



REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 17–20 September 2019

A meeting of the OIE Biological Standards Commission was held at the OIE Headquarters in Paris, France, from 17 to 20 September 2019.

1. Welcome

Dr Matthew Stone, OIE Deputy Director General, International Standards and Science, welcomed the members of the Commission and thanked them, their institutions and their governments for making their expertise and time available to support the OIE's work.

Dr Stone provided the Commission with a brief overview of the development of the draft 7th Strategic Plan, noting its focus on scientific expertise and the use of multidisciplinary evidence in standard setting and capacity building; ensuring the OIE is a good partner, and targets collaborations for impact; improving monitoring and evaluation to demonstrate performance across our strategies, programmes and projects; and the development of internal data management, stewardship and governance practices that support the ongoing digital transformation of the OIE. He also provided a brief update on the culmination of the design phase of the OIE Observatory project; the OIE-WAHIS development project; and the ongoing work on the OIE Reference Centre system.

Dr Stone noted that the OIE's continuous improvement approach to ensuring good coordination across all the Specialist Commissions through the internal mechanism of the Common Secretariat is maturing and demonstrating its benefits. The recent focus had been on identifying and supporting discussions between Commissions on common issues. He finished his opening remarks by reassuring members that the OIE's performance management system for Specialist Commissions was providing very useful feedback, and all parties could now appreciate the process was important to optimise the performance of the elected Commissions and the OIE Secretariat working in partnership.

2. Adoption of Agenda

The proposed agenda was presented and adopted.

The Agenda and List of Participants are given at [Annexes 1](#) and [2](#), respectively.

2.1. Developing a process for designating agenda items to members of the Commission

During its conference call in June 2019, the Commission discussed the possibility of allocating responsibility for certain key agenda items to individual members of the Commission. The designated Commission member would have an in-depth understanding of the item and a clear overarching vision of the issues so that they could lead the discussions. The other members would continue to be adequately prepared for and contribute to discussions of all agenda items.

The proposal was endorsed by the Commission members who felt the approach would lead to more focused discussions and targeted outcomes. To begin the process, the six members were each assigned an agenda item for the next meeting in February 2020.

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

For this Agenda Item, the Commission was joined by Dr Steven Edwards, Consultant Editor of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)*.

3.1. **Update from General Session: questions on African swine fever, equine encephalomyelitis (Eastern, Western and Venezuelan) and equine influenza**

The Commission noted that Resolution No. 28 Amendments to the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* had been adopted with the condition that a paragraph in Chapter 3.8.1 *African swine fever (infection with African swine fever virus)* (ASF) on the role of carrier pigs in controlling the disease be deleted and referred to the OIE Scientific Commission for Animal Diseases for advice. The Biological Standards Commission reviewed the advice received from the Scientific Commission and agreed that the paragraph could be reinserted in the chapter with the following amendments:

Animals that have recovered from either acute or chronic infections may potentially become persistently infected, acting as virus carriers. The biological basis for the persistence of ASFV is still not well understood, nor it is clear what role it plays in the epidemiology of the disease ~~the extent to which carrier may shed the virus~~ (Carrillo *et al.*, 1994). ~~Recovered ASFV carrier pigs and persistently infected wild pigs constitute the biggest problems in controlling the disease. The serological recognition of carrier pigs has been vital for the success of eradication programmes in endemic ASF areas (Arias & Sanchez Vizcaino 2002, Sanchez Vizcaino et al. 2017).~~

This proposal would be included in the batch of draft chapters circulated to Members for first-round comment (see agenda item 3.6).

Regarding Chapter 3.5.5. *Equine encephalomyelitis (Eastern, Western and Venezuelan)*, a Member expressed its concern at the General Session that the important distinctions between Venezuelan equine encephalomyelitis (VEE) and Eastern and Western equine encephalomyelitis (EEE and WEE) had been lost by merging the existing two chapters into one single chapter. The Commission recognised the scientific validity of the comment. Before committing to splitting the chapter however, the Commission decided to first ask the Reference Laboratory expert to review and amend the chapter making sure that the information on VEE is clear and complete and that the distinction between VEE and EEE/WEE is explicit. The Commission would evaluate the amended chapter at its next meeting in February 2020 to ensure that the concerns had been addressed. If the chapter was still imprecise, the Commission would then consider separating it into two chapters.

Finally, in regard to Chapter 3.5.7. *Equine influenza*, a Member requested that it be added to the countries that are reported to be free of equine influenza virus as it had successfully eradicated the disease. The Commission decided to remove this sentence from the chapter: ~~“To date New Zealand and Iceland are reported to be free of equine influenza virus.”~~ The *Terrestrial Manual* is not the right forum for such information. Furthermore, the Commission agreed to remove any mention of the presence or absence of a disease at the country level. Contributors to the chapters would be asked to give information on the occurrence of a disease at the continental level and cross reference to WAHIS¹ for recent information on distribution at the country level.

¹ WAHIS: World Animal Health Information System (of the OIE)

3.2. Request to delete from the *Terrestrial Manual* recommendations for conducting abnormal toxicity test (ATT) and target animal batch safety test (TABST) for veterinary vaccines

The Commission discussed a proposal from a stakeholder organisation that the OIE should revise its *Terrestrial Manual* guidance regarding animal-based batch release testing for veterinary vaccines to delete all recommendations for conducting abnormal toxicity tests (ATT) and target animal batch safety tests (TABST). The Commission noted that *Terrestrial Manual* Chapters 1.1.8 *Principles of veterinary vaccine production* and 2.3.4 *Minimum requirements for production and quality control of vaccines* provide general guidance regarding alternatives to animal testing, in recognition of “3R” principles to refine, reduce, and replace use of animals for laboratory testing. Corresponding amendments to eliminate animal-based batch release testing are also being incorporated into the batch release testing sections of individual disease-specific chapters to further highlight the importance of eliminating animal-based testing for batch release of veterinary vaccines whenever feasible.

3.3. Vaccine section of the chapter on PPR²: target animal batch safety tests

The OIE Reference Laboratory experts on PPR agreed that the vaccine section of the *Terrestrial Manual* Chapter 3.7.9. required further amendments. In particular, the recommendation for conducting batch release safety testing in laboratory rodents could be omitted and the option for waiving the TABST if other quality controls are implemented could be added. The Commission reviewed and endorsed the revised vaccine section of the chapter, which would be included in the batch of draft chapters circulated to Members for first-round comment (see agenda item 3.6).

3.4 Review of Member comments on February 2019 report

The Commission noted comments that had been received from a Member on the report of the February 2019 meeting:

- In reply to a comment on the chapter on African horse sickness, the Commission stated that it is not appropriate to give details of validation data in the chapter: cut-off values are included for guidance and individual laboratories should do their own in-house validation;
- Regarding equine influenza (EI), the Member asked if the OIE has evaluated any commercial ELISA³ kit suitable for EI antibody testing. The Commission pointed out that the chapter includes a reference to one such study: Galvin *et al.*, 2013;
- The Commission noted the comment on the chapter on ASF, which would be forwarded to the experts when the chapter is next updated;
- Finally, the Commission confirmed that the chapter on Middle East respiratory syndrome (infection with Middle East respiratory syndrome coronavirus) has been drafted and includes diagnostic methods, as requested.

3.5. Revisiting the recommendation to keep the mallein test in the chapter on glanders

The International Horse Sports Confederation (IHSC) asked if the Commission could reconsider its position on keeping the mallein test in the chapter on glanders.

The Commission is aware that there are some problems and challenges with the mallein test:

- Possible interference with other diagnostic assays (i.e. subsequent false positive results with other diagnostic assays on animals recently tested with a mallein test);

² PPR: peste des petits ruminants

³ ELISA: Enzyme-linked immunosorbent assay

- Possible insufficient standardisation of mallein purified protein derivative (PPD). Provisions for the production of mallein PPD are outlined in the *Terrestrial Manual* but are less detailed as the provisions provided for other PPD (for instance tuberculin);
- Possible misuse of the mallein tests. Whilst intradermo-palpebral test is the most sensitive, reliable and specific mallein test, some other routes of administration of the mallein test are reported in the field (intra-muscular, intra-dermal, subcutaneous);
- Lack of practicality and safety of the administration of mallein tests (including for operators).

However, in consultation with the OIE Reference Laboratory experts, the Commission decided to keep the test in the *Terrestrial Manual* because it is useful in certain circumstances and used in some Members. The text of the chapter, states clearly that the “test is not generally recommended because of animal welfare concerns, however it can be useful in remote endemic areas where sample transport or proper cooling of samples is not possible”.

