and veterinary products. The rationale provided by the Centre is that it is unique in the region and provides a broad spectrum of technical services to Members in the region. The Commission believed that all the four focus areas cannot be combined within one Centre and asked the Centre to consider dividing up into separate Centres for each focus area; in some cases, the Centre would need to form a consortium with existing Centres in the region.

In the Europe region, one Centre that had been asked to form a consortium with another Centre in the same country with overlapping activities, agreed to the proposal and requested guidance on how to form the consortium. The Centre also asked could it maintain its status for the remaining speciality area 'food safety' by including 'feed safety' in the title to become OIE Collaborating Centre for Food and Feed Safety in the region. At the February 2021 meeting, the Commission determined that food safety and feed safety are separate and that the Centre would need to submit a separate application for Collaborating Centre status for feed safety as this is a new domain. With regard to its food safety mandate, the Commission invited the Centre to form a consortium with the already existing Centre in the region. The necessary guidance to establish the consortium will be provided.

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

The Commission reviewed the feedback received from two Collaborating Centres that were not complying with key performance criteria according to their 2019 annual reports. The Commission accepted the explanation provided by both Centres.

The Commission advised the first Centre to better use the annual report template in order to describe all the activities covered in their ToR. The report is a way to gain visibility for the Centre's activities: the Commission therefore expects to see evidence that the Centre is playing an active role in collaborative research programmes, publishing widely in the area of expertise, and contributing to updating the relevant *Terrestrial Manual* chapters.

For the second Centre, the Commission appreciated the efforts it is taking to improve its performance and looks forward to reviewing the 2020 annual report.

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

Following the September 2020 meeting, 11 Collaborating Centres that had submitted incomplete 5-year work plans were asked to provide more information on their profile, networks, international collaboration, specific details in their work plans including time frames for activities or missing authorisation signatures. Two Centres that submitted identical work plans were asked to submit individual workplans or consider merging the Centres into one. Reminders were sent to those Centres that had not submitted their work plans.

At the February 2021 meeting, the Commission reviewed the feedback received from ten Centres and approved the corrections to the 5-year work plans. One Centre will be asked to clarify how they plan to implement activities that were not completed in year 2020 due to Covid-19 pandemic situation.

Two Centres that had submitted identical workplans, resubmitted thoroughly revised individual work plans for each Centre and the Commission found them satisfactory.

One Centre that did not provide feedback will be reminded to submit their completed work plan by correcting the period to 2020–2024, listing the activities in the activity table under each ToR including time frames in months, and signing the document.

The Commission reviewed the new 5-year work plans received from Centres that had not previously submitted one, and approved the range of activities proposed by two Centres and their relevance to the identified main focus areas and specialties. One Centre that is categorised under the focus area 'Training and education' reported a broad range of activities in their work plan covering other focus areas including animal health management, animal production, veterinary products and wildlife health and biodiversity. The Centre will be asked to revise the plan to reflect activities in focus area 'Training and education'; the Centre would need to apply for designation as separate Collaborating Centre in the other focus areas before 5-year work plans would be requested and review. Four Collaborating Centres that had still not submitted a work plan would be sent a reminder.

5. Ad hoc Groups

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

5.1. Ad hoc Group on Replacement of the International Standard Bovine Tuberculin

This *ad hoc* Group has been meeting for the past 5 years, with the primary task to develop a new ISBT³. This was in recognition that the present bovine international standard, developed and maintained by WHO, was running out and deteriorating. WHO agreed that it would be appropriate for OIE to develop the new standard.

3 ISBT: international standard for bovine tuberculin

The Group met by video conference on 9 December 2020 and 12 January 2021 to discuss, finalise, and endorse a revised version of the protocol used to assess the potency of the candidate tuberculin that had been identified as a suitable replacement for the current ISBT.

The decision to revise the original protocol was made to address some concerns raised by external experts regarding the procedures to evaluate the potency of the candidate tuberculin against the current ISBT, as well as the methods to conduct data analysis and interpret test results.

The revised protocol describes additional testing procedures to assess the potency of the candidate tuberculin as well as the preferred method to perform the statistical analysis.

Preliminary results identified some issues with the assigned potencies as compared with the ISBT in both trials. The Group discussed several hypotheses that could explain the results and agreed on the need to conduct another trial with a new *M. bovis* AN5 strain to confirm the hypothesis. The results will not be ready by May 2021 and, consequently, the new international standards will not be ready for adoption at the 88th General Session. The Resolution to adopt the new ISBT will thus be postponed to 2022.

5.2. Expert consultation to review the OIE *Terrestrial Manual* chapter 3.4.6 Bovine tuberculosis

Work on updating the chapter in the OIE *Terrestrial Manual* is continuing with the aim of having a draft ready for review at the next meeting of the Commission in September this year. Following two rounds of Member comment, the chapter could be proposed for adoption in May 2022.

5.3. Ad hoc Group on Sustainable Laboratories, 11 December 2020

The OIE convened a brief virtual meeting of the *ad hoc* Group on Sustainable Laboratories in December 2020 to inform them of the advancements on the economics component of the project. The Group was introduced to the Economics Team from the University of Liverpool and the Institute for Infectious Animal Diseases of Texas A&M University (IIAD), the latter being the OIE Collaborating Centre on Biological Threat Reduction. The Economics Team briefed the Group on the work done to date, and discussed the economic sustainability key performance indicators (KPI) proposed for integration into the PVS⁴ Sustainable Laboratories Tool.

