



REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 3–6 September 2018

The newly elected OIE Biological Standards Commission met at the OIE Headquarters from 3 to 6 September 2018. Dr Monique Eloit, Director General of the OIE, welcomed the Members of the Commission and congratulated them on their election or re-election: Prof. Emmanuel Couacy-Hymann, President, Dr Franck Berthe, First Vice-President, Dr John Pasick, Second Vice-President, and Prof. Ann Cullinane, Dr Ana Nicola and Dr Joseph. O'Keefe, members of the Commission. She wished them a successful mandate.

Dr Eloit drew the Commission's attention to the expectations of the OIE Member Countries regarding the working procedures of the Specialist Commissions: that they be transparent, efficient and that decisions should be science based. She committed to maintain good relations with the Biological Standards Commission to ensure that the priorities of the Commission's work plan correspond with those of the OIE.

1. Welcome and orientation

Noting that this was the first meeting of the newly elected Specialist Commissions it was agreed that the opening session of all Specialist Commission meetings would be dedicated to a half-day 'Induction session'. The purpose of these sessions, for new and previously elected members, was to start to get to know each other, to better understand how the work of each of the Commission's fits into the mission of the OIE and to clarify the roles of Commission members and OIE Secretariat and other staff. There was general agreement that this new initiative was very valuable for all concerned and will assist in ensuring the success of the work of each Commission. The OIE will continue to explore other novel ways of supporting the Commissions in their work.

2. Adoption of Agenda

The proposed agenda was presented and adopted.

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

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

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

3.1. Update from February 2018 meeting: review of a validation dossier for a quantitative real-time PCR¹ method for detection of *Taylorella equigenitalis* directly from swabs

This item was postponed to February 2019 to give the Reference Laboratory experts time to review the supplementary information submitted by the test developers.

3.2. Update from General Session – Chapter 2.5.11 Glanders and melioidosis

The Commission noted the comments made by the Delegate of Australia during the General Session on the chapter on glanders and melioidosis.

3.3. Review of a validation study of a serological diagnostic assay with high specificity and sensitivity for glanders in equids

The Commission reviewed the final report of a validation study that had been coordinated by one of the OIE Reference Laboratories for glanders. The study found that Western Blot and ELISA² had higher specificity than the CFT³, which is the test currently recommended in the *Terrestrial Manual* for “Individual animal freedom from infection prior to movement”. On the other hand, the sensitivity of the CFT was found to be higher than the two tests cited above. The Commission agreed that it would be of benefit to include a sentence and a reference to this study in the *Terrestrial Manual* chapter, to raise awareness of it among users of the *Manual*. However, given the relatively narrow geographical coverage of the isolates (positive samples) used in the study and the variation in the stages of development and availability of the tests used in the study, the Commission felt it was too early to include the tests in the *Terrestrial Manual* chapter. The OIE Reference Laboratories would be asked to review the chapter and amend it in light of the study’s conclusions.

In response to a question on guidance for additional research efforts, the Commission advised that any future studies should address the issue of geographical coverage of the isolates (positive samples) as this is very important in horse movement management.

3.4. Request to review the continued inclusion of the mallein test in the *Terrestrial Manual*

The International Horse Sports Confederation asked that the Commission consider the necessity of maintaining the mallein test in the *Terrestrial Manual* chapter on glanders. As alternative tests exist (e.g. PCR), the Commission agreed that it could no longer recommend use of the mallein test. The OIE Reference Laboratories, in their review of the chapter (see agenda item 3.3 above), would be asked to consider removing the test on animal welfare grounds unless they can submit rationale for keeping it.

3.5. Panaftosa/VPH-PAHO/WHO⁴ initiative – ELISA for glanders diagnosis

The Commission welcomed this South American initiative and will ask the OIE Reference Laboratories to take it into account in their review of the *Terrestrial Manual* chapter on glanders. The Commission also recommended that the OIE Reference Laboratory that undertook the validation study (see item 3.3 above), liaise with the group led by Panaftosa so that the data from this study could be included in the validation study. The Commission would also greatly encourage the Panaftosa group to make their samples available to the OIE Reference Laboratory.