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

The Commission reviewed 25 draft chapters and approved 24 for circulation, some subject to clarification of certain points by the experts, for first-round Member comment and eventual proposal for adoption by the Assembly in May 2020. The 24 chapters and a brief summary of the main amendments are:

- 2.1.2. Biotechnology in the diagnosis of infectious diseases: thoroughly updated by a virtual expert consultation. The revision is so extensive that the changes have not been marked in the interest of clarity
- 3.1.7. Epizootic haemorrhagic disease (infection with epizootic hemorrhagic disease virus): updated and expanded the section on the real-time reverse-transcription PCR⁴
- 3.1.10. Japanese encephalitis (vaccine section): removed the mouse inoculation test as effective *in-vitro* methods exist; updated the characteristics of the vaccine strains, the final product batch tests and the requirements for authorisation/registration/licensing
- 3.1.11. Leishmaniosis: updated description of the disease, added a paragraph on the role of the vector; thoroughly updated agent identification test methods section; deleted test for cellular immunity as not relevant to veterinary applications; added a section on *Leishmania* species, subspecies or strains identification; amended the outline of production and minimum requirements for vaccines
- 3.1.15. Paratuberculosis (Johne’s disease): deleted the complement fixation test and agar gel immunodiffusion test as they have poor sensitivity and specificity and are no longer recommended. Amended the fitness for purpose of bacterial culture for population freedom in Table 1 *Test methods available and their purpose*
- 3.1.21. *Trypanosoma evansi* infection (surra in all species): updated the introduction; added Table 1. *Test methods available and their purpose*; updated the PCR and card agglutination test methods; updated test application section
- 3.3.3. Avian infectious laryngotracheitis: added sentence on differential diagnosis and on evidence of highly virulent and transmissible strains emerging as a result of recombination; added some amendments to the molecular methods section

⁴ PCR: polymerase chain reaction

- 3.3.5. Avian mycoplasmosis (*M. gallisepticum*, *M. synoviae*): updated description of the disease and differential diagnosis; added Table 1. *Test methods available and their purpose*; updated *in-vitro* culture section; thoroughly updated molecular methods – detection of nucleic acids section, including addition of conventional and real-time PCRs; updated introductory text to the vaccine section; added a section on requirements for authorisation/registration/licensing (of vaccines); updated the references
- 3.3.6. Avian tuberculosis: updated section on nucleic acid recognition methods
- 3.3.14. Newcastle disease: added Table 1. *Test methods available and their purpose*; updated phylogenetic classification; updated molecular techniques in diagnosis
- 3.4.2. Bovine babesiosis: deleted the complement fixation test as it is no longer used, and added the immunochromatographic test as it is useful in field situations
- 3.4.4. Bovine genital campylobacteriosis (vaccine section): largely deleted the vaccine section
- 3.4.5. Bovine spongiform encephalopathy: removed histopathology as a recommended diagnostic method as it has lower sensitivity compared with agent identification methods and has been superseded by them, but retained it in the chapter for reference purposes (**Note**: one OIE Reference Laboratory did not agree with this amendment); updated URLs for material on the OIE Reference Laboratory website
- 3.4.8. Contagious bovine pleuropneumonia (infection with *Mycoplasma mycoides* subsp. *mycoides*): modified the taxonomy, updated strain typing section; amended the ranking of some tests in Table 1. *Test methods available and their purpose*
- 3.4.11. Haemorrhagic septicaemia: added Table 1. *Test methods available and their purpose*; added real-time PCR and loop-mediated isothermal amplification assays
- 3.4.12. Lumpy skin disease: deleted electron microscopy and agar gel immunodiffusion from the diagnostics section as it cannot be recommended because of the cross-reaction with antibodies to bovine papular stomatitis and pseudocowpox virus; amended the text on the ELISA; updated the outline of production and minimum requirements for conventional vaccines section
- 3.4.16. Animal trypanosomes of African origin (excluding infection with *Trypanosoma evansi* and *T. equiperdum*): amended the ranking of some tests in Table 1. *Test methods available and their purpose* in particular downgrading rodent inoculation; deleted *in-vitro* culture section as it is unreliable; updated DNA amplification tests, indirect fluorescent antibody test and antibody-detection ELISA sections; added test applications section
- 3.5.8. Equine piroplasmiasis: amended the ranking of some tests in Table 1. *Test methods available and their purpose*; updated molecular methods section; deleted complement fixation protocol as it is no longer recommended to qualify horses for movement, requested input from the OIE expert as to the transmission risk of PCR-negative, competitive ELISA-positive horses
- 3.6.2. Rabbit haemorrhagic disease: extensively updated chapter to reflect the changing patterns of disease and technical developments; deleted haemagglutination and haemagglutination inhibition test methods; updated the characteristics of the vaccine strains and the requirements for authorisation/registration/licensing
- 3.7.4. Contagious caprine pleuropneumonia: deleted complement fixation and indirect fluorescent antibody tests in favour of better, more modern methods.
- 3.7.8. Ovine pulmonary adenomatosis (adenocarcinoma): minor updates; added immunohistochemistry; updated references

- 3.9.2. Camelpox: Minor updates
- 3.9.5. Cysticercosis (including infection with *Taenia solium*): deleted procedure for diagnosis in humans; deleted sections on meat inspection as more appropriate for the *Terrestrial Code*;
- 3.x.xx Middle East respiratory syndrome (infection with Middle East respiratory syndrome coronavirus): new chapter; the Commission agreed to create a new section in the *Terrestrial Manual* on Camelidae diseases for this chapter and the chapter on camelpox

The batch of draft chapters will also include three other chapters: African swine fever (see agenda item 3.1), peste des petits ruminants (see agenda item 3.3), and avian influenza (see agenda item 9.3.2).

The chapters can be downloaded from the following address:

http://web.oie.int/download/Terr_Manual/MAILING_OCT_2019.zip

Members are reminded that they should submit the rationale for all their proposed changes to the texts, and include references where relevant for the Commission to consult. The deadline for comments is **8 January 2020**.

The Commission noted the draft revision to Chapter 1.1.4. *Biosafety and biosecurity: Standard for managing biological risk in the veterinary laboratory and animal facilities*, but felt the chapter needed further work. Experts who could take the lead on this task were identified.

3.7. Review of *Terrestrial Manual* status: selection of chapters for update in 2020/2021 review cycle

The Commission examined the status of chapters that had previously been identified for update in the 2019/2020 review cycle. The Commission decided to add to the list chapters that had last been updated in 2014. The following 27 chapters have thus been identified:

- 1.1.1. Management of Veterinary Laboratories
- 2.1.3 Managing biorisk: examples of aligning risk management strategies with assessed biorisks
- 2.3.1 The application of biotechnology to the development of veterinary vaccines
- 3.1.3 Bluetongue (infection with bluetongue virus)
- 3.1.5 Crimean–Congo haemorrhagic fever
- 3.1.12 Leptospirosis
- 3.1.14. Nipah and Hendra virus diseases
- 3.1.23. Vesicular stomatitis
- 3.2.1 Acarapisosis of honey bees (infestation of honey bees with *Acarapis woodi*)
- 3.2.4 Nosemosis of honey bees
- 3.2.7 Varroosis of honey bees (infestation of honey bees with *Varroa* spp.)
- 3.3.4. Avian influenza (infection with avian influenza virus)
- 3.3.9. Fowl cholera
- 3.3.15 Turkey rhinotracheitis (avian metapneumovirus)
- 3.4.1. Bovine anaplasmosis
- 3.4.6. Bovine tuberculosis
- 3.4.7 Bovine viral diarrhoea
- 3.5.3 Infection with *Trypanosoma equiperdum* (dourine in horses)
- 3.5.10 Equine viral arteritis (infection with equine arteritis virus)
- 3.6.1 Myxomatosis
- 3.7.7. Ovine epididymitis (*Brucella ovis*)

- 3.8.6. Porcine reproductive and respiratory syndrome
- 3.8.7. Influenza A virus of swine
- 3.8.10 Transmissible gastroenteritis
- 3.9.1 Bunyaviral diseases of animals (excluding Rift Valley fever and Crimean–Congo haemorrhagic fever)
- 3.9.6 *Listeria monocytogenes*
- 3.9.10 Verocytotoxigenic *Escherichia coli*

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

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

This item was postponed to February 2020 to give the Reference Laboratory experts time to complete a reproducibility study on PCRs including the above-mentioned PCR.

4. OIE Reference Centres

4.1. Applications for OIE Reference Centre status

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

OIE Collaborating Centre for Continuing Education and Veterinary Capacity Building

Centre National de Veille Zoosanitaire (CNVZ), 38, Avenue Charles Nicolle, Cite Mahrajène 1082, Tunis, TUNISIA

Tel.: (+216) 71.84.97.90 / 71.84.98.12

Email: bo.cnvz@iresa.agrinet.tn

Designated Contact Point: Dr Mohamed Naceur Baccar.