As main outcomes, the Group expressed its appreciation of the work, proposals, and presentations of the Economics Team and agreed that the work of the Team's was advancing well and in the right direction. The Group provided initial feedback to the Economics Team on which KPIs for economic sustainability are the most important ones that merit focus moving forward, and on the gaps and missing indicators. The Group proposed that each KPI should be reviewed in-depth and further consultation with the Group was needed. As a result, the Economics Team developed an expert elicitation exercise to collect the Groups' point of view on the importance and feasibility of each KPI and ranking them regarding application, importance, availability of data, and benchmarking. Whether the exercise will be conducted more broadly involving Laboratory Focal Points or OIE Experts is being considered.

The next full AHG virtual meeting is tentatively targeted for the first semester of 2021. During the next meeting, the experts will discuss the progress on the enhanced tools (improvements made, testing, etc.), be briefed on the planned pilot remote mission, provide feedback and recommendations, finalise values and unit costs for the models, and endorse the streamlined data collection and visualisation tools.

4 PVS: Performance of Veterinary Services

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

At its September 2019 meeting, the Code Commission had requested that an *ad hoc* Group be convened to revise *Terrestrial Code* Chapter 4.6 *General hygiene in semen collection and processing centres*, and Chapter 4.7 *Collection and processing of bovine, small ruminant and porcine semen*, as well as provisions in relevant disease-specific chapters of the *Terrestrial Code* and the *Terrestrial Manual*, in order to resolve inconsistencies among the chapters and ensure that relevant texts reflect the latest scientific evidence and best practices regarding risk mitigation measures in the collection and processing of semen of animals. The *ad hoc* Group was also requested to consider the inclusion of provisions to address equine semen in these chapters.

The OIE Secretariat for the Code Commission updated the Biological Standards Commission on the work of the *ad hoc* Group, which had met virtually on two occasions between November and December 2020. The Group was focusing on Chapter 4.6 before starting any work on Chapter 4.7. The *ad hoc* Group had proposed a new draft structure for Chapter 4.6, which had been reviewed and approved by the Code Commission, which also provided some further guidance on the holdings and species to be covered in the chapter.

The Code Commission requested that the *ad hoc* Group be reconvened to continue this important work and finalise its report prior to the next meeting of the Commission in September 2021.

6. International Standardisation/Harmonisation

6.1. OIE Register of diagnostic kits

6.1.1. Update on new or renewed applications

The Secretariat for Registration of Diagnostic Kits (OIE SRDK) informed the Commission of the current status of the OIE Register of diagnostic kits. At present, there are 13 registered kits; four new applications (submitted in 2019 and 2020) and one application for extension of claim (submitted in 2020) are in various stages of review. One application (submitted in 2019) was withdrawn.

The Commission endorsed renewal of the Pourquier® IIF *Taylorella equigenitalis* kit (IDEXX Laboratories) for a 5-year period (until 2026). An OIE Resolution will be prepared accordingly for the 88th OIE General Session in May 2021.

The Commission also endorsed deferring the renewal of the Rapid MERS-CoV Ag Test (BioNote Inc.), and endorsed a List of Questions to be addressed to the manufacturer requesting additional information to demonstrate that the Rapid MERS-CoV Ag Test (Bionote Inc.) is still fit for the purposes as specified in its 2016 registration, including additional information on the test's specificity and sensitivity, and potential cross-reactivity with COVID-19.

The Commission endorsed moving the renewal date for the Check&Trace Salmonella (Check-Points B.V.) to 2025, as this kit had undergone scientific evaluation for an extension of claim in 2020.

One diagnostic kit renewal will commence in 2021 (for renewal in the year 2022): *Mycobacterium bovis* Antibody Test Kit (IDEXX Laboratories).

6.1.2. Endorsement of updated SOP for OIE Register of diagnostic kits

The OIE SRDK had introduced changes to the *Standard Operating Procedure (SOPs) for OIE Registration of Diagnostic Kits* and the *Application Form for the Certification of Diagnostic Kits validated as fit for specific purposes (Application Form)* after consultation with OIE Collaborating Centres and the industry association for animal diagnostic kits.

These changes aimed to bring the guidance in these documents up to date with the application of the current procedure, recognising that a more thorough update of the SOP may need to be scheduled in the future. The proposed changes to the SOPs concerned principally the addition of information regarding provisional recognition, and the allowed timeframe for applicants to prepare responses to the Review Panel's questions. The proposed changes to the Application Form related principally to the addition of information to the instructions provided to applicants in Sections 2, 3 and 4 to assist applicants in preparing their response, the addition of more detailed references to the OIE *Terrestrial Manual* and *Aquatic Manual*, and changes to the question on the intended purpose of test (Section 2.2.3).

These changes were endorsed by the BSC and are provided in [this document](#).

The Commission agreed with the proposal and, subject to corresponding endorsement by the Aquatic Animal Health Standards Commission and Director General approval, agreed that the revised SOP should be posted on the OIE website to replace the current version, so all applicants will be fully informed of the new procedure.

<https://www.oie.int/en/scientific-expertise/registration-of-diagnostic-kits/procedure-for-submission/>

<https://www.oie.int/en/scientific-expertise/registration-of-diagnostic-kits/download-application-form/>

7. Resolutions for the General Session

7.1. Resolutions that will be presented in May 2021

The Commission noted that the following resolution would be proposed for adoption at the General Session in May 2021:

- A resolution proposing the adoption of the 38 draft chapters for the *Terrestrial Manual*;
- A resolution proposing the new OIE Collaborating Centres.

