



REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Virtual meeting, 7–11 February 2022

PART B

A virtual meeting of the OIE Biological Standards Commission was held from 7 to 11 February 2022. The list of participants and agenda can be found at [Annex 1](#) and [Annex 2](#), respectively.

Considering the ongoing COVID-19 pandemic, the 89th Annual General Session will be held in a semi-hybrid format from Monday 23 to Thursday 26 May 2022. During this 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 2022 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 89th General Session; and **Part B** (herewith) will provide information about other topics discussed at the Commission's February 2022 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 89th General Session, the OIE will once again organise information webinars to ensure that Members are 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 89th General Session, and in particular the process for the adoption of standards.

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

3.2. Follow-up from pre-General Session: Chapter 3.4.12 *Lumpy skin disease*

To address the EU comments received in the last General Session on the challenges encountered in recent years for the correct identification of emerging recombinant LSDV¹ field strains, the Commission obtained feedback from the OIE Reference Laboratory experts. The experts submitted a supporting document explaining the variability and rapidly evolving LSDV disease situation in various countries, the emergence of recombinant LSDV field strains in recent years and the difficulty in identifying these strains by currently adopted DIVA² PCR assays. Considering this, the experts recommended that for identifying LSDV strains, including recombinant viruses, whole genome sequencing should be done at the start of an outbreak. The rapid publication of the sequence data will facilitate research efforts to develop better tests.

1 LSDV: lumpy skin disease virus

2 DIVA: Detection of infection in vaccinated animals

The Commission accepted this recommendation and suggested that the experts insert suitable text in the *Terrestrial Manual* chapter explaining the impact of emerging recombinant field strains and the need to sequence the virus at the start of an outbreak to identify emerging and novel strains.

3.3. Follow-up from September 2021: conclusions and recommendations from the OIE *Scientific and Technical Review* issue on diagnostic test validation science

3.3.1. Progress on development of a template of the validation data requested for addition to a future online list of validated tests

At the September 2021 meeting, the Commission agreed to develop a template for the validation data that would be requested of applicants wishing to add their test to the future online list of OIE validated tests. To this end, the members of the Commission developed an adapted validation template that includes the different parameters that will be requested of applicants, which include: intended purpose(s); assay design, development, optimisation and standardisation; analytical sensitivity (ASe), analytical specificity (ASp), and repeatability; diagnostic sensitivity (DSe), diagnostic specificity (DSp) and cut-off; reproducibility; and monitoring the performance to assure the test maintains its fitness for purpose.

As a first step in a pilot scheme to test the template's suitability and usability, the document will be given to a small number of selected OIE Reference Laboratories for diseases for which there are tests known to have reached the OIE validation standard. The experts will be asked to fill in the template and return it to the Commission along with comments on their experience of participating in the pilot scheme.

3.3.2. Progress on development of a template for a new *Terrestrial Manual* section on the rationale behind the selection of tests included in Table 1. *Test methods available and their purpose*

At the last meeting in September 2021, the Commission agreed to include test validation data in the *Terrestrial Manual* disease chapters and to justify the selection of tests considered to be fit for purpose in Table 1, along with their rating, based on expert opinion. It was felt that this information would help the reader to find relevant information for the selection of tests while making sure that the selection process is science-based and transparent. The Commission felt that the challenge was how best to present the relevant information with an appropriate level of detail. The Commission agreed to a flexible approach allowing the Reference Laboratories to decide how they would like to present their data but in a harmonised manner. However, with the aim of providing a suitable example, it was agreed to specifically request the foot and mouth disease (FMD) experts to provide a rationale for the selection and scoring of tests in their latest revision of the *Terrestrial Manual* chapter. The Commission will assess the response at its next meeting and define the way forward.

3.3.3. *Terrestrial Manual* validation chapters: chapter 1.6 *Principles and methods of validation of diagnostic assays for infectious diseases* and chapters 2.2.1 to 2.2.8 in Section 2.2 *Validation of diagnostic tests*

The meeting was joined by Dr Axel Colling from the OIE Collaborating Centre for Diagnostic Test Validation Science in the Asia-Pacific Region, and Dr Ian Gardner, validation expert. The purpose of the meeting was to discuss with the Commission the workplan to review chapter 1.6 *Principles and methods of validation of diagnostic assays for infectious diseases* and the eight chapters 2.2.1 to 2.2.8 in Section 2.2 *Validation of diagnostic tests* of the *Terrestrial Manual*

Dr Colling discussed a proposal on how papers in the Special Issue (SI) of the OIE *Scientific and Technical Review* (<https://doi.org/10.20506/rst.issue.40.1.3205>) on Diagnostic test validation science could be used to review and update the validation chapters. The SI is an up-to-date compilation of the relevant standards (OIE and non-OIE) and guidance documents for all stages of diagnostic test validation and proficiency testing, including design, analysis as well as clear, complete and transparent reporting of validation studies in the peer-reviewed literature. Examples and case studies are used to help to guide readers in practical aspects of the validation process.

The Conclusions³ of the SI provide a useful summary of areas of interest for the chapter review, e.g. verification, POCT⁴, multiplex and new technologies, NGS⁵, example-based explanation of “test purposes and parameters”, BLCM⁶, accuracy standards such as STARD⁷ (to be included in the OIE validation template and SOP⁸) and “provisional recognition” for promising tests to name a few. The OIE owns the copyright for the SI, which means that the information can be referenced and freely used in the *Terrestrial Manual* as required.

It was agreed to review of chapter 1.1.6 and cross-referencing to papers in the SI. This would provide a better understanding of the work that is needed to review chapters 2.2.1. to 2.2.8.

Both experts were supportive of the inclusion of a rationale behind the recommendation of tests for different purposes, linked to validation parameters, in the disease specific chapters of the *Terrestrial Manual*.

3.4. Follow-up from September 2021: request to update Chapter 3.1.1 *Anthrax* to include a new easier to produce *Bacillus anthracis* capsule stain

Following the Commission September 2021 meeting, the OIE Reference Laboratories for anthrax were asked to review a request to include a new capsule stain method in the *Terrestrial Manual* chapter on anthrax. The method is quicker, more readily available and convenient. The experts agreed that the method has been sufficiently validated and should be included in the chapter. The updated chapter, including this addition, was added to the next review cycle (2022/2023).

3.5. Member comments on chapters 2.3.1 *The application of biotechnology to the development of veterinary vaccines* and 3.1.17 *Rabies (infection with rabies virus and other lyssaviruses)*

A Member had submitted comments on two chapters not in the current review cycle. The Commission agreed to provide the comments to the experts with the request to address them when next updating their chapters.

3 Available at: <https://doi.org/10.20506/rst.40.1.3227>

4 POCT: point of care tests

5 NGS: next generation sequencing

6 BLCM: Bayesian latent class modelling

7 STARD: Standards for Reporting Diagnostic accuracy studies

8 SOPs: Standard operating procedures (for submission of a kit for inclusion in the OIE Register of Diagnostic Kits)

3.6. Correction to Table 1 Test methods available for the diagnosis of peste des petits ruminants and their purpose of Chapter 3.8.9 Peste des petits ruminants (infection with small ruminant morbillivirus)

The OIE Reference Laboratory experts for PPR⁹ informed the Commission of an error in the ratings for the virus neutralisation test and competitive ELISA for the purpose “Individual animal freedom from infection prior to movement”. The tests are rated “+++”: recommended for this purpose, but as antibody tests are not appropriate at all for this purpose they should be rated “-”. The Commission agreed that the Table should be corrected as shown:

Method	Purpose					
	Population freedom from infection	Individual animal freedom from infection prior to movement	Contribute to eradication policies	Confirmation of clinical cases	Prevalence of infection – surveillance	Immune status in individual animals or populations post-vaccination
Detection of immune response						
Virus neutralisation	+++	+++ =	-	++	++	++
Competitive ELISA	+++	+++ =	+++	+	+++	+++

3.7. Terrestrial Manual status: update on chapters selected for update in 2022/2023 review cycle

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

- 1.1.2. Collection, submission and storage of diagnostic specimens (last adopted May 2013)
- 1.1.4. Biosafety and biosecurity: Standard for managing biological risk in the veterinary laboratory and animal facilities (last adopted May 2015)
- 1.1.5. Quality management in veterinary testing laboratories (last adopted May 2017)
- 1.1.6. Principles and methods of validation of diagnostic assays for infectious diseases (last adopted May 2013)
- 1.1.7. Standards for high throughput sequencing, bioinformatics and computational genomics (last adopted May 2016)
- 1.1.9. Tests for sterility and freedom from contamination of biological materials intended for veterinary use (last adopted May 2017)
- 1.1.10. Vaccine banks (last adopted May 2016)
- 2.1.3. Managing biorisk: examples of aligning risk management strategies with assessed biorisks (last adopted May 2014)
- 2.3.1. The application of biotechnology to the development of veterinary vaccines (last adopted May 2010)
- 3.1.1. Anthrax (last adopted in May 2018)
- 3.1.5. Crimean–Congo haemorrhagic fever (last adopted May 2014)
- 3.1.8. Foot and mouth disease (infection with foot and mouth disease virus) (last adopted in May 2021)
- 3.1.18. Rift Valley fever (infection with Rift Valley fever virus) (last adopted May 2016)
- 3.1.21. Trichinellosis (infection with *Trichinella* spp.) (last adopted May 2017)