The Commission had consulted the OIE Terrestrial Animal Health Standards Commission, which gave a favourable opinion on this application. The Commission noted that there is an existing OIE Collaborating Centre for the same topic in the Africa region, and suggested either a consortium between the existing and potential new Collaborating Centre or, at the Council's discretion, consideration of whether the circumstances justified an exceptional designation for the sub-region. The Council will make its final decision at its next meeting in February 2020.

During the meeting, the Commission was informed of the creation of the OIE Platform for Collaborating Centres for Training and Education. All OIE Centres involved in training and education are invited to join the OIE Platform, the objective of which is to support the delivery of OIE Strategic Plan through innovative training projects. The Commission agreed that in the case of training and education, there is merit in increasing cooperation/collaboration at the inter-regional level. The OIE Platform will be asked to submit a single 5-year work plan (see agenda item 4.7) for all participating Collaborating Centres (currently eight) rather than individual ones. In this way, the Platform will serve as an example of networking to provide a common service to the OIE.

OIE Collaborating Centre for Quality Management Systems

Abu Dhabi Agriculture and Food Safety Authority, PO Box 52150, Mohammed Bin Zayed City, Capital Mall, Abu Dhabi, UNITED ARAB EMIRATES

Tel.: (+971-2) 818.10.08

Email: yld.office@adfca.gov.abudhabi

Designated Contact Point: Dr Salama Suhail Mohammed Al Muhairi.

OIE Reference Laboratory for Brucellosis (*Brucella abortus*, *B. melitensis*, *B. canis*)

Central Veterinary Research Laboratory, PO Box 597, Dubai, UNITED ARAB EMIRATES

Tel.: (+971-4) 337.51.65

Email: cvrl@cvrl.ae

Designated Reference Expert: Prof. Ulrich Wernery.

OIE Reference Laboratory for Foot and mouth disease

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.: (+204) 789.20.01
Email: Charles.nfon@canada.ca
Designated Reference Expert: Dr Charles Nfon.

OIE Reference Laboratory for Dourine

Anses Normandy, Laboratory for Animal Health, PhEED Unit, RD675, 14430 Dozulé, FRANCE
Tel.: (+33-2) 31.79.22.76
Email: laurent.hebert@anses.fr
Designated Reference Expert: Dr Laurent Hébert.

OIE Reference Laboratory for Rinderpest

USDA, APHIS, VS, NVSL, Foreign Animal Disease Diagnostic Laboratory, Plum Island Animal Disease Center, P.O. Box 848, Greenport, New York 11944, UNITED STATES OF AMERICA
Tel.: (+1-631) 323.33.44
Email: wei.jia@usda.gov
Designated Reference Expert: Dr Wei Jia.

OIE Reference Laboratory for Classical swine fever

CSIRO Australian Animal Health Laboratory, 5 Portarlington Road, Geelong, Victoria 3220, AUSTRALIA
Tel.: (+61) 52.27.50.00
Email: trevor.drew@csiro.au
Designated Reference Expert: Prof. Trevor Drew.

OIE Reference Laboratory for African swine fever

CSIRO Australian Animal Health Laboratory, 5 Portarlington Road, Geelong, Victoria 3220, AUSTRALIA
Tel.: (+61) 52.27.50.00
Email: d.williams@csiro.au
Designated Reference Expert: Dr David Williams.

An application had been received for an OIE Collaborating Centre for Emerging Animal Diseases (Detection and Response). The Biological Standards Commission accepted the application in principle. In accordance with the Internal Rules for OIE Collaborating Centres, the application needs to be endorsed by the Regional Commission for Asia, the Far East and Oceania. Should the outcome be positive, the Centre would need to form a consortium with other Centres in the region having a similar specialty.

An application had been received for an OIE Collaborating Centre for Traditional Veterinary Medicine. The Commission identified challenges associated with the potentially broad scope of the proposed Collaborating Centre and suggested a narrower focus. The Commission agreed that the view of the OIE Council on the principle of the OIE designating Centres on traditional medicines would be helpful. While recognising the applicant's broad expertise and experience, the Council nonetheless determined that the OIE is not yet in a position to designate a Centre on this topic until the scientific validity of efficacy and safety testing of traditional medicines is better understood, as well as conformity with CITES (Convention on Trade in Endangered Species). The OIE would nevertheless like to collaborate with the Centre and will invite the applicant to support work in the area of alternatives to antimicrobials.

An application had been received for an OIE Reference Laboratory for Middle East respiratory syndrome. Although the laboratory clearly had a great deal of experience with the disease, the proposed expert did not fulfil the expectations of an OIE Expert. The Commission therefore did not accept the application.

Another application had been received for an OIE Reference Laboratory for Brucellosis (*Brucella abortus*, *B. melitensis*, *B. suis*). Again, the proposed expert did not fulfil the expectations of an OIE Expert. The Commission therefore did not accept the application.

Finally, an application had been received for an OIE Reference Laboratory for African swine fever. The Commission noted that the proposed expert is already the designated expert at two other OIE Reference Laboratories for important diseases. Reviewing the annual reports (see agenda item 4.4), revealed that the laboratories do not seem to be very active. As an OIE Reference Laboratory designation requires a high level of commitment, the Commission was reluctant to accept that the designated expert would cover a third disease. The Commission therefore did not accept the application.

4.2. Changes of experts at OIE Reference Centres

The Commission reviewed four nominations for changes of experts at OIE Reference Laboratories and felt that none could fulfil the expectations of an OIE Expert. The Commission reiterated that OIE designated experts must have experience in the application of diagnostic techniques for the disease in question and must be able to provide adequate evidence of expertise (e.g. a body of published papers in peer-reviewed journals) so as to be able to provide sound scientific advice on all aspects of the disease to Members.

4.4. Review of new and pending applications for laboratory twinning

As of September 2019, 57 projects have been completed, 39 projects are underway and 8 are on hold before beginning.

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

- i) *United Kingdom – Kazakhstan* for avian influenza and Newcastle disease: the Commission supported the technical contents of this project.
- ii) *New Zealand – Liberia* for viral haemorrhagic fevers: the Commission supported the technical contents of this project.
- iii) *Switzerland – Turkey* for ovine chlamydiosis: the Commission supported the technical contents of this project.

● Reference Laboratories – implementation of the SOPs⁵

4.4. Follow-up of in-depth review of all annual reports for activities in 2018 based on the performance criteria to identify any that are not complying

The Commission reviewed the performance of all the Reference Laboratories by an in-depth analysis of all the annual reports submitted in 2018 to ensure that each laboratory is fulfilling the Terms of Reference (ToR) to the benefit of OIE Members and performance criterion iii) of the *Procedures for Designation of OIE Reference Laboratories* (the SOPs).

The Commission identified 13 Reference Laboratories that were not complying with the key ToR. The OIE Reference Laboratories concerned would be informed of the outcome of the review and asked to provide feedback and an explanation of their situation and possible reasons for the lack of activity; the Delegate will be in copy of all correspondence.

The Commission observed that fulfilling the criteria of the ToR is likely to depend on a range of factors such as the importance and prevalence of the disease and species affected. The objective of asking for an explanation for what appears to be under-performing laboratories is to initiate a dialogue with the laboratory concerned to better understand the problems and find solutions for improvement. The Commission suggested that the Reference Laboratories should be asked to use the comment section at the end of the annual report template to explain why there was no or little activity with the disease during the reporting period or to provide explanations for the difficulties faced in fulfilling the ToR.

One laboratory that had not submitted its annual report will be sent a letter reminding it that it was not complying with the performance criteria, which could lead to the delisting procedure being initiated.

⁵ SOP: Standard Operating Procedure

The Commission noted that as rinderpest has been eradicated, the report template is not adapted to the OIE Reference Laboratories for this disease. A member of the Commission was tasked with drafting a template requesting information on emergency preparedness, maintenance of expertise and up-to-date reagents, networking, etc.

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

4.5. Follow-up of in-depth review of all annual reports for activities in 2018 based on the performance criteria to identify any that are not complying

As for the Reference Laboratories, the Commission also undertook an in-depth analysis of all the annual reports of the Collaborating Centres submitted in 2018 to ensure fulfilment of the ToR.

The Commission identified two Collaborating Centres that were not complying with the performance criteria. The two Centres would be informed of the outcome of the review and asked to provide feedback and an explanation of their situation and possible reasons for the lack of activity for review at the February 2020 meeting; the Delegate will be in copy of all correspondence.

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

4.6. Update on the mapping exercise for the existing Centres against the list of main focus areas and specialties and discussion on the next steps

Following the February 2019 meeting, all Collaborating Centres having an activity that fits within the list of identified main focus areas and specialties of interest to the OIE and where there is no overlap with any other OIE Collaborating Centre in the region, were informed that the Commission is not proposing any change to their designation.