The following resolutions would be proposed for adoption by the alternative procedure before the General Session in May 2021:

- A resolution proposing the new OIE Reference Laboratories for terrestrial animal diseases;
- A resolution proposing the renewal of an already registered diagnostic kit to the OIE Register.

8. Conferences, Workshops, Meetings

• *Future Conferences, Workshops, Meetings*

8.1. WAVLD⁵ International Symposium, Lyon, France 2023

The 20th International Symposium of the WAVLD was to have been held in Lyon, France in 23–26 June 2021. Traditionally, the Biological Standards Commission organises a 1-day seminar held during the WAVLD Symposium. The OIE is a member of the Scientific Committee of the International Symposium. Due to the COVID-19 pandemic and travel restrictions and difficulties around visa, air travel and requirements, the WAVLD Executive board has decided that:

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

5 WAVLD: World Association of Veterinary Laboratory Diagnosticians

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

9. Liaison with other Commissions

9.1. Horizontal issues among the Specialist Commissions

9.1.1. 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 to support Member notification. In September 2020, the first tranche of **nine** priority diseases was approved by the Scientific Commission following consultation with the Code Commission: theileriosis in cattle, equine influenza, surra (*Trypanosoma evansi*), leishmaniosis, dourine (*Trypanosoma equiperdum*), Crimean–Congo haemorrhagic fever, Nipah virus encephalitis, Q fever and tularemia.

The Biological Standards Commission was presented with a Table showing the status of the **nine** diseases in the first tranche. Four case definitions were presented to the Biological Standards Commission: equine influenza, dourine, surra and leishmaniosis. The Commission commended the progress made and provided some comments on the case definition for infection with equine influenza virus for consideration by the Scientific Commission, and encouraged the OIE Secretariat to continue with the development of case definitions for OIE-listed diseases on the workplan.

9.1.2. SOP for determining if a pathogenic agent of terrestrial animals meets the OIE definition for an emerging disease

According to Article 1.1.4. of the *Terrestrial Code*, Veterinary Authorities shall notify the OIE when an emerging disease has been detected in a country, zone or compartment, and send periodic reports subsequent to a notification for the time necessary to have reasonable certainty that the disease has been eradicated or the situation has become stable, or until sufficient scientific information is available to determine whether it meets the criteria for inclusion in the OIE List as described in Chapter 1.2.

Despite the fact that a definition for emerging disease is provided in the Glossary of the *Terrestrial Code*, there is no systematic process to determine that an emerging disease of terrestrial animals meets the definition for an emerging disease, and as a result Members are not consistent in their interpretation of the definition, which has caused inconsistencies regarding notifications of emerging diseases from Members.

In order to facilitate the reporting of emerging diseases of terrestrial animals by Members with a transparent and consistent approach, further guidance to Members, beyond the definition for emerging disease, as to when a disease can be considered to meet the OIE definition of an emerging disease, is needed. Furthermore, the means through which the information on emerging diseases notified by Members is considered by the OIE and the process to determine the outcomes described in Article 1.1.4. requires elaboration.

To solve this issue, the OIE developed an SOP that describes the sequence of steps for the determination of an emerging disease, and roles and responsibilities of relevant entities. To facilitate its implementation, the SOP is supported by a guidance document for the interpretation of the definition for emerging diseases.

Both the SOP and the guidance document were presented to the Biological Standards Commission for information and comment. The Commission provided feedback for consideration by the Scientific Commission.

The Commission was informed that the SOP will be available in the OIE website after Scientific Commission's consideration and Director General approval.

9.2. Scientific Commission for Animal Diseases

9.2.1. Feedback on review of Collaborating Centre application on Economics of Animal Health

The Scientific Commission was asked its view on an application received for an OIE Collaborating Centre on Economics of Animal Health (Europe region). The Scientific Commission was informed that the application is a milestone within the OIE-led project Global Burden of Animal Disease (GBADs) (<https://oiebulletin.com/?p=11531&lang=fr>). The Scientific Commission noted that determining the global burden of animal disease is an important tool to justify funding of disease control programmes and also contributes to the risk assessment process informing, in particular, the consequence assessment step. Furthermore, the development of uniform methodologies to estimate the economic impact of disease will allow valid comparisons between different regions. The Scientific Commission noted that overlaps might be present between the proposed Collaborating Centre and the Risk Analysis & Modelling OIE Collaborating Centre Consortium based at the Royal Veterinary College and the Animal and Plant Health Agency (UK). The Scientific Commission fully endorsed the proposal, and recommended links be established with other OIE Collaborating Centres working in the field of epidemiology.

9.3. Terrestrial Animal Health Standards Commission

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

9.3.1. Updates from the September 2020 Code Commission meeting

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.

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

In draft Chapter 12.7 *Infection with Theileria equi and Babesia caballi (equine piroplasmosis)*, Article 12.7.5 *Recommendations for the importation of equids*, the Biological Standards Commission agreed with a comment that Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals were subjected to a serological **and** agent identification test with molecular techniques for the detection of *T. equi* and *B. caballi*. This recommendation aligns with the *Terrestrial Manual* chapter and was stated previously by the Biological Standards Commission: "The Biological Standards Commission emphasised that positive serology findings without clinical or pathological signs would require a combination of tests to confirm infection in a subclinically infected carrier. A combination of PCR and serological tests is essential to determine whether an animal is free from infection" (from report of the February 2020 meeting).