⁹ PPR: Peste des petits ruminants

- 3.2.2. American foulbrood of honey bees (infection of honey bees with *Paenibacillus larvae*) (last adopted May 2016)
- 3.2.3. European foulbrood of honey bees (infection of honey bees with *Melissococcus plutonius*) (last adopted May 2016)
- 3.2.4. Nosemosis of honey bees (last adopted May 2013)
- 3.3.6. Avian tuberculosis (last adopted May 2014)
- 3.3.8. Duck virus hepatitis (last adopted May 2017)
- 3.3.13. Marek's disease (last adopted May 2017)
- 3.4.1. Bovine anaplasmosis (last adopted May 2015)
- 3.4.7. Bovine viral diarrhoea (last adopted May 2015)
- 3.4.11. Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (last adopted May 2017)
- 3.4.15. Theileriosis (last adopted in May 2018)
- 3.6.9. Equine rhinopneumonitis (infection with equid herpesvirus-1 and -4) (last adopted May 2017)
- 3.6.10. Equine viral arteritis (infection with equine arteritis virus) (last adopted May 2013)
- 3.8.1. Border disease (last adopted May 2017)
- 3.8.2. Caprine arthritis/encephalitis and Maedi-visna (last adopted May 2017)
- 3.8.12. Sheep pox and goat pox (last adopted May 2017)
- 3.9.7. Influenza A virus of swine (last adopted May 2015)
- 3.9.9. Teschovirus encephalomyelitis (last adopted May 2017)
- 3.10.1. Bunyaviral diseases of animals (excluding RVF fever and Crimean–Congo haemorrhagic fever) (2021)
- 3.9.10. Transmissible gastroenteritis (last adopted May 2008)
- 3.10.4. Infection with *Campylobacter jejuni* and *C. coli* (last adopted May 2017)
- 3.10.8. Toxoplasmosis (last adopted May 2017)
- 3.10.10. Verocytotoxigenic *Escherichia coli* (last adopted May 2008)

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

4. Liaison with other Commissions

4.1. Horizontal issues among the Specialist Commissions

4.1.1. Review of case definitions

i) Infection with *Coxiella burnetii* (Q fever)

The Commission recommended that a requirement for additional evidence be added to Option 2, noting the possibility for laboratory error and that the specificity of PCR testing can vary between countries based on epidemiological conditions and depending on the test protocol used.

Furthermore, the Commission inserted the requirement that nucleic acid specific to *Coxiella burnetii* has been detected and confirmed in samples from an animal host, as PCR alone may not distinguish between *Coxiella burnetii* and *Coxiella*-like organisms.

The Commission expressed concern about the use of serology in an individual animal to confirm infection with *C. burnetii*, even when this is accompanied by supporting evidence (that the animal host is epidemiologically linked to a suspected or confirmed case of infection with *C. burnetii*).

ii) Infection with camelpox virus (camelpox)

The Commission requested confirmation that the text is correct as written e.g. ‘orthopoxvirions’, questioning whether ‘poxvirions’ was intended.

The Commission discussed the need for additional supporting evidence for Option 3, and commented that, if the identity of the pathogenic agent was confirmed by sequencing, then the additional requirements might not be required. However, they noted that if the epidemiological link was present, then sequencing may not be required.

The Commission noted inconsistencies in the report, including in the case definition, with the expressions ‘clinical signs of’ and ‘clinical signs consistent with’, and expressed their preference for the use of ‘clinical signs consistent with’.

The Commission considered that Option 4 is only appropriate for use in non-endemic countries

iii) infection with avian metapneumovirus (turkey rhinotracheitis)

Regarding Option 2, the Commission noted the technological advances made in recent years and agreed that if the identity of the pathogenic agent is confirmed using molecular sequencing, this could be sufficient to confirm the identity of the pathogenic agent. However, they noted the potential for laboratory error (for example, cross contamination) can never entirely be excluded, in which case molecular sequencing would certainly confirm the identity of the agent present, but this would result in incorrect confirmation of a case.

The Commission recommended removing ‘ribo’ from ‘ribonucleic’ for consistency.

Noting that antigens cannot be sequenced, the Commission recommended the Option 2 is split into two options, with the antigen option being supported by the requirement to provide additional supporting evidence.

The full reports of the expert groups responsible for the development of the case definitions for infection with *Coxiella burnetii* (Q fever) and Camelpox can be found at annexes 10 and 11 of the February 2022 report of the meeting of the Scientific Commission for Animal Diseases. The final versions of the case definitions for the purpose of notification to the OIE will be made available on the OIE website.

4.2. Scientific Commission for Animal Diseases

4.2.1. Follow-up General Session: emerging recombinant lumpy skin disease virus strains, their correct diagnosis and notification

See agenda item 3.2.

4.2.2. Review of assessments of diseases against listing criterion 3: delisting assessments

The Biological Standards Commission reviewed the experts’ assessment of paratuberculosis and infection with *Streptococcus equi* subsp. *equi* (*S. equi*, strangles) against listing criterion 3¹⁰ and agreed with their acceptance that both diseases fulfil this criterion.

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

The Commission was informed that the process of assessing diseases against the listing criteria had brought into question the appropriateness and usefulness of the criteria themselves, for example criterion 2¹¹. The Commission agreed that the criteria could usefully be reviewed and improved, including perhaps providing background information on the thinking rationale for each criterion.

4.3. Terrestrial Animal Health Standards Commission

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

4.3.1. Updates from the September 2021 Code Commission meeting

The Biological Standards Commission was updated by the Secretariat on the current topics under review by the Code Commission to ensure complementarity and alignment of the two Commission's respective work plans. It was agreed that regular meetings between the Bureaus of both Commissions should be established as it would offer an excellent mechanism to ensure alignment of relevant items on the work programmes and agendas of both Commissions. The Biological Standards Commission requested the OIE Secretariat to convene a meeting for September 2022.

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

The Biological Standards Commission's advice had been sought on a comment from a Member regarding point 4) of Article 11.10.5. *Recommendations for importation from countries or zones not free from infection with Theileria* to replace 'serological and agent identification tests' with 'serological or agent identification tests'.

In September 2021, the Biological Standards Commission recommended that serological and agent identification tests be used together ("and" rather than "or" in the Article). In the February 2022 meeting, the Biological Standards Commission commented that during the early stage of infection, animals may be seronegative until the antibodies reach the level detectable by sero-diagnostic methods, while such animals may be positive by PCR assays. Therefore, the Commission believes both PCR and serological tests are essential to determine whether an individual animal is free from infection. The Commission also quoted the example of equine piroplasmiasis where it is recommended to use both serological and PCR methods to determine that an animal is free from infection.

4.3.3. Technical questions on Chapter 8.8 *Infection with foot and mouth disease*

The Biological Standards Commission's advice had been sought on a number of technical issues in the draft *Terrestrial Code* chapter on Infection with foot and mouth disease. The Commission will consult the OIE Reference Laboratory experts before providing advice to the Code Commission at the September 2022 meeting.

4.3.4. Chapter 12.6 *Infection with equine influenza virus*

The Biological Standards Commission's advice was sought by the Code Commission to address a comment received on the revised *Terrestrial Code* Chapter 12.6. Infection with equine influenza virus circulated in its September 2021 report. In Article 12.6.6, the last paragraph, the Biological Standards Commission did not agree with a comment requesting to replace the need to conduct the test on samples collected on two occasions by a single testing.

11 Criterion 2: At least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the provisions of Chapter 1.4

The Biological Standards Commission noted testing on two occasions gave added assurance, and that these specific additional recommendations were aimed at the rare cases of countries that are free from equine influenza or are undertaking an eradication programme, and were justified in that context.

4.4. Aquatic Animal Health Standards Commission

None at this meeting.

5. OIE Reference Centres

5.1. Annual reports of Reference Centre activities in 2021

As of 29 March 2022, 225 out of 229 (98%) Reference Laboratories and 57 out of 62 (92%) Collaborating Centres had submitted annual reports for 2021 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 Members. 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.

5.2. Applications for OIE Reference Centre status

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

OIE Reference Laboratory for New World Screwworm (Cochliomyia hominivorax)

Panama–United States Commission for the Eradication and Prevention of Screwworm, Apartado
Postal 0816-07636 Panama, PANAMA
Tel.: (+507) 296.0006
E-mail: john.b.welch@usda.gov; info@copeg.org Website: www.copeg.org
Designated Reference Expert: Dr John B. Welch.