Four existing Collaborating Centres with clear overlapping activities were contacted with the request that they consider forming two consortia, for example by signing a MoU⁶ or other such arrangement. Two Centres agreed to the Commission's proposals. For the remaining two Centres, only one component replied and did not agree to the proposal. The Commission proposed further action and a possible way forward.

One Centre with four distinct main focus areas and specialties was asked if it would consider dividing the current Centre into distinct OIE Collaborating Centres for the identified specialties, bearing in mind that this may involve the formation of consortia with existing Centres in the region. The Centre agreed to the Commission's proposal.

Finally, one Centre that did not communicate with the OIE Headquarters was contacted with the request for feedback on the situation, including possible reasons for the difficulties the OIE has communicating with it and receiving replies, and proposing a solution. The Centre outlined its plans to overcome its problems; the Commission looks forward to further collaborating with it in the future.

At the February 2019 meeting, the Commission tasked the Secretariat with further evaluating the activity reports of existing Collaborating Centres that appeared to have overlapping activities to verify the situation. The Commission reviewed the list and identified six Centres with overlapping activities, which will be contacted with the request to consider forming three consortia. For four Centres in the Americas Region, the Commission decided to evoke the clause allowing, in exceptional cases, a Centre to be designated in a sub-region for linguistic reasons. The four institutes will therefore be left as stand-alone OIE Collaborating Centres.

All the Commission's decisions and proposals will be sent to the identified Collaborating Centres for consideration and feedback for the February 2020 meeting.

⁶ MOU: Memorandum of Understanding

4.7. Review of the template for the 5-year work plan

In accordance with the SOPs, OIE Collaborating Centres are designated for a fixed 5-year term with a review at the end of the term. The SOPs stipulate that Centres will be requested to submit a summary of their achievements at the end of the 5-year designated period and a proposal for the activities for the forthcoming 5 years. To assist with this requirement, the Commission developed a template for the 5-year work plan. The template focuses on six areas: administrative details, strategic summary, Collaborating Centre profile, networks and affiliations, work plan for the next 5 years and authorisation. The template will be sent to the OIE Collaborating Centres with a deadline of 15 January 2020; the replies will be reviewed by the Commission at its meeting in February 2020.

- **Reference Centre networks**

4.8. Update on progress and review of ToRs for the three identified Reference Laboratory networks

Following the Commission's recommendation to establish OIE Reference Laboratory networks for diseases of current global importance, namely African swine fever (ASF), PPR and rabies, the Secretariat contacted the experts who had been identified as potential leaders to establish these networks. The leaders: Reference Laboratory experts from South Africa (ASF), France (PPR), and Germany and USA (rabies), had all agreed to undertake the task and had submitted the draft goals and objectives of each network.

The Commission reviewed the documents and provided feedback. The Commission recommended that the networks should primarily be an OIE network of laboratories for the identified diseases, and that the key objectives should be similar and harmonised for all the networks. The goal of the network should be to expand the access to expertise beyond the OIE Reference Laboratories involving national laboratories, research institutions and universities. The conditions for membership to join the network from national laboratories, research institutions and universities should be defined. The leader (coordinator) of each network will be consulted to set criteria for assessment of memberships. The Commission's comments will be shared with the network leaders to harmonise the goals, objectives and planned activities for each network.

4.9. Review of the existing guidance to see if it can form the basis for an SOP for an OIE Reference Centre Network

The Commission examined the current Guidance for the Management of OIE Reference Centre Networks⁷. The Commission felt that the current information already provides an adequate amount of guidance for laboratory networking, but certain aspects need to be improved. In particular, the Commission would like to further develop the guidance into SOPs for the functioning and maintenance of networks. Each network should have a clear work plan and submit annual reports. A disclaimer should be included to state that OIE has no liability on the activities of the network.

The Commission is aware that the existing OIE Collaborating Centres on veterinary training and education have formed a network called the OIE Platform. In the framework of the OIE Platform, the Commission agreed that it would be possible to produce one single 5-year action plan for all Centres involved in place of individual ones.

The Commission also took note of the already existing networks on animal influenza (OFFLU⁸), foot and mouth disease (FMD), non-tsetse transmitted animal trypanosomoses (NTTAT) and bluetongue. The OFFLU, FMD and NTTAT networks have remained functional for a number of years and have regular activities, though with very different modus operandi, while the bluetongue network has been inactive for the past few years.

⁷ <http://www.oie.int/en/scientific-expertise/reference-laboratories/referencecentre-networks/>

⁸ OFFLU: Joint OIE-FAO Network of Expertise on Animal Influenza

5. *Ad hoc* Groups

- Update on activities of *ad hoc* Groups

5.1. *Ad hoc* Group to finalise the International Standard Bovine Tuberculin (ISBT) replacement project, and revise *Terrestrial Manual* chapter 3.4.6 Bovine tuberculosis: 5–7 November 2019

The Commission received an update on the ongoing project to prepare and calibrate a new reference tuberculin to replace the current International Standard Bovine Tuberculin (ISBT), which was produced in 1986 and has now become depleted. In a Preliminary Evaluation, the potency and specificity of two candidate tuberculins were evaluated in comparison with the current ISBT, and the results were satisfactory. A larger scale International Collaborative Study was subsequently conducted to further evaluate and calibrate the candidates in guinea-pigs, and to evaluate the candidates' fitness for purpose in cattle (experimentally infected cattle, or naturally sensitised 'reactor' cattle). This second phase of testing has now been completed, except for some cattle studies that were temporarily delayed. The *ad hoc* Group is scheduled to meet from 5 to 7 November 2019 to finalise the ISBT project and prepare a summary report for presentation to the Commission in February 2020, for endorsement. If the results of the evaluation and calibration studies are satisfactory, a draft Resolution recommending adoption of a new ISBT will be presented to the OIE Assembly for adoption in May 2020. The new ISBT standard would then be maintained in secure storage at the National Institute for Biological Standards and Control (United Kingdom) and made available for distribution to national regulatory agencies and tuberculin manufacturers for use in standardising national references and quality control of commercially manufactured tuberculins. In the third and fourth quarters of 2020, the *ad hoc* Group and collaborators will draft a manuscript for publication in a peer-reviewed scientific journal.

The *ad hoc* Group will also review and update the current text of the *Terrestrial Manual* Chapter 3.4.6 *Bovine tuberculosis*.

5.2. *Ad hoc* Group on High Throughput Sequencing and Bioinformatics and Computational Genomics (HTS-BCG)

The Commission was updated on the project to develop on OIE Pathogen Genomic Platform and was informed that the application for donor funds had not been successful. The OIE is evaluating other funding opportunities to progress the project.

6. International Standardisation/Harmonisation

6.1. OIE Register of diagnostic kits

6.1.1. Review of the registration procedure

The OIE Secretariat for Registration of Diagnostic Kits briefly introduced its plans to review and clarify or revise some administrative procedures that are described in the *SOP for OIE Registration of Diagnostic Kits – Guide and Administrative Forms*. It was agreed that the Secretariat would incorporate the proposed changes into an updated draft SOP, to be presented to the Commission at the February 2020 meeting and subsequent approval by the Director General.

6.1.2. Update and review of new applications or renewed applications

At present, there are 12 registered kits; five new applications are in various stages of review, including one with an extended claim. Two new applications have been received so far in 2019. At the General Session in May 2019, two diagnostic kits were renewed for 5 years (*TeSeE Western Blot* and *Newcastle Disease Virus antibody detection ELISA*), and one new diagnostic kit was added to the register (*Enferplex Bovine TB Antibody Test*).

The Commission was informed that evaluation of the dossier on “VetMAX™ African Swine Fever Virus Detection Kit” had been completed. Based on the final report from the expert evaluation panel, the Commission provided a favourable opinion for the inclusion in the OIE register of this diagnostic kit with the following purposes: VetMAX™ African Swine Fever Virus Detection Kit is fit for the purpose of detection of the African Swine Fever virus from blood, serum and tissues of pigs and wild pigs (including wild boars).

An abstract sheet of the validation data of the “VetMAX™ African Swine Fever Virus Detection Kit” kit, drafted in collaboration with the diagnostic kit manufacturer and the expert evaluation panel, and endorsed by the Commission, is included at [Annex 3](#) of this report.

6.2. Standardisation programme

6.2.1. Update on project to extend the list of OIE-approved reference reagents

The Commission evaluated the application for inclusion of diagnostic reagents for trichinellosis in the list of OIE-Approved Reference Reagents that was submitted by the Istituto Superiore di Sanita', OIE Reference Laboratory for trichinellosis. The Commission agreed that these sera should be officially designated as OIE-Approved International Standard Reagents for trichinellosis; they will be included in the list published online on the OIE website.