9.3.3. Question on Chapter 8.3 *Infection with bluetongue virus*

The Biological Standards Commission was informed that the IETS⁶ has amended the categorisation of bluetongue under the current IETS embryo categorisation system relating to disease risks in *in-vivo* derived bovine embryos. Category 1 was amended to state: Bluetongue virus, excepting BTV-8 and BTV-8 be added to category 4. The Commission, in consultation with an OIE Reference Laboratory expert, determined that the changes would not have an impact on the *Terrestrial Manual* chapter.

6 IETS : International Embryo Transfer Society

9.3.4. Question on Chapter 11.10 Infection with Theileria annulata, T. orientalis and T. parva

For Chapter 11.10 *Infection with Theileria annulata, T. orientalis and T. parva*, Article 11.10.5 *Recommendations for importation from countries or zones not free from infection with Theileria*, the Code Commission had received technical questions on diagnostic methods and timing of tests. The Biological Standards Commission referred these technical questions to the Reference Laboratory expert for advice.

9.3.5. Question on Chapter 10.4 Infection with high pathogenicity avian influenza viruses

The Code Commission had received a comment requesting the development of a procedure to identify low pathogenic avian influenza viruses having proven natural transmission to humans and causing severe consequences. The question arose due to the proposed modification of the OIE listed diseases to include zoonotic low pathogenicity avian influenza viruses and how to differentiate between high pathogenicity and low pathogenicity avian influenza with zoonotic potential. The Biological Standards Commission noted that the current *Terrestrial Manual* chapter, which had been thoroughly revised and updated and would be proposed for adoption this May, contains the procedures and criteria for assessment of pathogenicity.

9.3.6. Question on Chapter 12.2 Infection with Taylorella equigenitalis (contagious equine metritis)

In Chapter 12.2 *Infection with Taylorella equigenitalis*, Article 12.2.4 *Recommendations for importation of stallions or mares*, the Biological Standards Commission agreed to clarify that horses were subjected to *T. equigenitalis* identification tests (culture for *T. equigenitalis* or molecular testing), with negative results. The Commission did not agree with the proposal to replace “horses” with “the donor stallion” in the following sentence because the Article covers stallions or mares.

9.4. Aquatic Animal Health Standards Commission

9.2.1. Feedback on review of Collaborating Centre application on Economics of Animal Health

The Commission was impressed with this strong application and was pleased that aquatics was one of the central targeted areas of activity. The Commission fully endorsed the application.

10. Matters of Interest for Information

10.1. Update on OFFLU

The Commission was briefed on the OFFLU⁷'s contribution to the WHO Consultation on the Composition of Influenza Virus Vaccines of data on avian influenza (AI) and swine influenza (SI) for the period February to September 2020. A significant amount of genetic and antigenic data on zoonotic animal influenza viruses was shared with WHO at the September 2020 vaccine composition meeting. Animal health laboratories in countries representing Africa, Asia, Oceania, Americas and Europe contributed sequence data for 50 H5, 13 H7 and 29 H9 subtypes 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. The data collection for the February 2021 WHO meeting is currently underway.

Due to COVID-19 pandemic situation, several short OFFLU Committee meetings were arranged to bring together the core group of experts to discuss the strategic and operational activities of the network. The OFFLU executive committee held discussion with various technical activity leaders (avian, swine, equine, wildlife, epidemiology, socioeconomics) to elaborate the OFFLU work plan to deliver in 2021.

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

Equine influenza experts participated in the OIE panel of equine influenza expert meeting virtually in April 2020 to update the vaccine recommendations for the equine industry in 2020.

The swine influenza experts met virtually in December 2020 and shared data about the global swine influenza situation in pig populations by providing regional and country-specific reports from Asia, Europe, and Americas.

10.2. Update on rinderpest

The Commission was informed that the FAO⁸-OIE JAC⁹ had its 16th meeting on 8 December 2020 by videoconference hosted by FAO. There were no new research applications or RHF¹⁰ applications for review by the JAC at that meeting. The Committee received an update on the status of the application from India for an RHF, which has reached the stage where a site inspection is required before further discussion. The JAC was also updated on the activities of the RHF network. Since the Sequence and Destroy project was completed, there has been little to report from The Pirbright Institute, United Kingdom. CIRAD¹¹, France, has established a vaccine seed bank for global use with support from FAO. FADDL¹², USA, has been validating virus inactivation methods of extracted and lyophilised materials to meet the requirements of the Federal Select Agent Program and PIADC¹³ Biosafety, in order to proceed with a Sequence and Destroy project. The extension of shelf-life of LA-AKO RP vaccine from 4 to 5 years was officially approved by the national authority of Japan. IVDC¹⁴, China (People's Rep. of), will seek approval from the FAO-OIE Rinderpest Secretariat for a Sequence and Destroy project. The online secure database system that is hosted by the OIE and serves as the global inventory for RVCM¹⁵ is undergoing maintenance due to a malfunction that does not impact its security.

The Commission was informed that the OIE is preparing a call for proposals to undertake a risk assessment of rinderpest re-introduction 10 years after its eradication, considering the current distribution of RVCM and emerging technologies. This work will include a review of progress done in sequestration and destruction over the past 10 years. At present, seven countries hold RVCM outside an RHF. Vietnam is expected to destroy its RVCM during the first semester of 2021. Finally, the Commission was informed that FAO and OIE are in the process of signing a co-branding agreement applicable to past and future rinderpest communication materials.