¹ PCR: polymerase chain reaction

² ELISA: enzyme-linked immunosorbent assay

³ CFT: complement fixation test

⁴ Panaftosa: Pan American Foot-and-Mouth Disease Center/Veterinary Public Health, PanAmerican Health Organization/World Health Organization

3.6. Update from General Session – use of the Frenkel method in the manufacture of FMD⁵ vaccines

In May 2017, the proposal to delete text on the use of the bovine tongue epithelium method for vaccine production from the chapter on FMD was put on hold and the chapter was adopted with the text still included. In September 2017, the Commission further considered the method and, taking into account the necessity of following good manufacturing practices (GMP) in vaccine production, which requires that the purity of source materials be certified (i.e. FMD vaccine manufactures using epithelium cells must prove that the cells comply with the same quality control requirements as alternative source materials, e.g. cell lines), the fact that the use of epithelium cells could potentially lead to increased levels of non-structural proteins (NSP) in vaccinated animals, impairing FMD surveillance in a vaccinated population, and for animal welfare considerations, the Commission reaffirmed its opinion that the method cannot be recommended in an OIE Standards text. To assist the Member Country concerned to phase out this practice and introduce an alternative method, the Commission agreed to retain the text for 3 more years (until May 2020).

At the General Session in May 2018, the Member Country in question committed to submitting a file on its production method, which would prove the purity of the final product.

At this meeting, the Commission reviewed the file submitted and noted that according to the Member Country, the method meets the national criteria for quality. The method could therefore be retained in the *Terrestrial Manual*. However, the Commission continues to support the cautionary words in both the chapter on FMD: “Cattle tongue epithelium in surviving conditions in medium with salts but without products of biological origin, may be acceptable for vaccine production but only if the method of production is entirely compliant with the standard requirements referred to in chapter 1.1.8. Principles of veterinary vaccine production” and in Chapter 3.7.2. *Minimum requirements for the production and quality control of vaccines*: “The use of primary cells has an inherently higher risk of introducing extraneous agents compared with the use of cell lines and should be avoided where alternative methods of producing effective vaccines exist. Indeed, some control authorities only allow the use of primary cells in exceptional cases.” The Commission would therefore encourage the Member Country to consider phasing out the method in the next few years.

3.7. Comments from *ad hoc* Group on Evaluation of Member Country BSE⁶ Risk Status

The Commission noted the comments from the *ad hoc* Group and agreed to add the *Terrestrial Manual* chapter on BSE to the next review cycle (2019/2020).

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

The Commission reviewed 13 draft chapters and approved 12 for circulation, some subject to clarification of certain points by the experts, for first-round Member Country comment and eventual proposal for adoption by the Assembly in May 2019. The 12 chapters and a brief summary of the main amendments are:

- 2.1.5. Echinococcosis (infection with *Echinococcus granulosus* and with *E. multilocularis*): updated or deleted diagnostic methods, included a Table on the global distribution of *E. granulosus* (s.l) with associated genotypes found in different animal hosts
- 2.1.13. New World screwworm (*Cochliomyia hominivorax*) and Old World screwworm (*Chrysomya bezziana*): removed paragraphs on treatment and control