6.2.2. Updating the three existing guidelines to 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

A member of the Commission presented the first draft of a template to be attached to the guidelines for antibody standards. The purpose of the template is to facilitate data collection and submission from applicant laboratories. The Commission evaluated positively the template. Given that the guidelines have not been reviewed since their first publication, it was proposed to begin a review process to reflect changes in diagnostic practices, take into account the need for additional information on reagents and also to streamline the process for inclusion in the list of OIE-approved reference reagents. The Commission member offered to review the guidelines for antibody standards by the next meeting of the Commission in February 2020. The review of the guidelines for antigens and PCR standards will follow to ensure consistency of content, format and style across guidelines.

6.3. OIE Biobank project

6.3.1. Kick off meeting for the OIE biobank project, 15–17 October 2019

The Commission was updated on the progress that had been made with the project to develop an OIE Virtual Biobank. The Commission was informed that the OIE is organising a kick-off meeting of the project, which will be held from 15 to 17 October 2019. Meeting participants include experts in biobanking, laboratory diagnostics, IT systems and animal diseases, as well as the project team from the Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna (IZSLER, Brescia, Italy), OIE Collaborating Centre for Veterinary Biologicals Biobank, which will implement the web-based system. The main objectives of the meeting are to discuss the metadata to be attached to biobank materials and the IT solution proposed by IZSLER and described in the project's business plan. The Commission designated its representative to this meeting.

7. Follow-up from the General Session

7.1. Excerpt from the Final Report: Comments from Delegates

The Commission noted the comments from the Delegates following the presentation of its activities for the previous year given at the General Session in May 2018.

The Commission also noted that some of the “for action” comments had been addressed (see agenda items 3.1 and 9.2.1).

In response to a comment for more transparency in the procedure for the OIE Register of diagnostic kits, the Secretariat for Registration of Diagnostic Kits reported on a plan to provide a concise summary of each kit's intended use and pertinent supporting validation data, as an appendix to the Commission's reports, so that Delegates have adequate time to consider kits being proposed for adoption. The Commission endorsed this proposal, and it was agreed that the modified procedure will be incorporated into a revised version of the SOPs that is currently under preparation (see agenda item 6.1.1).

8. Conferences, Workshops, Meetings

- **Past Conferences, Workshops, Meetings**

8.1. 19th WAVLD⁹ Symposium, 19–22 June 2019, Chiang Mai, Thailand: 1-day OIE Seminar (Friday 21 June)

The 1-day OIE Seminar had been held during the 19th WAVLD Symposium, 19–22 June 2019, Chiang Mai, Thailand. The Seminar had been divided into two parts: the morning session on *Laboratory Quality Management Systems: The Costs and Benefits of Quality* and the afternoon session on *Biobanking and Reference Materials*. A presentation entitled: *African Swine Fever: Setting standard laboratory diagnostics and laboratory networking in Asia* had also been included in the programme.

Dr Ana Nicola and Dr Ann Cullinane attended the seminar. Response to the event and the OIE's engagement and involvement throughout the conference was positive from the WAVLD Executive Board, as well as from conference participants. The next International Symposium of the WAVLD will occur in Lyons, France in June 2021.

- **Future Conferences, Workshops, Meetings**

8.2. Third International Symposium on Alternatives to Antibiotics, Bangkok, Thailand, 16–18 December 2019

The theme of the 3rd International Symposium is “Challenges and Solutions in Animal Health and Production”, with seven topics: 1) vaccines; 2) microbial-derived products; 3) phytochemicals; 4) immune-derived products; 6) Innovative drugs, chemicals and enzymes and 7) Regulatory pathways to enable the licensing of alternatives to antibiotics.

9. Liaison with other Commissions

9.1. Horizontal issues among the Specialist Commissions

9.1.1. SOP for listing/delisting disease in coordination: role of BSC in evaluating listing criteria 3 related to diagnostics

The OIE has developed an SOP for the decision to add (or remove) pathogenic agents of terrestrial animals to (or from) the OIE List and to define the roles and responsibilities of Specialist Commissions, subject-matter experts, OIE Headquarters, and Members Countries in this process. In accordance with the procedure, the assessment of a pathogenic agent against the criteria for inclusion in the OIE List by subject matter experts is taken into account. It was agreed that the Biological Standards Commission would be responsible for Criterion 3 as it concerns diagnostic tests and clear case definitions. (Criterion 3 of Chapter 1.2. of the *Terrestrial Code*: 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 would provide its opinion to the Scientific Commission on the expert consultation report regarding any assessment against criterion 3.

9.1.2. Definitions of Competent Authority, Veterinary Authority and Veterinary Services in OIE Standards

The OIE Secretariat provided some background information about the Code Commission's decision to amend the definitions for Competent Authority, Veterinary Authority and Veterinary Services in the Glossary of the *Terrestrial Code*, noting that the proposed amendments were circulated for Member comments in the Code Commission's September 2018 report and that comments received were considered by the *ad hoc* Group on Veterinary Services that met in July 2019.

⁹ WAVLD: World Association of Veterinary Laboratory Diagnosticians

The Biological Standards Commission was informed that the OIE Secretariat is seeking input from all Specialist Commissions on the proposed amended definitions in relation to each Commission's work and any consequences of these amendments. The opinions provided by the Specialist Commissions will be considered by an internal OIE group to ensure any cross-Commission issues can be addressed and any consequences of these amendments on other OIE work can be considered. A representative from each Commission will be included in this group.

9.2. Scientific Commission for Animal Diseases

Matters from the Scientific Commission for Animal Diseases to the Biological Standards Commission

9.2.1. Question regarding carrier status of animals following infection with African swine fever

See agenda item 3.1.

9.2.2. Question from the *ad hoc* Group on Bovine Spongiform Encephalopathy (BSE) Risk Assessment and Surveillance

The Commission considered the recommendation of the *ad hoc* Group on BSE Risk Assessment and Surveillance, which met in March 2019, that the literature overview on “*Atypical BSE: the risk of being recycled in a cattle population and its zoonotic potential*” (Appendix IV of the *ad hoc* Group report) be referred to the Biological Standards Commission in support of the update of Chapter 3.4.5. of the *Terrestrial Manual*. The Group also recommended that consistency should be ensured between the list of behavioural or clinical signs related to BSE defined in Article 11.4.20. of draft Chapter 11.4. of the *Terrestrial Code* and those listed in Chapter 3.4.5. of the *Terrestrial Manual*. The Commission will be kept informed of the progress of draft Chapter 11.4. towards adoption so that the *ad hoc* Group's recommendations can be considered in a timely manner should they imply an amendment to the *Terrestrial Manual* chapter.

9.2.3. Developing case definitions: input from OIE Reference Laboratories

The Commission was informed of a proposal to develop a case definition for all OIE listed diseases and the request that the Commission be involved in the process, along with relevant OIE Reference Centres or subject-matter experts. The Commission agreed to this proposal as it is essential to have case definitions, and such definitions would include diagnostic testing regimes.

9.3. Terrestrial Animal Health Standards Commission

Matters from the Terrestrial Animal Health Standards Commission to the Biological Standards Commission

The Biological Standards Commission provided the following advice to the Code Commission on technical comments from OIE Members on draft *Terrestrial Code* chapters.

9.3.1. Questions on the equine influenza chapter

The Biological Standards Commission's advice was sought on the proposal from a Member to add a new point to Article 12.6.6. *Recommendations for the importation of domestic equids for unrestricted movement*. The Commission advised to accept the comment, but to add a reference to the *Terrestrial Manual*. The revised text would be:

3) were tested, with negative results, four to six days after commencement of pre-export isolation and again during the four days before export using a validated type A influenza pan-reactive assay targeting the matrix gene as described in the *Terrestrial Manual*; and

In the same Article, a Member proposed adding the words “and considered effective against the virus lineages as recommended by OIE” after the words “vaccinated in accordance with the recommendations of the manufacturer with a vaccine complying with the standards described in the *Terrestrial Manual*”.

The Biological Standards Commission advised to accept the comment as the proposed wording facilitates the use of updated vaccines and vaccines that have not been updated but that have been shown to be effective against the virus lineages that are in circulation. Cross protection against heterologous viruses has been demonstrated for some adjuvanted vaccines. (PAILLOT R., GARRETT D., LOPEZ-ALVAREZ M.R., BIRAND I., MONTESSO F. & HORSPOOL L. [2018]. The Immunity Gap Challenge: Protection against a Recent Florida Clade 2 Equine Influenza Strain. *Vaccines* [Basel], 6 [3]. pii: E38. doi: 10.3390/vaccines6030038.)

In the same Article, a Member questioned point a) “between 14 and 90 days before shipment either with a primary course or a booster; or” in respect of the young horses or primo-vaccinates.