10.3. Update on COVID-19

The Commission was updated on the activities of the OIE in response to COVID-19. The OIE remains fully mobilised and is working with its network of experts and partners, including WHO and FAO, to support its Members in responding to this One Health crisis by taking a multi-sectoral approach. Through the support of the *ad hoc* Group on COVID-19 and the human–animal interface, the OIE is regularly assessing the reports of both natural and experimental infection in animals to inform the development of risk-based guidance. This includes regularly reviewing and updating the Questions and Answers Page on the COVID-19 Portal, a list of events reported by OIE Members of natural infection of animals with SARS-CoV-2 and the OIE Technical Factsheet on Infection of animals with SARS-CoV-2. The Commission was also updated on the work of the OIE *ad hoc* Group on COVID-19 and safe trade in

8 FAO: Food and Agriculture Organization of the United Nations.

9 JAC: Joint Advisory Committee for Rinderpest

10 RHF: rinderpest holding facility

11 CIRAD: Centre de coopération internationale en recherche agronomique pour le développement (Agricultural Research for Development).

12 FADDL: Foreign Animal Disease Diagnostic Laboratory.

13 PIADC: Plum Island Animal Disease Center

14 IVDC: National Institute for Viral Disease Control and Prevention

15 RVCM: rinderpest virus containing materials

animals and animal products that was considering the risk to human health posed by international trade in mink pelts. In response to the reported outbreaks in mink, the OIE developed Guidelines for working with farmed animals of species susceptible to infection with SARS-CoV-2 and has formed a joint OIE and FAO advisory group on viral evolution of SARS-CoV-2 in animals.

In December 2020, the OIE hosted two global webinars for OIE Delegates, OIE Laboratories Focal Points and key partners to share experiences on the impact of COVID-19 on veterinary laboratories and to identify challenges, innovations and opportunities that arose during the pandemic. Presentations were given by OIE Members to demonstrate how veterinary laboratories were able to support the public health response to COVID-19 by testing human specimens for SARS-CoV-2, both at the individual laboratory level and through a network of laboratories. The interactive discussions focused on strengthening the One Health Concept and what lessons have been identified from the pandemic from which we can learn for the future both for animal and public health emergencies. The OIE is currently consolidating the outputs of the webinars into a report and a short policy brief to share with the participants and the OIE's network. The report and summary policy brief will be used to inform the OIE Sustainable Laboratories initiative and other capacity building work of the OIE and to continue to advocate for the inclusion of Veterinary Services in whole-of-government frameworks for emergencies and disasters.

Lastly, the OIE is continuing to work on a future programme called the OIE Wildlife Health Management Framework which aims to anticipate, reduce, and manage risk of spill over events of pathogens between wildlife, livestock, and humans at the animal/human/environment interface.

10.4. Global Laboratory Leadership Programme

Historically, the OIE has provided workforce development opportunities to National Focal Points for Veterinary Laboratories in the form of regional seminars. To enhance and extend the OIE's training offering for laboratory systems leaders, the OIE partnered with WHO to found the GLLP¹⁶, in collaboration with the CDC¹⁷, the APHL¹⁸, the ECDC¹⁹ and FAO.

The GLLP Partnership will enable the OIE to provide a more comprehensive laboratory systems workforce development offering to Veterinary Services' stakeholders and to expand access for Veterinary Services staff. GLLP will complement existing face-to-face training and provide access to virtual training through the OIE's Training Portal. The aim of the OIE's involvement in this partnership is to ensure that animal health laboratory leaders can benefit from laboratory leadership training, that their context and needs are included and addressed, and that they have access to training materials, both through the OIE Training Portal and through WHO's Health Security Learning Platform.

To support the application of the GLLP's Laboratory Leaders Competency Framework, in 2020 the OIE mobilised the expertise of more than 40 OIE experts representing all 5 OIE Regions, from more than eight OIE Reference Centres, the OIE Biological Standards Commission, and OIE Partner WAVLD. These experts supported the development of the GLLP Learning Package materials (three Sections (Laboratory Management, Laboratory Leadership, and Laboratory Systems), nine units and 42 modules). All material has a strong One Health focus. The modules are focused on laboratory surveillance, outbreak investigation, preparedness, response, recovery, biosafety, biosecurity, shipment of dangerous goods, laboratory systems, leadership, communication, and management. The GLLP Learning Package materials will be available in 2021. Materials include instructor's guides, participant's guides, slide decks, programme implementation guide and mentoring guide in both face-to-face and virtual learning formats, targeted at health laboratory system management and leadership.

16 GLLP: Global Laboratory Leadership Programme

17 CDC: Centers for Disease Control and Prevention (United States of America)

18 APHL: Association of Public Health Laboratories (United States of America)

19 ECDC: European Centre for Disease Prevention and Control

10.5. Sustainable laboratories data analysis and advocacy paper

With the generous support of Global Affairs Canada, the OIE is undertaking a project to address laboratory biosafety and biosecurity, innovation, and resource sustainability to reduce biological threats. The OIE is analysing PVS Pathway data to inform a position paper on the investment needs for sustainable laboratories, and will hold a technical consultation to establish the research agenda for evidence-based biosafety in low-resource settings. The OIE is expanding the PVS Sustainable Laboratories toolbox with economic and laboratory management expertise, supporting Laboratory Twinning Projects, and exploring open innovation as an approach to addressing laboratory sustainability challenges. Specific information on the biosafety research roadmap, the open innovation, and laboratory twinning is available in dedicated sections of this report.