OIE Reference Laboratory for African swine fever

National Centre for Foreign Animal Disease, Canadian Food Inspection Agency, Canadian Science
Centre for Human and Animal Health, 1015 Arlington Street, Suite T2300, Winnipeg, Manitoba
R3E 3M4, CANADA
Tel.: (+1-204) 789.20.01
E-mail: aruna.ambagala@canada.ca
Designated Reference Expert: Dr Aruna Ambagala.

OIE Reference Laboratory for African swine fever

USDA, APHIS, VS, NVSL, Foreign Animal Disease Diagnostic Laboratory, Plum Island Animal
Disease Center, P.O. Box 848, Greenport, NY 11944, UNITED STATES OF AMERICA
Tel.: (+1-631) 323.3256
E-mail: Ping.Wu@usda.gov; website: <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services>
Designated Reference Expert: Dr Ping Wu.

OIE Reference Laboratory for chronic wasting disease

National Veterinary Services Laboratories, USDA, APHIS, VS, 1920 Dayton Avenue, Ames, Iowa
50010, UNITED STATES OF AMERICA
Tel.: (+1-515) 337.7175
E-mail: aaron.d.lehmkuhl@usda.gov;
Designated Reference Expert: Dr Aaron Lehmkuhl.

OIE Reference Laboratory for bovine tuberculosis

National Veterinary Services Laboratories, USDA, APHIS, VS, 1920 Dayton Avenue, Ames, Iowa 50010, UNITED STATES OF AMERICA

Tel.: (+1-515) 337.7034

E-mail: Ping.Wu@usda.gov; website: <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/lab-info-services>

Designated Reference Expert: Dr Tyler C. Thacker.

An application had been received for an OIE Reference Laboratory for avian influenza. The Commission noted that there was a lack of publications in peer-reviewed scientific journals specific for avian influenza and of the organisation of or participation in interlaboratory proficiency tests specific for avian influenza. The applicant does not produce their own reagents or have full genome sequencing and bioinformatic capabilities. The Commission also found that the application lacked details regarding international collaboration and the provision of training. The Commission therefore did not approve the application.

The Commission reviewed and endorsed “in principle” an application from a Member in Africa for an OIE Collaborating Centre for Quality Control of Veterinary Vaccines. As there is currently an OIE Collaborating Centre for the same topic in this region, the applicant will be invited to contact that Centre to discuss how best they work together as a consortium with a joint 5-year work plan.

Two applications had been submitted from a Member, one for an OIE Collaborating Centre for a Centre on Safety of Animal Feed and the second for an OIE Collaborating Centre for Residue Analysis of Pesticides and Heavy Metals in Food. The Commission agreed that as there is large overlap in these activities and in the interest of cost effectiveness through shared resources and expertise, that the applicants could join together to form one Collaborating Centre for, for example, Residue Analysis of Pesticides and Heavy Metals in Food and Feed. The applicants would be asked to consider this proposal and to resubmit a new application with a joint 5-year work plan for review at the September 2022 meeting.

Finally, an application had been received for an OIE Collaborating Centre for Surveillance and molecular identification of arthropod vectors of animal and zoonotic diseases. The Commission found that the application lacked evidence of international activities in the area of research, training and development of methods. The Commission therefore did not approve the application.

5.3. 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:

African horse sickness

Dr Carrie Batton to replace Dr Simon Carpenter at the Pirbright Institute, Woking, UNITED KINGDOM

Bovine spongiform encephalopathy

Dr Waqas Tahir to replace Dr Stephanie Czub at the Canadian Food Inspection Agency, National Centres for Animal Diseases, Lethbridge, CANADA

Contagious equine metritis

Dr Kristina Lantz to replace Dr Matthew Erdman at the National Veterinary Services Laboratories, Ames, Iowa, UNITED STATES OF AMERICA

Equine rhinopneumonitis

Dr Lutz Goehring to replace Dr Peter Timoney at the Maxwell H. Gluck Equine Research Centre, Kentucky, UNITED STATES OF AMERICA

Foot and mouth disease

Dr Sabrina Galdo to replace Dr Andrea Pedemonte at SENESA, Buenos Aires, ARGENTINA

Foot and mouth disease

Dr Joseph Hyera to replace Dr George Matlho at Botswana vaccine institute, BOTSWANA

Foot and mouth disease

Dr Santina Grazioli to replace Dr Emiliana Brocchi at the Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna (IZSLER) Brescia, ITALY

Marek's disease

Dr Yongxiu Yao to replace Dr Venugopal Nair at the Pirbright Institute, Woking, UNITED KINGDOM

Swine influenza

Dr Mia Kim Torchetti to replace Dr Sabrina Swenson at the Diagnostic Virology Laboratory, National Veterinary Services Laboratories, Ames, Iowa, UNITED STATES OF AMERICA

Swine vesicular disease

Dr Giulia Pezzoni to replace Dr Emiliana Brocchi at the Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna (IZSLER) Brescia, ITALY

Vesicular stomatitis

Dr Rachel Tell to replace Dr Sabrina Swenson at the Diagnostic Virology Laboratory, National Veterinary Services Laboratories, Ames, Iowa, UNITED STATES OF AMERICA

5.4. Review of new and pending applications for laboratory twinning

As of February 2022, 68 projects have been completed, 30 projects are underway and three are awaiting contract signature before beginning.

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

- i) **Germany – Egypt** for glanders: the Commission supported the technical contents of this project.
- ii) **China (People's Rep. of) – Pakistan** for brucellosis: the Commission supported the technical contents of this project.

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

Following a recommendation from the Commission at the September meeting, the OIE Secretariat facilitated a discussion among three OIE Reference Laboratories for African horse sickness to discuss the concerns raised regarding inconsistencies in results obtained using the real-time RT-PCR method and the implications this has for trade or free status. A representative of the Commission also joined the discussion.

The summary of the discussion was presented to the whole Commission. Despite the discussions among the laboratories, the nature of any discrepancy in the tests or interpretation could not be unequivocally clarified. Although the most likely reason could be the low amount of AHSV RNA in the sample, close to the cut-off point of the methods.

The OIE Reference Laboratories agreed that test results near the limit of detection may be difficult to replicate between laboratories and even within laboratories and harmonisation of such weakly positive samples is almost impossible. The Reference Laboratories also proposed to review the *Terrestrial Manual* chapter on AHS to check if there is a need for modification or update.

The Commission again stressed that different laboratory results among OIE Reference Laboratories may lead to confusion in terms of import status and has implications for trade or free status. The Commission therefore suggested that the three OIE Reference Laboratories, and an additional South African laboratory that is involved in AHS diagnosis, should try to harmonise the test methods by participating in a ring test aimed at comparing results obtained in the different labs using their current methods. The laboratories should agree between themselves on the best way of running the ring trial. One of the Reference Laboratories will be asked to initiate this ring trial by producing a test panel, ideally consisting of blood samples from horses infected with different AHS serotypes and from horses vaccinated with the different vaccines currently used in South Africa. On receipt, samples should be titrated out, followed by extraction and PCR, to measure the limit of detection for each sample. The Commission also suggested that the experts draft text for the *Terrestrial Manual* chapter explaining the situation with regard to the interpretation of results obtained using weak positive samples.

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

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

One Reference Laboratory had indicated in the 2018 annual report that it is no longer permitted to work on the disease in question. At the last meeting in September, this laboratory asked for more time so that it could resolve the issue with its veterinary services. The laboratory did not submit a response for review at this meeting, but it did submit an annual report of activities in 2021. On reviewing the report, the Commission found very few activities and no evidence of testing, publications, conferences, trainings, or production of reagents. The laboratory also remarked that the country is free from the disease and no samples had been submitted either from the region or further afield. The Commission therefore recommended to ask the laboratory 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.

The second Reference Laboratory that had failed previously to submit a certificate of accreditation to ISO 17025 or equivalent quality management system has now submitted the necessary certificate. The Commission accepted the accreditation certificate and expects an increased level of activities to be reported by the Reference Laboratory in the future.

5.7 Follow-up September meeting: feedback from the Laboratories that are not complying with the key ToR according to 2020 annual report

At the last meeting in September, the Commission identified 53 Reference Laboratories that had a low level of activities due to the impact of the Covid-19 pandemic situation and agreed to follow-up closely during the 2021 annual report review cycle. Therefore, no laboratory had been contacted for feedback on the 2020 annual reports.