The Biological Standards Commission advised that receiving a mix of equine influenza vaccines during the primary vaccination schedule does not have a detrimental impact on the antibody response that correlates with protection. (DILAI M., PIRO M., EL HARRAK M., FOUGEROLLE S., DEHHAOUI M., DIKRALLAH A., LEGRAND L., PAILLOT R. & FASSI FIHRI O. [2018]. Impact of Mixed Equine Influenza Vaccination on Correlate of Protection in Horses. *Vaccines* [Basel], 6 [4]. pii: E71. doi: 10.3390/vaccines6040071.)

In the same Article, point b) “between 14 and 180 days before shipment, if they are older than four years of age, previously having received at least four doses of the same vaccine at intervals not greater than 180 days” a Member questioned the rationale for accepting the equine influenza vaccine protocol for biosecurity purposes as it is based on work that has not been published

The Biological Standards Commission confirmed that a scientific publication on this study is in preparation by the Irish Equine Centre, OIE Reference Laboratory for equine influenza. It will be published in a peer-reviewed open access journal.

The Member also proposed deleting the words “the same” before “vaccine” from point b).

The Biological Standards Commission agreed as mixing vaccines is common practice and does not have a detrimental impact. (RYAN M., GILDEA S., WALSH C. & CULLINANE A. [2015]. The impact of different equine influenza vaccine products and other factors on equine influenza antibody levels in Thoroughbred racehorses. *Equine Vet. J.*, 47, 662–666.)

Also in point b) a Member proposed replacing the interval for administering the vaccine from 180 to 201 days.

The Biological Standards Commission agreed, but acknowledged that currently, there are no published data to support.

9.3.2. Questions on the avian influenza chapter

The OIE *ad hoc* Group on avian influenza had revised the *Terrestrial Code* chapter, which includes an updated definition of high pathogenicity avian influenza. The proposed amendments would have an impact on the section in the *Terrestrial Manual* chapter on assessment of pathogenicity. As both chapters should be aligned, the Biological Standards Commission agreed to ask the experts to revise this section on determination of strain virulence of the *Terrestrial Manual* chapter so that it could be circulated for first-round Member comment in October 2019 with a view to presenting it for adoption in May 2020 at the same time as the *Terrestrial Code* chapter.

Should the remaining text of the *Terrestrial Manual* chapter need revision, the OIE Reference Laboratories would be asked to undertake this task for the 2020/2021 review cycle.

9.3.3. OIE Standards on semen

The Commission was reminded that there is a lack of harmonisation between the recommendations given in *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*, and methodologies in the relevant chapters in the *Terrestrial Manual*.

To address this issue, it is proposed to convene an *ad hoc* Group of experts experienced in contemporary procedures in animal reproduction, and in the risk assessment of diseases transmissible via semen and the biosecurity measures required to mitigate such risks. Representatives from the Code Commission and the Biological Standards Commission would also participate as observers.

The Biological Standards Commission welcomed this initiative and nominated a member to participate in this work.

9.4. Aquatic Animal Health Standards Commission

None at this meeting.

10. Matters of Interest for Information

10.1. Update on OFFLU

The Commission was briefed on the OFFLU contribution of avian influenza (AI) data for the period October 2018 to February 2019 to WHO Consultation on the Composition of Influenza Virus Vaccines. Significant amount of genetic and antigenic data on zoonotic AI was shared with WHO at the February 2019 vaccine composition meeting in Beijing, China. Animal health laboratories in 25 countries representing Africa, Asia, the Americas and Europe contributed sequence data for 94 H5, H7 and H9 and antigenic data for selected AI viruses.

The Australian Animal Health Laboratory in Geelong is coordinating the next round (2019) of the OFFLU proficiency test exercise among the ten OIE-FAO Reference Centres and one WHO Collaborating Centre. Several OFFLU experts participated in an OIE *ad hoc* Group meeting in June 2019 to advise on a proposed revision to the chapter on avian influenza in the *Terrestrial Animal Health Code*. The OFFLU Secretariat held teleconferences among OIE and FAO Reference Centres and national laboratories to share updated situation reports and research data regarding avian influenza outbreaks in wildlife/wild birds.

10.2. Sustainable Laboratory Biosafety and Biosecurity initiative

With the 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 will analyse PVS¹⁰ 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. Informed by these projects, the OIE will expand the PVS Sustainable Laboratories toolbox for new users and new uses, support Laboratory Twinning Projects, and convene an Open Innovation Consortium. The Biological Standards Commission considers this area of work to be of critical need to Members and therefore will advise on guidelines or additional standards to be developed as a result of the project, specifically on meeting minimum facilities and equipment requirements for veterinary diagnostic laboratory facilities. The *ad hoc* Group on Sustainable Laboratories will be convened in October 2019 will be able to advise the Biological Standards Commission on these topics.

¹⁰ PVS: Performance of Veterinary Services

10.3. Update on VICH¹¹ activities

The Commission was updated on the 37th VICH Steering Committee, 11th VICH Outreach Forum and 6th VICH Public Conference entitled *Unlocking Africa's Potential*, which took place from 23 February to 1 March 2019 in Cape Town, South Africa. There are two draft concept papers that might be of interest to the Commission, which will be circulated after their adoption: *Guideline for Safety Evaluation of Biotechnology-derived/Biological products* and *Harmonizing VICH guideline on Test on the Presence of Extraneous Viruses in veterinary viral vaccines*.

In the framework of the public–private partnership with HealthforAnimals, a manual was prepared on how to set up a basic pharmacovigilance system (i.e. minimum requirements). It was presented during the 6th Cycle OIE Focal Points Training Seminar for Veterinary Products in Addis Abba (Ethiopia, 9-11 July 2019) in combination with the existing VICH Guidelines as a model concerning pharmacovigilance. The aim is to expand it for each Region to introduce pharmacovigilance with the collaboration of the OIE Focal Points and OIE Collaborating Centres.

10.4. Update on rinderpest

During the 87th OIE General Session, two new Rinderpest Holding Facilities (RHF) were designated in categories A and B, and all the five RHF that had been designated in 2015 had their mandates extended for another 3-year period. At present, there are RHF in China (People's Rep. of), Ethiopia, France, Japan, United Kingdom and United States of America. The Sequence and Destroy project has reached its conclusion at The Pirbright Institute, where more than 3000 samples of rinderpest virus (RPV) were destroyed in June 2019. CIRAD¹² will follow from September 2019 onwards. Publications on the project's findings are expected in the future. Two RHF applications are still pending without advances in sight. The network of RHF will have its second meeting from 14 to 15 November 2019, in Tokyo, Japan. The OIE and FAO took advantage of this opportunity to also invite representatives from countries holding RPV-containing materials outside of RHF. As per the 2018 annual survey on RP, presented in May at the 87th OIE General Session, RPV-containing material are held outside of RHF in eight countries. This shows great progress since the declaration of eradication (more than 40 countries) and since the beginning of the survey, in 2013 (35 countries). The FAO-OIE Rinderpest Joint Advisory Committee (JAC) has been consulted in between meetings to advise on the approval of a number of research applications using RPV submitted by RHF. The next meeting of the JAC will take place in Paris in March 2020.

10.5. PPR vaccine: SOP for thermotolerance test

The Commission received a report on the work of the PPR GEP¹³ to develop a draft testing protocol titled "Recommended procedure for PPR vaccine thermotolerance test as part of the PPR GEP", which was prepared by the AU-PANVAC¹⁴. The Commission acknowledged that this protocol would be a very useful reference that could be cited in the *Terrestrial Manual* chapter once it has been made available, preferably through publication in a peer-reviewed scientific journal.

10.6 Working Group on Wildlife: compilation of references to diagnostic methods

The Commission was informed on the work of the Working Group on Wildlife regarding the development of a compilation of references to diagnostic methods appropriate for each pathogen on the non-listed wildlife pathogen and disease list. The Commission welcomed this initiative and proposed to review the document once finalised.

¹¹ VICH: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products

¹² CIRAD: Centre de coopération internationale en recherche agronomique pour le développement

¹³ PPR GEP: Peste des Petits Ruminants Global Eradication Program

¹⁴ AU-PANVAC: African Union Pan African Veterinary Vaccine Centre

10.7 A Guide to Training and Information Resources on the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences

The Commission noted the Guide.

11. Any Other Business

11.1. Work plan

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

11.2. Dates of the next Biological Standards Commission meeting

The Commission noted the dates for its next meeting: 11–14 February 2020.