Under this project, economic and laboratory management experts are advising the OIE on the internal validity of the PVS Sustainable Laboratory Tool, analysing data collected through the past PVS Sustainable Laboratories missions and will develop a position paper on Investment Needs for Sustainable Laboratories. To date, a detailed assessment of the current tool's calculations and formulae to provide an evidence-based review of the internal validity of the model has been completed; a guide on how laboratories can demonstrate value to their clients by highlighting benefit streams for the private sector, government, research partners, and donors according to the different functions a laboratory may serve at national, regional, and international levels, and economic analysis tools that can be used for these clients have been developed; and a literature review and expert consultation to inform the choice of indicators and identify data gaps has been undertaken. The next steps of the project are:

- Development of a proposal for future sustainability analysis
- Construction of models using the pre-existing data and missing parameters
- Arguments developed on the value of the laboratory expressed beyond being a service provider to the veterinary services and sustainability can be expressed in a form beyond an investment appraisal or currency amount
- Development of a position paper detailing the specific investment needs for laboratories and laboratory networks. Topics may include:
 - challenges for sustainability as revealed through analysis of past PVS Laboratory Missions
 - additional KPIs and other metrics necessary to evaluate laboratory sustainability
 - best practices to ensure consistent and high-quality outputs from revised tools and PVS mission methodology
 - case studies of how strategic and operational considerations contribute to “successful” and sustainable laboratories
 - recommendations for implementing the OIE's suite of tools in the real-world context of existing laboratories.

Given the challenges related to in-person missions and meetings during the COVID-19 pandemic, many activities of the project are unable to be implemented as planned. To innovate and find solutions during this challenging time, the OIE is developing the online PVS Sustainable Laboratories Tool where data entry, calculations, visualisations, and tools are available through an online portal and database. A virtual tool through an online portal will provide improved access to the inputs and outputs of the PVS Sustainable Laboratories missions and increase access for end users in remote areas or in areas that are difficult access for security, geographical, physical, or health-related reasons.

10.6. VICH: Brief report on the 39th VICH Steering Committee Meeting and 13th VICH Outreach Forum meeting (16–19 November 2020)

The Commission was updated on the 39th VICH Steering Committee and the 13th VICH Outreach Forum (VOF), which took place electronically from 16 to 19 November 2020.

The 13th meeting of the VOF, chaired by the OIE, drew over 90 participants representing 22 national regulatory agencies and animal health industry organisations. Following updates on VICH activities and related OIE activities, the VOF members took advantage of an open Q&A session. An online training webinar organised with the aim of better understanding of VICH Guideline 27 (*Antimicrobial Resistance – Guidance on pre-approval information for registration of new veterinary medicinal products for food producing animals with respect to antimicrobial resistance*) was held electronically for VOF members on 9 February 2021.

The Commission was informed that the VICH Steering Committee adopted VICH Guideline GL59 (*Biologicals*) *LABST – Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use* for implementation in VICH Members by November 2021. This Guideline completes the series of three VICH Biologicals Guidelines on harmonising criteria to waive target and laboratory animal batch safety testing, with the aim of reducing the need for these tests and improving animal welfare.

In addition, the Commission was informed that the document *VICH's priorities for its 5th phase (2021 – 2025)*, concerning VICH's next strategy, was adopted. The document underlines the importance to foster effective cooperation with the OIE, particularly with regard to the OIE's strategic focus on promoting good governance of veterinary medicinal products for OIE Members with the possibility to apply the harmonised technical requirements established in VICH Guidelines.

The 40th Steering Committee meeting is planned for 15 to 18 November 2021 in the offices of the European Medicines Agency (EMA) in Amsterdam.

10.7. Biosafety research road map

The Group, which is linked to the sustainable laboratories project, was convened to look at all aspects of biosafety to improve understanding and to identify the gaps in the knowledge on biosafety issues. To begin, the Group selected ten organisms and looked into activities that are typically undertaken with these organisms in laboratories to try to understand the biosafety precautions used and if there is any scientific basis for these precautions. The Group divided it into four subgroups: one Group focused on respiratory pathogens, one on zoonoses, one on viral haemorrhagic fevers, and the other on miscellaneous diseases and pathogens. A consultant has been hired to research the literature and gather baseline information on each organism. Each subgroup will look at two or three organisms in each category to focus on any gaps in the literature and identify the processes associated with each organism that might generate biosafety risks. This process is ongoing and the group continues to communicate offline.

10.8. Update on IAEA²⁰ Zodiac²¹ Project

The 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 was briefed on discussions between the OIE, FAO, and WHO through the Tripartite Secretariat mechanism and between IAEA and OIE directly. The OIE acted on the Commission's recommendation to ensure significant consultation at the strategic level through several meetings with IAEA, WHO, and FAO. IAEA has approached OIE to inform that following approval at the Board of Governors meeting in November 2020, IAEA had begun to implement the Zodiac Project. IAEA also wishes to establish an MOU with the OIE to cooperate "to better support countries through our respective programmes and to achieve synergy including in the implementation of the Zodiac Project." The OIE would aim through the development of the MOU to better understand the scope of the project so that

20 IAEA: International Atomic Energy Agency

21 ZODIAC: Zoonotic Disease Integrated Action

further discussions can be held at the operational and technical levels to avoid duplication, maximise the efficiency of resource management and ensure sustainability. The areas of overlap with OIE activities and other international players' activities and mandates highlighted by the Commission in Sept 2020 remain in the Zodiac proposal. The MOU proposal made by IAEA will be examined in 2021.