⁵ FMD: foot and mouth disease

⁶ BSE: bovine spongiform encephalopathy

- 2.5.1. African horse sickness (infection with African horse sickness virus): minor change to the blocking ELISA procedure (see also agenda item 3.10 below); included reference to clinical cases in dogs
- 2.5.3. Dourine (**NB: interim version:** included an *in-vitro* method for preparation of antigens for the CFT (method accepted by the Commission September 2017). **Interim version:** the Commission is aware that the classification of trypanosomes is currently under review and a further revision may be necessary in the near future.
- 2.5.5. Equine encephalomyelitis (Eastern, Western and Venezuelan) (**NB: merged version:** chapter merges two chapters: Eastern and Western with Venezuelan equine encephalomyelitis; includes updated diagnostic test methods
- 2.5.6. Equine infectious anaemia: text on inoculation of susceptible horses with suspect blood removed for animal welfare principles; references updated
- 2.5.7. Equine influenza (infection with equine influenza virus): inclusion of details, including primer sets and cycling parameters, for a real-time RT-PCR⁷ accepted by the Commission in February 2018
- 2.7.10. Peste des petits ruminants (infection with peste des petits ruminants virus): updated diagnostic methods in light of the global eradication programme
- 2.8.1. African swine fever (infection with African swine fever virus): extensive revision to the diagnostic tests section
- 2.8.3. Classical swine fever (infection with classical swine fever virus) (**NB: Vaccine Section only**): updated information on marker vaccines
- 2.9.7. Mange: minor updates to the diagnostic section
- 3.1. Laboratory methodologies for bacterial antimicrobial susceptibility testing: inclusion of a Table on phenotypic susceptibility testing methods available and their features

The chapters can be downloaded from the following address:

http://web.oie.int/downld/Terr_Manual/MAILING_OCT_2018.zip

Member Countries 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 **4 January 2019**.

The Commission noted the draft revision to Chapter 3.2. *Biotechnology in the diagnosis of infectious diseases*, but felt the chapter needed further work. An OIE Collaborating Centre that could take the lead on this task was identified.

3.9. Descriptions of test methods in the *Terrestrial Manual*: Commission's commitment to avoiding naming commercial products

The Commission reaffirmed its commitment to avoiding naming commercial products in the *Terrestrial Manual*, and agreed that the following text be added to the instructions for authors:

Use of Commercial Names in the OIE *Terrestrial Manual*

As an international standard-setting organisation, the OIE does not endorse or recommend chemical and biological reagents, diagnostic kits or vaccines, from specific commercial suppliers or manufacturers in OIE international standards. Methods given in the *Terrestrial Manual* should be generic in nature but scientifically accurate such that an individual laboratory can replicate the method using materials sourced from available suppliers. All diagnostic methods should have been validated in accordance with Chapter 1.1.6 *Principles and methods of validation of diagnostic assays for infectious diseases*, and where that validation relates to a

⁷ RT-PCR: reverse-transcriptase PCR

specific commercial kit or reagents, that should be stated (without naming the commercial product) with the explanatory note that modifications (e.g. in times or temperatures) may be required for other kits or reagents and should be validated locally before use. Where a peer-reviewed published paper is available for the validation of a commercial kit, the reference may be cited, again without naming the commercial product in the *Terrestrial Manual*. Similarly, the use of Registered or Trademarked proprietary names should be avoided.

Where appropriate, readers should be directed towards kits on the OIE Register (but allowing for the fact that Register listings may change), and should also be advised to consult OIE Reference Laboratories for advice on specific methods.

3.10. Review of a validation study of a serological diagnostic assay for AHS⁸

The Commission noted the validation study for a blocking ELISA that had been conducted by a consortium of partners led by an OIE Reference Laboratory for AHS. The study had led to some minor amendments to the description of the assay method given in the *Terrestrial Manual* chapter on AHS, which the Commission approved. The amended chapter will be included in the batch of chapters to be circulated for first-round Member Country comment.

3.11. Discussion on the *Terrestrial Manual* chapter review process and the role of the Commission in the review cycle

For this Agenda Item the Commission was joined by an external expert, Dr Moritz Klemm from the European Commission, in his capacity of former member of the Extended Bureau Group.

In February 2018, the Commission implemented its new procedure for handling comments from Member Countries and Experts on draft chapters for the *Terrestrial Manual*, aimed at further improving its transparency. The Commission examined the situation with the aim to identify possibilities for further progress.

The discussion began with a presentation of the current process and identification of potential weaknesses and constraints. Owing to the speed of scientific advancements, especially in the field of diagnostics, the *Terrestrial Manual* needs to be updated regularly and relatively quickly. A proposal to extend the length of the review cycle was considered and rejected because it could delay the publication of updates, potentially rendering them scientifically obsolete.