5.8. Further develop SOPs to include provisions for suspending laboratories and for handling laboratories that temporarily have no designated 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. At the February 2021 meeting, the Biological Standards Commission approved updates to the SOPs to include provisions for temporary suspension of Reference Laboratory status and for laboratories temporarily with no expert. The Aquatic Animal Health Standards Commission agreed with the proposals at their September 2021 meeting. Finally, the updated SOPs were endorsed by the Deputy Director General for International Standards and Science. The revised SOPs can be found at [Annex 3](https://www.oie.int/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-2) or on the OIE Website at: <https://www.oie.int/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-2>

Along with corresponding update to the guidelines for applicants for OIE Reference Laboratory status: <https://www.oie.int/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-8>

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

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

At the September 2021 meeting, two Centres in the same Member with similar titles and core activities had asked to remain as separate Centres: one focusing on viral diseases and the other on bacterial diseases. The Commission agreed to this proposal. The Centre for diagnosis and control of bacterial diseases accepted the proposal. A reminder will be sent to the other Centre to confirm that it accepts the proposal that it remain a separate Centre for diagnosis and control of viral diseases. The Centre for bacterial diseases also accepted a separate proposal to establish a stand-alone Collaborating Centre on Food Safety under the focus area ‘Animal production and food safety’ in the sub-region for linguistic and cultural reasons.

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

One Centre that had shown a low level of activity in its 2019 annual report had reassured the Commission at that time that it would improve its performance in 2020. The Centre finally submitted a very late report (received 26 September 2021) for activities in 2020. The Commission reviewed the Centre’s performance and found it satisfactory.

5.11. Follow-up September meeting: feedback from the Centres that are not complying with the key ToR according to 2020 annual report

The Commission reviewed the feedback received from five Collaborating Centres that were not complying with key performance criteria according to their 2020 annual reports. The Commission accepted the explanations provided by all Centres.

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

The Commission reviewed the feedback on the review of 5-year work plans from three Collaborating Centres and approved the corrections submitted by two Centres. The third Centre will be asked to fill in the activity column: currently they have simply listed the categories in ToR for Collaborating Centres.

A reminder will be sent to the last remaining Centre that has not submitted its 5-year work plan giving a deadline of mid-May 2022. The Commission stressed that non-submission of a 5-year work plan would call into question the Centre's continued designation.

- **Reference Centre networks**

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

The OIE Rabies Reference Laboratory Network (RABLAB) provided a scientific rationale to support proposed amendments to the *Terrestrial Code* Chapter 8.14, on the provisions for importation of dogs from countries or zones infected with rabies virus, and developed recommendations for an official control programme for wildlife-mediated rabies. The network is currently exploring options to ensure the continuation of distribution of the OIE anti-rabies positive reference serum of dog origin. The serum standard has been produced by one of the OIE Reference Laboratories since 1991, but this laboratory will not be able to do it in the future. The distribution of the standards is guaranteed for at least the next 2 years, but an alternative producer needs to be identified. The use of lateral flow device test to support dog-mediated rabies surveillance is also included in the workplan of the network.

The PPR Reference Laboratories network organised its first workshop in November 2021 with the participation of national laboratories from different regions. The workshop discussed the expectations of participants in the network, identified areas that the network should concentrate on and drafted the work plan for the coming year. The network launched its own website (<https://www.ppr-labs-oie-network.org/>) to share PPR Reference Laboratory activities, protocols, shipment of samples, available reagents, proficiency testing, capacity building and training materials, standards and guidelines and to disseminate network activities. The website is hosted by the OIE Reference Laboratory in France, which currently leads the network.

The OIE ASF¹² Reference Laboratory network held regular meetings to exchange scientific and technical expertise, including information on significant outbreak situations in the Americas and China (People's Rep. of). The network provided an overview on the commercially available point of care (PoC) ASF diagnostic tests for rapid field applications (<https://www.oie.int/en/document/the-oie-asf-reference-laboratory-networks-overview-of-african-swine-fever-diagnostic-tests-for-field-application/?aiEnableCheckShortcode=true>). They are working on a laboratory manual including diagnostic algorithms to detect low virulent and novel emergent variants. In addition, the network is exploring ways to establish an open access information sharing platform for ASFV genome sequence data, developing training programmes to assist at-risk countries, including the organisation of proficiency tests .

5.14. Outcomes of OIE Reference Centre meeting in SADC region, December 2021

The Commission was briefed on the outcomes of the Virtual Meeting of the OIE Reference Laboratories and Collaborating Centres in the SADC¹³ sub-region in December 2021 hosted by the OIE Sub-Regional Representation for Southern Africa. The meeting was attended by all the OIE Reference Centre experts in the sub-region with the objective to cooperate on current activities, capacity building programmes, collaborations, and twinning projects. Some of the challenges faced by the laboratories, especially issues around cost of confirmatory diagnosis, production and distribution of reference reagents, proficiency testing, problems with sample shipment, and required skills and qualifications for OIE experts were clarified.

12 ASF: African swine fever

13 SADC: Southern African Development Community

One of the main challenges expressed was the tendency of some national laboratories in the region to send samples for confirmatory diagnosis to OIE Reference Laboratories outside the region and not using the laboratories reference capacity of the sub-region. The sub-regional representation for Southern Africa assured to follow up on this issue and will encourage OIE Members to use the Reference Laboratories in the region. Those laboratories that have undergone successful OIE twinning projects expressed the desire to apply for OIE Reference Laboratory status.

5.15. OIE Training Portal and OIE Training Platform activities: a good example of OIE Collaborating Centre collaboration

The OIE Platform for the Training of Veterinary Services is an innovative mechanism to combine technical and pedagogical expertise from OIE partners, mainly OIE Reference Centres, for the preparation of quality OIE training programmes, their delivery and evaluation. Currently, the eight OIE Collaborating Centres on Training and Education are full members of the OIE Platform and have voluntarily engaged in many training activities in the 2021–2025 OIE Training Platform Work Plan, as part of fulfilling their OIE ToR. This win–win approach to building the OIE global training expertise community will expand by progressively incorporating other OIE Collaborating Centres and Reference Laboratories as they progressively organise as networks.

The first annual Report (2021) of the OIE Platform for the Training of Veterinary Services – which serves as the OIE Collaborating Centres on training and education network Report – is now available on the OIE Training Portal. It demonstrates the active engagement of the eight OIE Collaborating Centres in delivering the OIE Platform 5-year Work Plan with the production of OIE training guidelines for e-module development, the development of the OIE Competency-based Training Framework and the development of e-modules on Veterinary Services leadership. An even richer programme of activity is planned for 2022 that will help consolidate the under development OIE Training System.

5.16. Request to change title of an OIE Collaborating Centre

The OIE Collaborating Centre on Animal Welfare and Livestock Production Systems requested the Commission to change its title to 'Animal Welfare and Sustainable Livestock Systems' to highlight the importance of the relationship between animal welfare and sustainable livestock systems by having the word 'sustainable' in the title and also in relation to the submitted five year work plan. The Commission examined the proposal and approved the new title.

6. *Ad hoc* Groups

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

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

This OIE *ad hoc* Group was convened because of the urgent need to replace the current ISBT¹⁴ and establish a reference standard for use in calibration of purified protein derivative tuberculins and the development and evaluation of 'second generation' diagnostic tests for bovine tuberculosis. The Group has been working on this task since May 2017. In February 2021, the Commission was informed that a Resolution to adopt the new ISBT would not be presented at the 88th General Session of the OIE (May 2021) as further studies were required for correct calibration of the new candidate tuberculin.

14 ISBT: International Standard Bovine Tuberculin

The Group had agreed a revised protocol to assess the potency of the candidate tuberculin that had been previously identified as a suitable replacement for the current ISBT. Unfortunately, the trial was initially delayed due to delays in receipt of the *M. bovis* AN5 strains (used for sensitising the guinea-pigs), but was completed, and results were discussed by the Group in October 2021.

This trial to estimate the potency of the candidate tuberculin ('candidate B') showed considerably lower-than-expected assigned potencies compared with the current BIS¹⁵, which has a potency of 32,500 IU/mg. Candidate B was assigned a relative activity between 60 and 70% (21,000 IU/mg), much less than the agreed minimum target of 30,000 IU/mg. The Group noted that the potency was estimated relative to that of a BIS sample, which is assumed to be correct, and agreed that this assumption should be tested. Consequently, the Group recommended that two possibilities be evaluated: 1) that the original BIS standard used by the manufacturer of candidate B had degraded and that its actual potency was less than assumed, resulting in incorrectly high assessments of the potency of the candidate B samples provided for consideration; and 2) that the current BIS is subject to precipitation (aggregation) when reconstituted, which would result in incorrect estimates of potency for samples assessed relative to a precipitated standard preparation.

These two possibilities are currently being investigated. The Group will discuss the results and prepare a report for presentation to the Commission at its September 2022 meeting.