10.9. *Ad hoc* Group on alternative strategies for the control and elimination of *Mycobacterium tuberculosis* complex infection in livestock

The meeting of the OIE *ad hoc* Group on Alternative Strategies for the Control and Elimination of *Mycobacterium tuberculosis* complex Infection in Livestock was held via videoconference on 29 September 2020.

The *ad hoc* Group was convened to:

- Consider and address three of the ten priorities set out in the Roadmap for Zoonotic Tuberculosis²². The three priorities are: i) the need to reduce the TB prevalence in livestock; ii) the development of policies and guidelines for surveillance and control of TB in animals; and iii) the implementation of community-based interventions to reduce burden of TB in humans and livestock, recognizing the cultural and socioeconomic realities of each setting;
- Explore and recommend actionable strategies to control TB in livestock other than by test and slaughter.

Keys issues and outcomes of the meeting

- The Group noted that wildlife was not considered along with livestock as a target animal population of TB control strategies in the ToR, and acknowledged that the control of TB in wildlife requires a set of measures different from those in livestock. To keep the scope of work narrow and avoid adding complexity, the Group agreed to not include wildlife in the ToR.
- The Group agreed that there is a need to develop innovative strategies for controlling TB in livestock in economically disadvantaged areas where slaughter is not an option and the zTB burden in humans is unacceptably high. However, the Group noted that another key challenge to be addressed in these areas is the lack of expertise and technical capacity, and suggested also considering ways to improve the efficient use of existing tools by the Veterinary Services rather than focusing solely on innovation. It also acknowledged that 'one size does not fit all' and that selected TB control strategies would need to be flexible and adaptable to the changing conditions of real-world scenarios.
- The Group agreed to clarify that these TB control strategies can also refer to locally applicable interventions (i.e. at herd level) that may be scaled up to cover larger areas while taking into account the relevant socioeconomic and cultural settings.
- The Group recognised that one of the critical tasks of this initiative is to elicit expert opinion on TB control strategies by means of interviews with external experts other than *ad hoc* Group members. The Group reviewed a draft list of questions for expert elicitation, and finalised a first tranche of external experts to be interviewed.

A formal survey tool is being developed. Interviews with external experts will be conducted during 2021.

²² The Roadmap for Zoonotic Tuberculosis is a multisectoral roadmap that details ten priorities for addressing zoonotic tuberculosis in people and animals. It has jointly been developed by WHO, OIE, FAO and the International Union Against Tuberculosis and Lung Disease (Union).

A follow-up *ad hoc* Group meeting is planned in 2021 to discuss the results of the survey and formulate recommendations on new control strategies to control TB in livestock.

11. Any Other Business

11.1. Work plan

The updated work plan was agreed and can be found at [Annex 3](#).

11.2. Dates of the next Biological Standards Commission meeting

The Commission noted the dates for its next meeting: 6–9 September 2021.

.../Annexes

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION
Paris, 8–9, 11–12 February 2021

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MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 8–9, 11–12 February 2021

Agenda

1. **Welcome**
2. **Adoption of Agenda**
3. **Manual of Diagnostic Tests and Vaccines for Terrestrial Animals**
 - 3.1. Review of Member comments received on draft chapters and their endorsement for circulation for second-round comment and proposal for adoption in May 2021
 - 3.2. Request to include instructional training videos in *Terrestrial Manual* chapters
 - 3.3. Review of the instructions for authors
 - 3.4. Update from February 2018 meeting: review of a validation dossier for a quantitative real-time polymerase chain reaction method for detection of *Taylorella equigenitalis* directly from swabs
 - 3.5. *Terrestrial Manual* status: update on chapters selected for the 2021/2022 review cycle
4. **OIE Reference Centres**
 - 4.1. Annual reports of Reference Centre activities in 2020
 - 4.2. Applications for OIE Reference Centre status
 - 4.3. Changes of experts at OIE Reference Centres
 - 4.4. Review of new and pending applications for laboratory twinning
 - 4.5. Follow-up on the consultation with the Council
Reference Laboratories – Implementation of the SOPs
 - 4.6. Follow-up September meeting: further feedback from the Laboratories that are not complying with the key ToR according to their 2018 annual report
 - 4.7. Feedback from the Laboratories that are not complying with the key ToR according to 2019 annual report
 - 4.8. Annual report for Reference Laboratories for Rinderpest: adapted template
 - 4.9. Further develop the SOPs to include provisions for suspending laboratories and for laboratories temporarily with no expert
Collaborating Centres – Implementation of the SOPs
 - 4.10. Postponed from September: feedback on the mapping exercise for the existing Centres against the list of main focus area and specialties
 - 4.11. Follow-up September: feedback from the Centres that are not complying with the key ToR according to 2019 annual report
 - 4.12. Follow-up September: feedback on the review of the 5-year work plans received from Collaborating Centres
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. Expert consultation to review the OIE *Terrestrial Manual* chapter 3.4.6 Bovine tuberculosis
 - 5.3. *Ad hoc* Group on Sustainable Laboratories, 11 December 2020
 - 5.4. *Ad hoc* Group on the revision of *Terrestrial Code* chapters regarding the collection and processing of semen of animals, 9 November 2020 to 15 January 2021