.../Annexes

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 17–20 September 2019

Agenda

1. Welcome

2. Adoption of Agenda

- 2.1. Developing a process for designating agenda items to members of the Commission

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

- 3.1. Update from General Session: questions on African swine fever, equine encephalomyelitis (Eastern, Western and Venezuelan) and equine influenza
- 3.2. Request to delete from the *Terrestrial Manual* recommendations for conducting abnormal toxicity test (ATT) and target animal batch safety test (TABST) for veterinary vaccines
- 3.3. Vaccine section of the chapter on peste des petits ruminants: target animal batch safety tests
- 3.4. Review of Member comments on February 2019 report
- 3.5. Revisiting the recommendation to keep the mallein test in the chapter on glanders
- 3.6. Review of draft chapters received and their endorsement for circulation for first-round Member comment
- 3.7. Review of *Terrestrial Manual* status: selection of chapters for update in 2020/2021 review cycle
- 3.8. Update from September 2018 meeting: review of a validation dossier for a quantitative real-time PCR method for detection of *Taylorella equigenitalis* directly from swabs: **POSTPONED**

4. OIE Reference Centres

- 4.1. Applications for OIE Reference Centre status
- 4.2. Changes of experts at OIE Reference Centres
- 4.3. Review of new and pending applications for laboratory twinning (four projects)
Reference Laboratories – Implementation of the SOPs
- 4.4. Follow-up of in-depth review of all annual reports for activities in 2018 based on the performance criteria to identify any that are not complying
Collaborating Centres – Implementation of the SOPs
- 4.5. Follow-up of in-depth review of all annual reports for activities in 2018 based on the performance criteria to identify any that are not complying
- 4.6. Update on the mapping exercise for the existing Centres against the list of main focus areas and specialties and discussion on the next steps
- 4.7. Review of the template for the 5-year work plan
Reference Centre networks
- 4.8. Update on progress and review of ToRs for the three identified Reference Laboratory networks
- 4.9. Review of the existing guidance to see if it can form the basis for an SOP

5. Ad hoc Groups

Update on activities of ad hoc Groups

- 5.1. Ad hoc Group to finalise the International Standard Bovine Tuberculin (ISBT) replacement project, and revise *Terrestrial Manual* chapter 3.4.6 Bovine tuberculosis: 5–7 November 2019
- 5.2. Ad hoc Group on High Throughput Sequencing and Bioinformatics and Computational Genomics (HTS-BCG)

6. International Standardisation/Harmonisation

- 6.1. OIE Register of diagnostic kits
 - 6.1.1. Review of the registration procedure
 - 6.1.2. Update and review of new applications or renewed applications
- 6.2. Standardisation programme
 - 6.2.1. Update on project to extend the list of OIE approved reference reagents
 - 6.2.2. Updating the three existing guidelines to 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
- 6.3. OIE Biobank project
 - 6.3.1. Kick off meeting for the OIE biobank project, 15–17 October 2019

7. Follow-up from the General Session

- 7.1. Excerpt from the Final Report: Comments from Delegates (see also items 3.1, and 9.2.1)

8. Conferences, Workshops, Meetings

Past Conferences, Workshops, Meetings

- 8.1. 19th WAVLD Symposium, 19–22 June 2019, Chiang Mai, Thailand: 1-day OIE Seminar (Friday 21 June)

Future Conferences, Workshops, Meetings

- 8.2. Third International Symposium on Alternatives to Antibiotics, Bangkok, Thailand, 16–18 December 2019

9. Liaison with other Commissions

- 9.1. Horizontal issues among the Specialist Commissions
 - 9.1.1. SOP for listing/delisting disease in coordination: role of BSC in evaluating listing criteria 3 related to diagnostics
 - 9.1.2. Definitions of Competent Authority, Veterinary Authority and Veterinary Services in OIE Standards
- 9.2. Scientific Commission for Animal Diseases
 - 9.2.1. Question regarding carrier status of animals following infection with African swine fever
 - 9.2.2. Question from the *ad hoc* Group on bovine spongiform encephalopathy (BSE) risk assessment and surveillance
 - 9.2.3. Developing case definitions: input from OIE Reference Laboratories
- 9.3. Terrestrial Animal Health Standards Commission
 - 9.3.1. Questions on the equine influenza chapter
 - 9.3.2. Questions on the avian influenza chapter
 - 9.3.3. OIE Standards on semen
- 9.4. Aquatic Animal Health Standards Commission

10. Matters of Interest for Consideration or Information

- 10.1. Update on OFFLU
- 10.2. Sustainable Laboratory Biosafety and Biosecurity initiative
- 10.3. Update on VICH activities
- 10.4. Update on rinderpest
- 10.5. PPR vaccine: SOP for thermotolerance test
- 10.6. Working Group on Wildlife: compilation of references to diagnostic methods
- 10.7. A Guide to Training and Information Resources on the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences

11 Any Other Business

- 10.1. Work plan
- 10.2. Dates of the next Biological Standards Commission meeting: 11–14 February 2020

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION
Paris, 17–20 September 2019

List of participants

MEMBERS

Prof. Emmanuel Couacy-Hymann

(President)

Professor of Virology, Central
Laboratory for Animal Diseases
(LANADA/CLAD)
BP 206 Bingerville
CÔTE D'IVOIRE
Tel.: (225-22) 403.136 / 403.138
chymann@hotmail.com
chymann@gmail.com

Prof. Ann Cullinane

(Member)

Head of the Virology Unit
Irish Equine Centre
Johnstown
Naas
Co. Kildare
IRELAND
Tel.: (353-45) 86.62.66
ACullinane@irishequinecentre.ie

Dr Franck Berthe

(Vice-President)

Senior Livestock Specialist, Food and
Agriculture Global Practice, World
Bank, 1818 H Street NW, Washington,
DC 20433
UNITED STATES OF AMERICA
Tel.: (1-202) 458.76.85
fberthe1@worldbank.org

Dra. Ana Maria Nicola

(Member)

Head, Brucellosis Department
(OIE/FAO Laboratory/Reference
Center), General Directorate of
Laboratories and Technical Control,
National Service of Agri-Food Health
and Quality (SENASA), Talcahuano
1660, CP1640 Martínez, Buenos Aires
ARGENTINA
Tel.: (54-11) 48 74 67 31
(Ext.: 26.31 or 27.30)
anicola@senasa.gob.ar
nicolaana@hotmail.com

Dr John Pasick

(Vice-President)

Formerly Canadian Food Inspection
Agency, National Centre for Foreign
Animal Disease, 1015 Arlington Street
Winnipeg, Manitoba R3E 3M4
CANADA
Tel.: (1-519) 738.45.11
jmpasic55@gmail.com

Dr Joseph S. O'Keefe

(Member)

Ministry for Primary Industries,
P.O. Box 40-742
Upper Hutt, 5140
NEW ZEALAND
Tel.: (64) 894.56.05
Joseph.O'Keefe@mpi.govt.nz
okeefej@mpi.govt.nz

CONSULTANT EDITOR OF THE TERRESTRIAL MANUAL

Prof. Steven Edwards

c/o OIE 12 rue de Prony
75017 Paris
FRANCE
Tel.: (33-1) 44.15.18.88
steve-oie@cabanais.waitrose.com

OIE HEADQUARTERS

Dr Elisabeth Erlacher-Vindel

Head, OIE Antimicrobial Resistance
and Veterinary Products Department
(AMRVPD)
e.erlacher-vindel@oie.int

Ms Sara Linnane

Scientific Editor, OIE Science
Department
s.linnane@oie.int

Dr Gounalan Pavade

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

Dr Gregorio Torres

Head, OIE Science Department
g.torres@oie.int

OIE Procedure for Registration of Diagnostic Kits

Abstract sheet

Name of the diagnostic kit: VetMAX™ African Swine Fever Virus Detection Kit
Manufacturer: Thermo Fischer Scientific_ LSI S.A.S.

Disease: African Swine fever (ASF)

Pathogen Agent: ASF Virus P72 gene

Type of Assay: TaqMan® real-time PCR detection

Purpose of Assay: Fit for the purpose of detection of the African Swine Fever virus from blood, serum and tissues of pigs and wild pigs (including wild boars)

Species and Specimen: blood, serum and tissues of pigs and wild pigs (including wild boars)

1. Information on the kit

General information on the kit can be found on the Thermofischer website www.thermofischer.com

Tel: +33 (0)4.72.54.82.82

Fax: +33 (0)4.72.54.82.83

2. Summary of validation studies

Analytical characteristics

Repeatability: PCR Repeatability is evaluated on three sessions by the same technician with the same material. Assays are performed with DNA of a quantified plasmid pASFV, diluted in TE 1X buffer to obtain 3 concentrations level (high/medium/low). Each sample is tested in triplicate. Repeatability of VetMAX™ African Swine Fever Virus Detection Kit shows coefficients of variation (CV) between 0.89 % and 3.01 %.