7. International Standardisation/Harmonisation

7.1. OIE Register of diagnostic kits

7.1.1. Update on new or renewed applications

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

- The assessment of the application of *Enferplex Bovine TB antibody* test – for approval of supplementary data for validation of milk testing (currently provisionally approved claim) is ongoing and requires the written endorsement by the Commission if it is to be proposed for adoption by OIE Resolution in May 2022.
- The assessment of the application of *BOVIGAM Mycobacterium bovis* Gamma Interferon Test for cattle – addition of a new claim – water buffalo (ThermoFisher Prionics) Submission No. 20150110 (2015, renewed 2020). The applicant provided the new dossier that is under evaluation.
- The renewal process for Rapid MERS-CoV Ag Test (BioNote Inc. – Submission No. 20160212) is ongoing. The applicant provided the new dossier that is under evaluation.
- The renewal process of the *Mycobacterium bovis Antibody Test Kit* (IDEXX Laboratories) Submission No. 20120107 (2012, renewed 2017) was initiated by the applicant.

The Commission agreed to a derogation from the current SOP for the OIE Registration procedure for diagnostic kits, namely, to apply a written procedure for endorsement of any potential final assessment reports, validation abstract studies and draft a Resolution to try to avoid a 1-year delay for adoption of the kit.

15 BIS: Bovine International Standard (tuberculin)

In addition, the OIE SRDK reviewed the question related to the co-branding of the Thermo Fisher Scientific VetMAX™ African Swine Fever Virus Detection Kit. OIE SRDK informed the Commission about the recommended path forward allowing the coexistence of OIE's certification within the scope of cobranding with a distribution partner. Moreover, OIE SRDK suggested that further discussions be held on how to update the current OIE SOP. The Commission did not oppose to OIE SRDK recommendations.

8. Follow-up from the General Session

8.1. Resolutions that will be presented in May 2022

The Commission noted that the following resolutions would be proposed for adoption at the General Session in May 2022:

- A resolution proposing the adoption of 19 draft chapters and the glossary of terms 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 2022:

- 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.

9. Matters of Interest for Information

9.1. Update on OFFLU

The OIE continued to coordinate the OFFLU¹⁶, hosting the [OFFLU Secretariat](#) and maintaining the [OFFLU website](#). During the current season, the avian influenza epidemic continued with a high number of detections reported in poultry and wild birds resulting in the death and slaughter of millions of affected poultry throughout the continents of Africa, Asia and Europe. In response to these outbreaks, OFFLU network experts participated in teleconferences to share epidemiological and molecular data on currently circulating viruses and released [situation updates](#) and [statements](#) needed to inform surveillance and control policies.

OFFLU and WHO were in regular communication to share public health and animal health data so that risk assessments could be continually updated and to establish consensus on issues related to the animal–human interface, including pandemic preparedness. OFFLU participated in the [February and September 2021 WHO Vaccine Composition Meetings](#) and made available over 298 H5, 1 H7 and 17 H9 avian influenza virus sequences representing over 30 countries globally. Equally, 495 H1 and 304 H3 swine influenza virus sequences were contributed. Antigenic data were generated by the hemagglutination inhibition (HI) assay using WHO Collaborating Centre and OFFLU ferret origin reagents. Equine influenza experts updated the vaccine recommendations for 2021 based on current surveillance and outbreaks data.

In October 2021, OFFLU experts updated the [Cleavage site document](#), which provides information regarding amino acid sequences at the influenza A cleavage site assisting in the differentiation of low and high pathogenicity avian influenza A viruses through molecular analyses.

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

OIE Reference Centres on avian influenza participated in the OFFLU proficiency testing coordinated by the Australian Centre for Disease Preparedness (ACDP), Australia aimed at harmonising the diagnostic protocols used at different geographical locations to detect various subtypes.

OFFLU [technical activities](#) continued to deliver concrete outputs that contribute to the mitigation of risks posed by zoonotic animal influenza viruses to public and animal health.

9.2. Update on rinderpest

The Commission was informed that inspections of the laboratories in India and Ethiopia related to a potential FAO¹⁷-OIE Rinderpest holding facility (RHF) designation and to rinderpest vaccine production, respectively, are still on hold while awaiting the lifting of COVID-19 related travel restrictions. The seven RHF that were designated, or for which the 3-year designation period was extended in 2019 are being assessed for another mandate extension this year. As it is unlikely that site inspections of the RHF that were first designated in 2015 can be done before May 2022 due to the spread of the COVID-19, FAO and OIE will exceptionally extend the designation period of these facilities for 1 year, pending the acceptance of the inspection and production of a composite report for the past 3 years. The two facilities that were first designated in 2019 will have their 3-year extension processed this year through the submission of a composite report for the past 3 years. In 2021 there was no reduction in the number of OIE Members holding rinderpest virus containing material outside of FAO-OIE designated RHF, which remained at six OIE Members. FAO and OIE will resume in-person advocacy and destruction efforts once the global health situation allows. The project for undertaking risk assessment of rinderpest re-introduction 10 years after its eradication, implemented by a consortium of OIE Collaborating Centres, is nearing its conclusion. The final version of the risk assessment will be delivered to the OIE in April 2022. This work includes a review of progress done in sequestration and destruction over the past 10 years, which was submitted to the OIE in January 2022.

9.3. Update on COVID-19

The Commission was updated on the activities of the OIE in response to COVID-19. The OIE has continued to gather and disseminate the latest scientific evidence on the effect of SARS-CoV-2 on animals through regular meetings of the OIE *ad hoc* Group on SARS-CoV-2 at the animal-human interface and the joint OIE-FAO Advisory Group on SARS-CoV-2 evolution in animals. Both groups have advised the OIE on the latest events related to SARS-CoV-2 infection in animals and supported the production of guidelines, press releases, statements and social media messages. The findings related to white-tailed deer, the origin of the Omicron variant, hamsters, and other animals were discussed in a timely manner, allowing for the OIE to advise its Members accordingly. To date (January 2022), SARS-CoV-2 infection in animals has been reported by 35 OIE Members in 18 different animal species.

9.4. EuFMD¹⁸ /FAO project for a pre-qualification system for veterinary medicines

The Commission was informed that the FAO had contacted VICH¹⁹ to introduce a project that the FAO and EuFMD had recently launched for the development of a feasibility study for a pre-qualification system for veterinary medicines, similar to the WHO established pre-qualification system.

17 FAO: Food and Agriculture Organization of the United Nations

18 EuFMD: European Commission for the Control of Foot-and-Mouth Disease

19 VICH: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products

The FAO explained that it is seeking volunteers within the VOF²⁰ members from different countries/regions who would accept to join a Technical Stakeholder Advisory Group that would support the EuFMD in developing prioritisation criteria. The VOF members will be contacted by the FAO in the near future.

9.5. Update on Global Burden of Animal Diseases programme

The GBADs²¹ programme continues to work on developing methodologies to assess the economic burden of animal diseases in a systematic manner to include net loss of production, expenditure, and trade impacts. Focus has been on gathering data, advancing work on the prototype of an analytics platform, and refining methodologies to enable initial estimates of disease burden. Processes have also been initiated to start validation of methods.

10. Any Other Business

10.1. Work plan

The updated work plan was agreed and can be found at [Annex 4](#).

10.2. Dates of the next Biological Standards Commission meeting

The Commission noted the dates for its next meeting: 5–9 September 2022.

.../Annexes

20 VOF: VICH Outreach Forum

21 GBADs: Global Burden of Animal Diseases programme

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION
Virtual meeting, 6–10 September 2021

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MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Virtual meeting, 7–11 February 2022

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 2022
- 3.2. Follow-up from the General Session: Chapter 3.4.12 *Lumpy skin disease*
- 3.3. Follow-up from September 2021: conclusions and recommendations from the OIE *Scientific and Technical Review* issue on diagnostic test validation science
 - 3.3.1. Progress on development of a template of the validation data requested for addition to a future online list of validated tests
 - 3.3.2. Progress on development of a template for a new *Terrestrial Manual* section on the rationale behind the selection of tests included in Table 1. *Test methods available and their purpose*
 - 3.3.3. *Terrestrial Manual* validation chapters: chapter 1.6 *Principles and methods of validation of diagnostic assays for infectious diseases* and chapters 2.2.1 to 2.2.8 in Section 2.2 *Validation of diagnostic tests*
- 3.4. Follow-up from September 2021: request to update Chapter 3.1.1 *Anthrax* to include a new easier to produce *Bacillus anthracis* capsule stain
- 3.5. Member comments on chapters 2.3.1 *The application of biotechnology to the development of veterinary vaccines* and 3.1.17 *Rabies (infection with rabies virus and other lyssaviruses)*
- 3.6. Correction to Table 1 *Test methods available for the diagnosis of peste des petits ruminants and their purpose* of Chapter 3.8.9 *Peste des petits ruminants (infection with small ruminant morbillivirus)*
- 3.7. *Terrestrial Manual* status: update on chapters selected for the 2022/2023 review cycle