6. International Standardisation/Harmonisation

- 6.1. OIE Register of diagnostic kits
 - 6.1.1. Update and review of new or renewed applications
 - 6.1.2. Endorsement of updated SOP for OIE Register of diagnostic kits

7. Resolutions for the General Session

- 7.1. Resolutions that will be presented in May 2021

8. Conferences, Workshops, Meetings

Future Conferences, Workshops, Meetings

- 8.1. WAVLD International Symposium, Lyon, France 2023

9. Liaison with other Commissions

- 9.1. Horizontal issues among the Specialist Commissions
 - 9.1.1. Update on case definitions
 - 9.1.2. SOP for determining if a pathogenic agent of terrestrial animals meets the OIE definition for an emerging disease
- 9.2. Scientific Commission for Animal Diseases
 - 9.2.1. Feedback on review of Collaborating Centre application on Economics of Animal Health
- 9.3. Terrestrial Animal Health Standards Commission
 - 9.3.1. Updates from the September 2020 Code Commission meeting
 - 9.3.2. Questions on Chapter 12.7 *Infection with Theileria equi and Babesia caballi (equine piroplasmosis)*
 - 9.3.3. Question on Chapter 8.3 *Infection with bluetongue virus*
 - 9.3.4. Question on Chapter 11.10 *Infection with Theileria annulata, T. orientalis and T. parva*
 - 9.3.5. Question on Chapter 10.4 *Infection with high pathogenicity avian influenza viruses*
 - 9.3.6. Question on Chapter 12.2 *Infection with Taylorella equigenitalis (contagious equine metritis)*
- 9.4. Aquatic Animal Health Standards Commission
 - 9.4.1. Feedback on review of Collaborating Centre application on Economics of Animal Health

10. Matters of Interest for Consideration or Information

- 10.1. Update on OFFLU
- 10.2. Update on rinderpest
- 10.3. Update on COVID-19
- 10.4. Global Laboratory Leadership Programme
- 10.5. Sustainable laboratories data analysis and advocacy paper
- 10.6. VICH: Brief report on the 39th VICH Steering Committee Meeting and 13th VICH Outreach Forum meeting (16–19 November 2020)
- 10.7. Biosafety research road map
- 10.8. Update on IAEA Zodiac Project
- 10.9. *Ad hoc* Group on alternative strategies for the control and elimination of *Mycobacterium tuberculosis* complex infection in livestock

11. Any Other Business

- 11.1. Work plan
 - 11.2. Dates of the next Biological Standards Commission meeting
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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 second-round comment	February/March 2021
	2) Remind authors of the chapters identified previously for update but not yet received and invite authors of chapters newly identified for update	On-going
	3) Convene virtual expert consultation to update chapter 1.1.4 on biosafety/biosecurity	April 2021
	4) Continual communication with Working Group on Wildlife to identify needs for specific diagnosis of wildlife diseases	Ongoing
Consultation with the Council on Reference Centres	1) Inform the Aquatic Animals Commission of the consultation with the Council and outcome for feedback before implementation of the recommendations (appointment of Reference Laboratory experts; applications from the private sector; lack of testing of international samples)	September 2021
Collaborating Centres	1) Implementation of the adopted SOPs:	
	a) identify "miscategorised" Collaborating Centres and write to them to resolve the situation.	March 2021
	b) review new "map" that has resulted from the mapping exercise	September 2021
	c) send feedback to those Centres that need to complete or submit their 5-year work plans	March 2021
	2) Send feedback to Centres re: review of annual reports for 2018 and 2019	March 2021
3) In-depth review of all annual reports for activities in 2020 based on the performance criteria to identify any that are not complying	April–July for September 2021	
Reference Laboratories	1) Send feedback to labs re: review of annual reports for 2018 and 2019	March 2021
	2) In-depth review of all annual reports for activities in 2020 based on the performance criteria to identify any that are not complying	April–July for September 2021
	4) Seek the opinion of the Aquatic Animals Commission on the proposed amendments to the SOPs for Reference Laboratories re: provisions for suspending laboratories and for laboratories temporarily with no expert	September 2021
Reference Centre Networks	1) Follow up with the three newly launched Reference Laboratory networks (ASF, PPR and rabies)	On-going

Subject	Issue	Status and Action
Standardisation/ Harmonisation	1) Project to extend the list of OIE approved reference reagents	On-going
	2) 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 September 2021
	3) Project to develop Replacement International Standard Bovine Tuberculin: finalise report and propose for adoption	For September 2021
Ad hoc Groups	1) <i>Ad hoc</i> Group on Sustainable Laboratories	First semester 2021
	2) <i>Ad hoc</i> Group on the revision of <i>Terrestrial Code</i> chapters regarding the collection and processing of semen of animals	Final report for September 2021
Projects	1) Veterinary Biobanking (project)	Ongoing
	2) High Throughput Sequencing and Bioinformatics and Computational Genomics (HTS-BCG)	On hold awaiting funding
Conferences, Workshops and Meetings with participation by BSC Members	1) Biosafety research roadmap	Ongoing
	2) WAVLD OIE seminar: theme and programme and speakers	June 2023
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
Twinning Programme	Assess the status of the post-twinning labs: dashboard. Gather feedback from the labs, way forward. Review geographical distribution	September 2021
Develop laboratory standards for emerging diseases	1) Discuss the <i>Terrestrial Code</i> chapter once adopted with the aim of introducing a corresponding chapter for the <i>Terrestrial Manual</i>	After May 2022

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