The Commission agreed to leave the review cycle unchanged for the present time, but resolved to increase their engagement in the updating process. To this end, the members were assigned chapters from the batch approved for circulation for first-round comment (see agenda item 3.8 above). In January 2019, the Consultant Editor would undertake an initial review of the Member Country comments separating those that are editorial from comments that require discussion. Each Commission member would be sent their assigned chapters, along with these comments and the traceability sheet (cf report of the meeting of the BSC, September 2017). At the February meeting, each Commission member will present to the Commission the chapters they were assigned along with the Member Country comments and their (the Commission member's) proposed amendments. The Commission will discuss and reach a consensus agreement on the highlighted issues, which the member will describe in the traceability sheet appended to the report. In this way, the Member Countries will have a report of the discussions and decisions. A link to the draft chapters will also be provided in the report, for ease of reference.

⁸ AHS: African horse sickness

4. OIE Reference Centres

4.1. Update on existing procedures for the establishment and maintenance of OIE Reference Centres

Before the Commission addressed this agenda item, a presentation was given to remind members of the existing procedures and update them on recent developments in the procedures for the establishment and maintenance of OIE Reference Centres (SOPs⁹).

4.2. Applications for OIE Reference Centre status

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

OIE Reference Laboratory for Equine infectious anaemia

Division for the Diagnosis of Viral Diseases and Leptospirosis, Istituto Zooprofilattico Sperimentale delle Regioni Lazio e Toscana (IZSLT), Via Appia Nuova 1411, 00178 Rome, ITALY
Tel.: (+390-6) 79.09.93.15
Email: teresa.scicluna@izslt.it ; Website: <http://www.izslt.it/>
Designated Reference Expert: Dr Maria Teresa Scicluna.

OIE Reference Laboratory for Glanders

Anses Maisons-Alfort, Animal Health Laboratory, Bacterial Zoonoses Unit, 14 rue Pierre et Marie Curie, 94701 Maisons-Alfort Cedex, FRANCE
Tel: +33 (0)-1 49.77.26.86
Email: karine.jaroucau@anses.fr
Designated Reference Expert: Karine Laroucau.

OIE Reference Laboratory for Rabies

National Reference Laboratory for Rabies, Institute for Diagnosis and Animal Health, Dr Nicolae Staicovici Street, No. 63, Sector 5, Bucharest 050557, ROMANIA
Tel.: (+40-374) 32.2.13
Email: office@ihad.ro ; Website: www.idah.ro
Designated Reference Expert: Dr Vlad Vuta.

OIE Collaborating Centre for Identification of animal pathogens of potential concern for global health and development of tools for their detection and characterisation

Institut Pasteur, 25–28 rue du Docteur Roux, 75724 Paris cedex 15, FRANCE
Tel: +33 (0)-1 45.68.80.00
Email: jean-claude.manuguerra@pasteur.fr ; Website: www.pasteur.fr
Contact Point: Jean-Claude Manuguerra.

Regarding this Collaborating Centre, the Commission was fully convinced of the excellent quality and high level scientific expertise of the applicants, which would be an invaluable asset to the OIE should the Collaborating Centre be adopted by the Assembly. Given the future steps in the implementation of the SOPs for Collaborating Centres (see agenda item 4.6 below), the Centre would be informed that it may eventually need to consider forming a consortium with other Centres in Europe having similar specialties in the future.

4.3. 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:

⁹ SOPs: Standard Operating Procedures for OIE Reference Laboratories: <http://www.oie.int/en/scientific-expertise/reference-laboratories/sops/> ; and for Collaborating Centres: <http://www.oie.int/en/scientific-expertise/collaborating-centres/sops/>

Highly pathogenic avian influenza and low pathogenic avian influenza (poultry),
Prof. Yoshihiro Sakoda to replace Prof. Hiroshi Kida at the Hokkaido University, JAPAN

Bovine spongiform encephalopathy
Dr Yoshifumi Iwamaru to replace Prof. Takashi Yokoyama at National Agricultural Research Organization, Prion Diseases Research Unit, National Institute of Animal Health, Ibaraki, JAPAN

Rinderpest
Dr Takehiro Kokuho to replace Dr Kazuo Yoshida at the National Reference Laboratory for Rinderpest, Exotic Disease Research Division, National Institute of Animal Health, Tokyo, JAPAN