4. Liaison with other Commissions

- 4.1. Horizontal issues among the Specialist Commissions
 - 4.1.1. Review of case definitions
- 4.2. Scientific Commission for Animal Diseases
 - 4.2.1. Follow-up General Session: emerging recombinant lumpy skin disease virus strains, their correct diagnosis and notification)
 - 4.2.2. Review of assessments of diseases against listing criterion 3: delisting assessments
- 4.3. Terrestrial Animal Health Standards Commission
 - 4.3.1. Updates from the September 2021 Code Commission meeting
 - 4.3.2. Technical questions on Chapter 11.10 *Infection with Theileria annulata, T. orientalis and T. parva*
 - 4.3.3. Technical questions on Chapter 8.8 *Infection with foot and mouth disease*
 - 4.3.4. Chapter 12.6 *Infection with equine influenza virus*
- 4.4. Aquatic Animal Health Standards Commission
 - 4.4.1. Nothing for this meeting

5. OIE Reference Centres

- 5.1. Annual reports of Reference Centre activities in 2021
- 5.2. Applications for OIE Reference Centre status
- 5.3. Changes of experts at OIE Reference Centres
- 5.4. Review of new and pending applications for laboratory twinning
- 5.5. Inconsistencies among OIE Reference Laboratories in results obtained using the real-time RT-PCR for African horse sickness

Reference Laboratories – Implementation of the SOPs

- 5.6. Follow-up September meeting: further feedback from the Laboratories that are not complying with the key ToR according to their 2018 annual report
- 5.7. Follow-up September: feedback from the Laboratories that are not complying with the key ToR according to 2020 annual report
- 5.8. Further develop SOPs to include provisions for suspending laboratories and for handling laboratories that temporarily have no designated expert

Collaborating Centres – Implementation of the SOPs

- 5.9. Follow-up September meeting: feedback on the mapping exercise for the existing Centres against the list of main focus area and specialties
- 5.10. Follow-up September: feedback from the Centres that are not complying with the key ToR according to 2019 annual report
- 5.11. Follow-up September: feedback from the Centres that are not complying with the key ToR according to 2020 annual report
- 5.12. Follow-up September: feedback on the review of the 5-year work plans received from Collaborating Centres

Reference Centre networks

- 5.13. Update on the three Reference Laboratory networks (rabies, PPR and ASF)
- 5.14. Outcomes of OIE Reference Centre meeting in SADC region, December 2021
- 5.15. OIE Training Portal and OIE Training Platform activities: a good example of OIE Collaborating Centre collaboration
- 5.16. Request to change title of an OIE Collaborating Centre

6. Ad hoc Groups

Update on activities of past *ad hoc* Groups

- 6.1. *Ad hoc* Group on Replacement of the International Standard Bovine Tuberculin: update on the replacement ISBT

7. International Standardisation/Harmonisation

- 7.1. OIE Register of diagnostic kits:
 - 7.1.1. Update and review of new or renewed applications

8. Resolutions for the General Session

- 8.1. List of resolutions that will be presented in May 2022

9. Matters of Interest for consideration or information

- 9.1. Update on OFFLU
- 9.2. Update on rinderpest
- 9.3. Update on COVID-19
- 9.4. EuFMD/FAO project for a pre-qualification system for veterinary medicines
- 9.5. Update on Global Burden of Animal Diseases programme

10. Any other business

- 10.1. Workplan
- 10.2. Dates of the next Biological Standards Commission meeting: 5–9 September 2022

11. Meeting review

PROCEDURES FOR DESIGNATION OF OIE REFERENCE LABORATORIES

1. Scope and background

In May 2011, the World Assembly of Delegates of the OIE (hereafter the Assembly) adopted new Terms of Reference (ToRs) and Internal Rules for OIE Reference Centres. The ToRs for Reference Laboratories had emphasised their role in developing and recommending test methods, storing and distributing reference reagents, providing advice, diagnostic support and training to OIE Members, and their reporting obligations. From 2011, the ToRs added the recommendation that laboratories establish and maintain a network with other OIE Reference Laboratories designated for the same pathogen or disease and organise regular inter-laboratory proficiency testing to ensure comparability of results, as well as organise inter-laboratory proficiency testing with laboratories other than OIE Reference Laboratories for the same pathogens and diseases to ensure equivalence of results.

OIE Reference Laboratories are designated to pursue scientific and technical problems relating to a named disease or pathogen. The designated Expert should be a leading member of a multidisciplinary team helping the Reference Laboratory to provide scientific and technical assistance and expert advice on diagnosis and control of the disease or pathogen for which the Reference Laboratory is responsible. Reference Laboratories should also provide scientific and technical training for personnel from Member Countries, and coordinate scientific and technical studies in collaboration with other laboratories or organisations, including through OIE Laboratory Twinning.

The integrity and credibility of the OIE is intimately linked to the quality of the science to which it has access. The OIE depends very heavily on its designated Reference Laboratories and disease experts for scientific advice and support, both to the OIE Headquarters in developing standards, participating in *ad hoc* Groups and providing general advice, and to individual Members.

The OIE has developed this document on the Procedures for designation of OIE Reference Laboratories to assist Members, current OIE Reference Laboratories and experts, and applicant laboratories to better understand the applicable procedures.

2. Submission of an application

The OIE work programme cycle runs from May to May, of which the General Sessions of the Assembly are the start and end points. There are two Specialist Commissions responsible for evaluating OIE Reference Laboratory applications: Biological Standards Commission and Aquatic Animal Health Standards Commission for OIE Reference Laboratories for terrestrial and aquatic animal diseases, respectively. These Commissions meet twice in a cycle, with the first meeting usually held August/September and the second meeting in February/March; these dates can vary each cycle based on the availability of the members of the relevant Commissions (cf. Figure 1).

Applications should be submitted 45 days before the date scheduled for the meetings of the relevant Commission. The 45-day period gives the OIE sufficient time to screen, translate into English when necessary, and process the dossiers for the Commission's evaluation. Deadlines must be strictly observed to allow a full evaluation of the dossiers by the members of the Commission prior to the meeting. Applications received after the deadline are examined at the next Commission meeting.

The applicant laboratory should submit the information using the guidelines for applicants for OIE Reference Laboratory status published on the OIE website: <https://www.oie.int/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-8>. Applications must be limited to no more than 20 pages in A4 format, single-spaced using Times New Roman font size 10pt. Relevant appendices may be attached with clear cross-referencing to the core document. All documents must be prepared in one of the official languages of the OIE (English, French or Spanish).

While evaluating a submitted dossier, the Commission may have questions for the applicant laboratory. These questions will be sent by letter signed by the Director General of the OIE after the Commission meeting. The applicant laboratory should provide written answers by an appointed deadline or by the deadline prior to the next meeting of the Commission (45 days before the date scheduled for the next meeting of the relevant Commission).

3. Preliminary screening of application

On submission of the dossier, the OIE Headquarters (Science Department) acknowledges its receipt and confirms the meeting dates of the relevant Commission. If a gap in the information provided is identified, the OIE Headquarters may request the submission of an amended application or additional information before a set deadline.

4. Evaluation by the relevant OIE Specialist Commissions

As stated previously, the Biological Standards Commission and the Aquatic Animal Health Standards Commission conduct evaluations of OIE Reference Laboratory applications for terrestrial and aquatic animal diseases, respectively.

The Terms of Reference, Internal Rules, Qualification and election procedures of members of the Commissions are found in the OIE *Basic Texts*. The members of the Commissions are elected or re-elected every 3 years by the Assembly.

Commission members are requested to comply with the OIE requirements and procedures regarding confidentiality and the management of conflicts of interest. The President of the Commission and the OIE Secretariat ensure that any members with conflicting interests in relation to a particular dossier do not take part in the discussions and final decision-making.

In accordance with the criteria for designation as an OIE Reference Centre listed in the OIE *Basic Texts*, and Resolutions adopted at each General Session with regard to the designation of OIE Reference Laboratories for terrestrial and aquatic animal diseases, all applications are assessed using standardised principles that include: the institution's ability, capacity and readiness to provide services; the scientific and technical standing of the institution concerned at the national and international levels; the quality of its scientific and technical leadership including internationally recognised expertise; the institution's prospective stability in terms of personnel, activity and funding; and the technical and geographical relevance of the institution and its activities to the OIE's programme priorities.

When conducting an evaluation of an applicant OIE Reference Laboratory, the Commission may also take into account any other information available in the public domain that is considered as pertinent to the evaluation of the dossier.

In accordance with the *Basic Texts* of the OIE, all formal correspondence between the Commission and outside individuals or bodies shall be issued through the office of the Director General of the OIE. All correspondence between an applicant laboratory and the OIE Headquarters is duly documented by the OIE Headquarters.