Analytical specificity: 100%

The analytical specificity of the kit was evaluated comparing PCR systems used in the kit (primers and probes) to ASFV sequences, present in National Center for Biotechnology Information public databases.

PCR inclusivity was evaluated on a panel of DNA extracted from 58 ASFV positive samples (organs, sera) from Centro de Investigacion en Sanidad Animal - Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (CISA-INIA).

PCR exclusivity was evaluated on pathogens typically found in the same ecological niches, or phylogenetically close, or because they have the same clinical signs in the target species. VetMAX™ African Swine Fever Virus Detection Kit is specific for African Swine Fever Virus and does not detect other tested pathogens.

Analytical sensitivity: 100%.

The detection limit of the PCR (LDPCR) is the lowest concentration of target nucleic acid that will generate a positive result with a confidence of 95% (NF U47-600 standard). In order to determine the LDPCR experimentally, we should test, in terms of intra test (replica) and inter test (independent sessions), a range of target nucleic acid flanking the expected LDPCR value. The LDPCR was determined on a quantified plasmid pASFV to estimate the copy number of nucleic acids. Three individual dilution ranges were prepared by performing six 2-fold serial dilutions. The LDPCR is expected to fall within this range of dilutions.

The detection limit of VetMAX™ African Swine Fever Virus Detection Kit is 16 copies of nucleic acid per PCR.

From the results obtained throughout the analysis of experimental samples from animals with positive status, the CISA-INIA conclude that the VetMAX™ African Swine Fever Virus Detection Kit has appropriate analytical sensitivity and repeatability to give a confident ASF diagnosis based on the detection of ASFV genome.

Diagnostic Characteristics

Threshold Determination: The determination of the threshold consists of assigning a threshold cycle (C_t) value for each sample which depends on PCR design and thermal cycler used for the amplification. The threshold value is determined from the External Positive Control, in the middle of the exponential phase, in accordance with the NF U 47-600 standard:

Reaction type	ASFV Target (FAM™ dye)	IPC target (VIC™ dye)	Interpretation
Positive control	$C_t = C_{tQC} \text{ ASFV} \pm 3 C_t$	$C_t < 45$ or $C_t > 45$	PCR is validated
Extraction control	$C_t > 45$	$C_t = C_{tQC} \text{ IPC} \pm 3 C_t$	DNA extraction is validated
No - template control	$C_t > 45$	$C_t > 45$	PCR reagents are validated

IPC: Internal Positive Control

Interpretation of the Results

ASFV Target (FAM™ dye)	IPC target (VIC™ dye)	Interpretation
$C_t < 45$	$C_t < 45$ or $C_t > 45$	ASFV detected
$C_t > 45$	$C_t = C_t \text{ NEC} \pm 3 C_t$	ASFV not detected
$C_t > 45$	C_t is outside this range: $C_t \text{ NEC} \pm 3 C_t$	Invalid result

NEC: Negative Extraction Control

Diagnostic sensitivity (DSn) and specificity (DSp) estimates and 95% confidence intervals

VetMAX™ African Swine Fever Virus Detection Kit		Specimens
Diagnostic sensitivity	DSn = 100 %	51 tissue assays have been tested Se = 100% [93.02 – 100.0%]
Diagnostic specificity	DSp = 100%	1563 blood and serum assays have been tested Sp = 100% [99.76 – 100.0%] 63 tissue assays have been tested Sp = 100% [94.31 – 100.0%]

Comparative performance

The results obtained by CISA-INIA, in the analysis of the domestic pig and the European wild boar field samples obtained from ASFV genotype II infected animals in the Eastern European countries have been combined to provide an overall estimate of the performance of the kit for diagnosing ASF in field conditions. Out of the 424 samples, the number of positives using the UPL-PCR was 400 (94%) and 387 (91%) using the kit VetMAX™ African Swine Fever Virus Detection Kit.

Agreement and discrepancies

Concerning the studies performed by CISA-INIA:

- From the analysis of 404 field samples obtained from epidemic areas in eastern Europe, the kappa value was 0.87 indicating near perfect agreement between the UPL reference method and VetMAX™ African Swine Fever Virus Detection Kit.
- From the analysis of 16 EURL ASF Reference panel, there was perfect agreement between the UPL reference method and VetMAX™ African Swine Fever Virus Detection Kit.
- Among the UPL reference method and VetMAX™ African Swine Fever Virus Detection Kit there was perfect agreement in the analysis of 136 experimental blood samples tested, with Ct values lower than 30.
- From the analysis of tissue samples, the ASFV genome was detected by the UPL-PCR and by the VetMAX™ PCR kit in 100% of tested tissues showing a 100% agreement among both methods.

Reproducibility

The robustness has been evaluated by checking the ability of the PCR run to remain unaffected by variations in critical parameters of a PCR reaction:

Test 1: T°C of hybridization +/- 1°C

Test 2: Time of hybridization +/- 10 %

Test 3: Volume of PCR mix +/- 10 %

Test 4: Volume of DNA +/- 10 %

VetMAX™ African Swine Fever Virus Detection Kit successfully passed the robustness challenge.

The testing of a unique panel of 15 biological samples (11 positive and 4 negative samples; characterized with CISA-INIA method; panel of 15 reference samples, inactivated and lyophilized) by both Thermo Fischer laboratory and CISA-INIA Valdeolmos with VetMAX™ African Swine Fever Virus Detection kit provided the following results: the Ct values obtained for the 15 samples showed coefficients of variation (CV) between 2.75 and 7.20%.

The kit provided consistent qualitative results, and the results were not affected by environmental factors.

Applications

The VetMAX™ African Swine Fever Virus Detection Kit is used for diagnosis of African Swine fever virus (ASFV).

For Veterinary Use Only and for in Vitro Use Only.

References

Tignon M. *et al.* (2011). Development and inter-laboratory validation of an improved new real-time PCR assay with internal control for detection and laboratory diagnosis of African Swine Fever virus. *Journal of Virological Methods*, **178** (1-2): 161-170.

Gallardo C. *et al.* (2015). Assessment of African Swine Fever diagnostic techniques as a response to the epidemic outbreaks in Eastern European Union countries: How to improve surveillance and control programs. *Journal of Clinical Microbiology*, **53**(8): 2555-2565.

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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 first-round comment	October 2019
	2) Remind authors of the chapters identified previously for update but not yet received. Inform the BSC of the date authors were first asked for their contribution	On-going
Collaborating Centres	1) Implementation of the adopted SOPs:	
	a) finish mapping of existing Collaborating Centres to identify their main focus areas and specialties, and overlapping specialties based on the annual reports	September 2019
	b) write to Centres to inform of outcome of discussions and propose a way forward: status quo or form a consortium	October 2019
	c) review feedback from Centres. Where there is agreement, ask for a 5-year proposed activity plan. Where there are divergent views, continue the dialogue	September 2019
	2) Letters to under-performing Centres asking for explanation or plan to improve activities	October 2019
	3) Feedback of review of annual reports for the Aquatic Commission on Centres that cover aquatic animal health issues	February 2020
Reference Laboratories	1) Letters to under-performing Labs asking for explanation or plan to improve activities	October 2019
	2) Improving annual report template for rinderpest labs	February 2020
Reference Centres	1) Further update the existing guidance for networks	For February 2020
	2) Provide feedback to the three leading Reference Laboratories identified for ASF, PPR and rabies networks	October 2019
	3) Develop technical criteria for joining the network	February 2020
Standardisation/ Harmonisation	1) Project to extend the list of OIE approved reference reagents	On-going
	2) Update two of the existing guidelines, and include the template as an annex for the data to be submitted with a request for approval to be added to the list of approved reagents	For February 2020
	3) Project to develop Replacement International Standard Bovine Tuberculin:	On-going, for 2020
	a) Review final report	February 2020
Ad hoc Groups	1) Replacement of the International Standard Bovine Tuberculin	5-7 November 2019
	2) High Throughput Sequencing and Bioinformatics and Computational Genomics (HTS-BCG):	On hold awaiting funding
	3) Veterinary Biobanking	15-17 October 2019

Subject	Issue	Status and Action
Conferences, Workshops and Meetings with participation by BSC Members	1) Regional Seminars for OIE National Focal Points for Veterinary Laboratories	
	a) Americas: second cycle	Date TBD, Mexico/Panama
	2) OIE <i>ad hoc</i> Group on PVS Sustainable Laboratories Tool	8–10 October 2019, OIE HQ
	3) Think tank meeting on animal health data codification to develop a standardised harmonised internationally recognised animal health data code	5–7 November 2019, OIE HQ
Develop laboratory standards for emerging diseases	1) Discuss the <i>Terrestrial Code</i> chapter once adopted in May 2019 with the aim of introducing a corresponding chapter for the <i>Terrestrial Manual</i>	After May 2020

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