5. Endorsement by the OIE Council

In accordance with Article 3 of Chapter 4 on the Internal Rules and relevant Resolutions previously adopted, all OIE Reference Laboratory applications are endorsed by the OIE Council before presented to the Assembly for approval.

6. Communication on the outcome of the evaluation with the applicant laboratory

After its meeting, the Commission produces a report that includes the outcomes of the evaluation of Reference Laboratory applications. The identity of the applicant laboratory is published in the report along with the recommendation that it be accepted by the Assembly for adoption by resolution. Unsuccessful applicants are informed by letter from the Director General of the OIE. This letter is not released in the public domain and the identity of the laboratory is not revealed in the Commission report.

In some cases, the Commission may have questions or require additional information before a final decision can be taken. This information should be submitted to the OIE by the appointed deadline for consideration by the Commission at its next meeting.

7. Designation of OIE Reference Laboratories by the Assembly

The Assembly, on the basis of the assessment by the relevant OIE Commission and the endorsement by the OIE Council, adopts by Resolution all new OIE Reference Laboratories. Official designation as an OIE Reference Laboratories comes into force only after adoption by Resolution of the Assembly.

Shortly after the General Session, the newly designated OIE Reference Laboratory will receive a letter from the Director General of the OIE. The OIE Headquarters also updates the list of Reference Experts and Laboratories on its website.

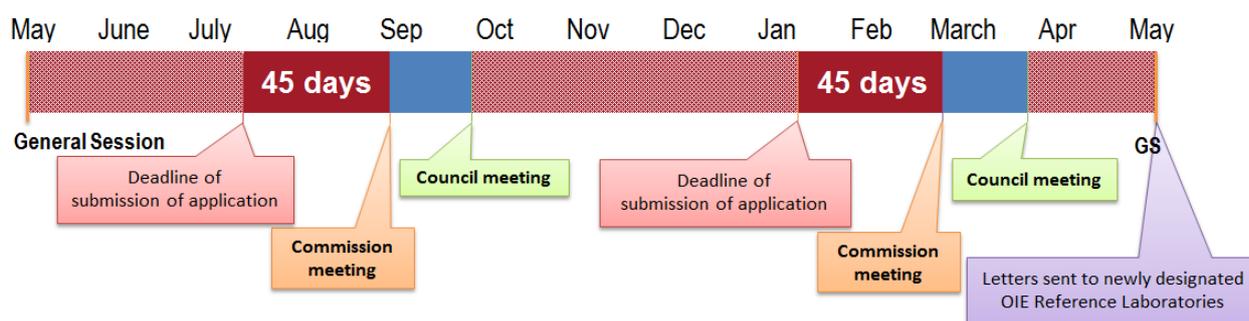


Figure 1. Timeline for applications for OIE Reference Centres.

8. Change of the OIE Reference Laboratory expert

In accordance with Resolution No. 34 adopted at the 81st General Session in May 2013, the Assembly delegated to the Council the authority to approve, on its behalf, the replacement of OIE designated Experts at existing OIE Reference Laboratories, provided that the nominations submitted by the head of the Reference Laboratory through the OIE Delegate of the country of location have been examined and endorsed by the relevant OIE Specialist Commission.

If the expert decides to relinquish the title of OIE designated expert and if the laboratory wishes to maintain its OIE Reference Laboratory status, an official letter – detailing the situation and enclosing a nomination for a replacement expert, including a curriculum vitae together with documentation of his or her work related on the disease or pathogen – should be submitted to the OIE through the Delegate of the country. The nomination will be considered by the relevant OIE Specialist Commission at its next meeting, and the decision will be notified to the OIE Reference Laboratory. The official change of OIE Reference Laboratory expert will take place only after the approval of the Council.

Given the meeting schedules of the Specialist Commissions and the Council, the possibility exists that an OIE Reference Laboratory could temporarily have no designated expert. The OIE expects that, under normal circumstances, Reference Laboratories will always have an OIE designated expert in place and will plan ahead to take into account retirement or resignation. Should the Specialist Commission not endorse a nomination for a replacement expert, the Reference Laboratory will have until the following Commission meeting to submit or re-submit a nomination. During the time between meetings, the Reference Laboratory will remain on the OIE list with the words “To be decided” replacing the name of the expert. The laboratory will need to provide a working email address to accompany the entry on the OIE list. If at the second meeting the Reference Laboratory either does not submit a new or renewed nomination, or the nomination is not endorsed by the Commission, the Reference Laboratory will be suspended and removed from the OIE list.

The Reference Laboratory will then have 1 year (two consecutive Specialist Commission meetings) to successfully fill the position of replacement expert and be reinstated on the OIE List. If after 1 year from the initial removal from the list, no nominee has been endorsed and the position is thus vacant, the Reference Laboratory designation will be withdrawn in accordance with Article 9 of the Internal Rules (cf. **Section 10**).

9. Suspension of OIE Reference Laboratory status

OIE Reference Laboratories are expected to fulfil their ToRs and Internal Rules. They must have an approved designated expert responsible for the implementation of the technical aspects of the ToRs. Should a Reference

Laboratory find that it is unable to fulfil the ToRs for a temporary period, for example due to the absence of a succession strategy resulting in the lack of an approved designated expert or temporary lack of diagnostic ability due to construction or restructuring of the laboratory's facilities, the Reference Laboratory should inform the OIE Headquarters immediately of the situation. The OIE Headquarters, in consultation with the relevant Specialist Commission, may decide to temporarily suspend the laboratory's OIE status until the laboratory can operate to the standard required of OIE Reference Laboratories. The period of suspension should be no longer than 2 years. During that period, the laboratory will be removed from the OIE list. At any time during the 2-year period, the laboratory's status could be reinstated upon receipt and acceptance by the relevant Specialist Commission of proof that the Reference Laboratory is operational to the required standard again. If in the 2-year period, the laboratory cannot provide proof of its operational ability, its designation shall be withdrawn in accordance with Article 9 of the Internal Rules (cf. **Section 10**).

10. De-listing of OIE Reference Laboratories

Upon the screening and analysis performed by the OIE Headquarters (cf. **Section 11.1**), the relevant Commission reviews the reports and activities of the Reference Laboratories. Where there is insufficient evidence of OIE mandate-related activities, the Commission may recommend to the Council and to the Assembly the withdrawal of the Reference Laboratory designation.

In accordance with Article 9 of the Internal Rules, a Reference Laboratory may revoke the designation at any time. If an OIE Reference Laboratory decides to withdraw its designation as such, an official letter should be submitted to the OIE through the Delegate of the country.

Moreover, in accordance with Article 9 of the Internal Rules, the designation of a Reference Laboratory shall be withdrawn if the Reference Laboratory fails to comply with the provisions of the ToRs and the present Rules. In such cases, the Director General of the OIE, after consulting the appropriate OIE Specialist Commission and OIE Council and notifying the Delegate of the country, proposes the withdrawal to the Assembly.

In 2016, the Specialist Commissions and the Director General of the OIE, identified five critical points for consideration when evaluating a laboratory's performance:

- i) the lack of submission of an annual report;
- ii) the lack of accreditation to ISO 17025 or equivalent quality management system, ideally with relevant tests included in the scope of the accreditation;
- iii) a pattern revealing lack of diagnostic activity or production and supply of reference material related to the disease or pathogen;
- iv) no response to requests from the OIE Headquarters for scientific expertise (e.g. inquiry of technical advice from OIE Member Countries, revision of the *Terrestrial manual* chapters, etc.);
- v) no response to requests from the OIE for administrative issues relating to transparency and confidentiality (e.g. not renewing the potential conflict of interests declaration or providing a confidentiality undertaking: <https://www.oie.int/en/who-we-are/structure/framework/>).

11. OIE Reference Laboratory Annual report

In accordance with Article 8 of the Internal Rules, the Reference Centre shall provide to the Director General a brief report of activities related to their ToRs at the end of each calendar year, according to the template established by the OIE Headquarters. A letter from the Director General of the OIE is sent to all designated experts of OIE Reference Laboratories for submission of the annual report.

Since December 2013, an on-line system for submitting annual reports the OIE Reference Laboratories has been in place.

The template of the annual report is structured around each ToR for OIE Reference Laboratories as adopted in May 2011. Questions are close-ended (yes/no answers) to generate more accurate and comparable information from the laboratories. Tables to allow for the collection of detailed information related to the activities carried out by the laboratories are also included. The on-line annual reporting system can be accessed via a dedicated link and a randomly generated username and password that are sent to all Experts of OIE Reference Laboratories in a letter signed by the Director General of the OIE during the last month of the reporting year. The deadline to submit the annual report of the OIE Reference Laboratory activities of each calendar year is usually by mid-January of the following year.

11.1. Review and analysis of the annual reports

The submitted annual reports are first screened and quantitatively analysed, based on the close-ended (yes/no) answers, by the OIE Headquarters. An overview of the analysis is presented to the relevant Commission at its February/March meeting.

OIE Reference Laboratories are expected to fulfil the ToRs adopted by the OIE World Assembly of Delegates as reflected in the annual report.

Any questions or concerns that may arise during the review of annual reports by the Commission can be referred to the concerned OIE Reference Laboratory through the office of the Director General of the OIE.

All annual reports of OIE Reference Laboratories are made available to all Member Countries on the OIE website (<https://www.oie.int/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-5>) shortly after the February meeting of the Commissions.

11.2. Lack of submission of the annual report

After the meeting of the relevant Commissions, laboratories that have not submitted their annual reports will be sent a letter of reminder, with the Delegate of the host Member Country in copy, to submit the report by an extended and prescribed deadline. For the laboratories that have still not submitted an annual report by the end of March, a reminder will be addressed directly to the Delegate, with the expert in copy, giving a 2-week deadline to reply to the OIE with an explanation of the situation or circumstances that may have prevented the laboratory from fulfilling this ToR.

Further communication by letter or direct communication during the General Session may be considered, if needed, prior to the final recommendation to de-list the laboratory, which would be taken by the Commission at the September meeting. This procedure could also be applied to laboratories falling under one of the four other de-listing criteria (cf. **Section 10**).

Contact: scientific.dept@oie.int

GUIDELINES FOR APPLICANTS FOR OIE REFERENCE LABORATORY STATUS

OIE Reference Laboratories must provide evidence of scientific leadership and of the capability to fulfil the [Terms of Reference](https://www.oie.int/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-1) (<https://www.oie.int/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-1>): all applicants should preferably be the national reference laboratory; they should be able to receive samples from other countries for diagnostic testing; they should demonstrate the capability and willingness to organise rather than just participate in proficiency tests; they should be capable of providing confirmatory diagnostic services, reference materials, training, etc., internationally; and the designated expert should have a number of recent relevant publications in peer-reviewed journals. A functioning Reference Laboratory requires input from experts in a number of different fields working on the same disease or pathogen. It is understood that the OIE designated expert is a leading member of such a multidisciplinary team who could consult other members of this team with different expertise in response to requests received while remaining the single contact point for all correspondence with OIE Members and others. Article 7 of the Internal Rules for OIE Reference Centres captures this idea when it states “For a Reference Laboratory, the OIE Expert is responsible for the implementation of the technical aspects of the terms of reference and may delegate specific responsibilities to other experts on an *ad hoc* basis.”

Applications should be submitted 45 days before the date scheduled for the meetings of the relevant Specialist Commission: both the Biological Standards Commission and the Aquatic Animal Health Standards Commission meet in February and September; the deadlines are therefore mid-December and mid-July. The 45-day period gives the OIE sufficient time to screen, translate into English when necessary, and process the dossiers for the Commission’s evaluation. Deadlines must be strictly observed to allow a full evaluation of the dossiers by the members of the Commission prior to its meeting. Applications received after the deadline will be examined in the next meeting of the Commission.

Applications shall be submitted in accordance with Article 1 of the [Internal Rules](https://www.oie.int/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-7) (<https://www.oie.int/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-7>) and should include the following information:

Administration and management

1. Name of expert (a curriculum vitae using this [template](#)).
2. Name and address of laboratory (telephone and e-mail address [fax numbers or Web site, if available]).
3. Name of the Head of laboratory (Responsible Official).
4. Demonstrate that legal and budgetary provisions are in place that provide assurance on the sustainability and functioning of the laboratory.
5. Provide documented proof (certificates) of accreditation to the ISO 17025 or equivalent quality management system, ideally with relevant tests included in the scope of the accreditation.

Technical expertise and experience

6. Give an overview of the expertise available in the disease- or pathogen-related multidisciplinary team in which the expert works: disciplines, number of experts in each discipline, level of expertise.
7. Give details of experience in diagnostic testing for the disease according to the OIE Standards nationally and internationally (approximate number of tests performed annually for each technique).
8. Provide additional information on expertise in diagnostic techniques (agent characterisation techniques, molecular techniques, monoclonal antibody techniques, etc.), epidemiology and control of the disease.
9. Give details of experience in standardisation and validation of diagnostic tests.
10. Demonstrate reagent production capability (provide details of current stock of reagents for the disease).

11. Demonstrate capability for timely international shipment and receipt of samples in accordance with the requirements for postage and packaging of biological materials described in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (<https://www.oie.int/en/what-we-do/standards/codes-and-manuals/terrestrial-manual-online-access/>), and the OIE *Terrestrial Animal Health Code* (<https://www.oie.int/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/>) or the OIE *Aquatic Animal Health Code* (<https://www.oie.int/en/what-we-do/standards/codes-and-manuals/aquatic-code-online-access/>).
12. Provide a list of completed research and methods development projects on the disease.
13. Provide a list of inter-laboratory proficiency tests that the laboratory regularly organises and participates in.
14. Give details of training and consultation experience for the disease in the last 2 years (courses provided, number of people trained, examples of international consultation).
15. Provide a list of scientific meetings that the laboratory has organised and participated in.
16. Provide a list of reference documents (chapters for the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (<https://www.oie.int/en/what-we-do/standards/codes-and-manuals/terrestrial-manual-online-access/>), OIE *Manual of Diagnostic Tests for Aquatic Animals* (<https://www.oie.int/en/what-we-do/standards/codes-and-manuals/aquatic-manual-online-access/>), etc.) to which the laboratory contributed.

Collaborations, confidentiality and conflicts

17. Provide a list of collaboration agreements with other laboratories, centres or organisations.
18. Provide guarantees to ensure that staff respect the confidential nature of certain subjects, results or communications, and with regard to management of potential conflict of interests through completion of the required declarations.
19. Provide a Confidentiality Undertaking and a Declaration of Interests form signed by the Head of the Institution on behalf of the Institution, in accordance with the Rules for OIE Reference Laboratories available online at: <https://www.oie.int/en/who-we-are/structure/framework#ui-id-6>.

The application will be processed by the OIE in accordance with Articles 2, 3 and 4 of the Internal Rules (<https://www.oie.int/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-7>).

A short summary of activities of relevance to the status of OIE Reference Laboratory (no more than one page) should be included.

Applications comprising the information requested in all the above-mentioned points must be no longer than 15–20 pages in A4 format, single-spaced using Times New Roman font size 10 pt. The application must be prepared in one of the official languages of the OIE (English, French or Spanish).

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	March 2022
	2) Remind authors of the chapters identified previously for update but not yet received and invite authors of chapters newly identified for update	On-going
	3) Create a list of OIE validated tests to be published on the OIE Website	
	a) Develop a template for the validation data that would be requested of applicants wishing to add their test to a future list	On going
	4) Add a new section to the disease-specific chapters to describe the rationale behind the selection of tests for different purposes given in Table 1 <i>Test methods available and their purpose</i> and an explanation for their score. Eventually, add links to the link of validated tests mentioned above	
	a) Develop a template for this new section.	On going
Collaborating Centres	1) Implementation of the adopted SOPs:	For February 2022
	a) review the remaining submitted 5-year work plans	September 2022
	2) Review of annual reports 2021	October 2022
Reference Laboratories	1) Put under-performing labs on watch list	On going
	2) Create document detailing past history of annual report reviews	For October 2022
Reference Centre Networks	1) Follow up with the three newly launched Reference Laboratory networks (ASF, PPR and rabies)	On-going
Standardisation/ Harmonisation	1) Project to extend the list of OIE approved reference reagents	On-going
	2) Update the existing guidelines, and include a template as an annex for the data to be submitted with a request for approval to be added to the list of approved reagents	On-going
	3) Project to develop Replacement International Standard Bovine Tuberculin: finalise report and propose for adoption	For February 2023
	4) Review the conclusions from the OIE <i>Scientific and Technical Review</i> issue on diagnostic test validation science re: the OIE Procedure for the Registration of Diagnostic Kits	September 2022
Ad hoc Groups	1) <i>Ad hoc</i> Group on Sustainable Laboratories	On-going
	2) <i>Ad hoc</i> Group on the revision of <i>Terrestrial Code</i> chapters regarding the collection and processing of semen of animals	On-going
Projects	1) Veterinary Biobanking (project)	Ongoing
	2) High Throughput Sequencing and Bioinformatics and Computational Genomics (HTS-BCG)	On hold awaiting funding

Subject	Issue	Status and Action
Conferences, Workshops and Meetings with participation by BSC Members	1) Biosafety research roadmap	Ongoing
	2) ISWAVLD OIE seminar: theme and programme and speakers	June 2023
Performance	Engage with the ongoing processes around performance issues with Reference Labs	On-going
Twinning Programme	Assess the status of the post-twinning labs: dashboard. Gather feedback from the labs, way forward. Review geographical distribution	For September 2022
Develop laboratory standards for emerging diseases	1) Discuss the <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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