Classical swine fever and Porcine reproductive and respiratory syndrome
Dr Katarzyna Podgórska to replace Prof. Zygmunt Pejsak at the National Veterinary Research Institute, Pulawy, POLAND

Trichinellosis
Dr Maria Angeles Gomez Morales to replace Dr Edoardo Pozio at the Istituto Superiore di Sanita, Rome, ITALY

Classical swine fever
Dr Helen Crooke to replace Prof. Trevor Drew at the Animal and Plant Health Agency, Weybridge, UNITED KINGDOM

Bovine viral diarrhoea
Dr Rebecca Strong to replace Prof. Trevor Drew at the Animal and Plant Health Agency, Weybridge, UNITED KINGDOM

4.4. Review of new and pending applications for laboratory twinning

Dr Gounalan Pavade from the OIE Programmes Department updated the Commission on the OIE Laboratory Twinning programme. As of September 2018, 47 projects have been completed, 31 projects are underway and 8 are awaiting funding before beginning.

Eight new twinning proposals were presented to the Commission for technical review.

- i) **Germany – Namibia** for rabies: the Commission supported the technical contents of this project and asked that the last objective be reworded to: “to initiate laboratory training through joint research projects to study rabies epidemiology and support rabies control in the country and in adjacent areas”.
- ii) **Germany – Cameroon** for viral haemorrhagic fevers (under EBO-SURSY project): the Commission supported the technical contents of this project and asked for confirmation that the two LANAVET laboratories mentioned in the proposal had adequate laboratory biosafety and biosecurity levels and human resources to manage the project activities. The Commission also requested that the work plan should clearly define the trainings and meetings allotted to each of the two laboratories and how both laboratories will contribute to achieving the objectives of the project.
- iii) **Belgium – Burundi** for FMD: the Commission recommended shortening the duration of the project by reducing the number of trainings and, where possible, scheduling the trainings at the candidate laboratory. The Commission asked for confirmation that the candidate laboratory experts involved in the project are permanent staff to ensure sustainability and success of the project.
- iv) **France – Turkey** for Q fever: the Commission observed there are no preliminary data available to support the presence of Q fever in Turkey though the project’s aim is to establish the epidemiological situation of the disease in Turkey. The Commission commented that the aim of the proposal does not fall within the scope of laboratory twinning projects.

- v) *United Kingdom – India* for infectious bovine rhinotracheitis (IBR): the Commission supported the project’s technical work plan to further strengthen IBR diagnosis in India through this collaboration.
- vi) *United Kingdom – PANVAC¹⁰* for establishing capacity for independent evaluation of FMD vaccines in Africa: the Commission approved the project’s objective and work plan and recommended that PANVAC should devote separate biocontainment facilities necessary to handle this work.
- vii) *United States of America – Thailand* for developing diagnostic and surveillance capacity for wildlife: the Commission commented that the project proposal misses baseline information about wildlife-associated disease risks to domestic animal and public health in Thailand and the region. The diagnostic techniques and technical expertise for capacity building mentioned in the proposal were very generic. The technical proposal does not provide a detailed plan for sample collection from wildlife and how samples will be used for wildlife disease surveillance.
- viii) *France – Senegal* for Rift Valley fever (under EBO-SURSY project): the Commission supported the objectives and the technical work plan of the project.

- **Reference Laboratories**

4.5. Follow-up February 2018 meeting: analysis of the annual reports of Reference Laboratory activities in 2017

In February 2018, the Commission began the process of implementing the *Procedures for designation of OIE Reference Laboratories* (the SOPs) by evaluating the reports against the performance criteria, in particular against the second criterion: accreditation to ISO 17025 or equivalent quality management system (QMS). As a result of this analysis, 17 OIE Reference Laboratories for diseases of terrestrial animals had been suspended by Resolution at the General Session in May 2018 with the possibility of being reinstated within 2 years should they achieve accreditation in that time.

To further evaluate the performance of the OIE Reference Laboratories, the Commission determined that whereas it is important to identify underperforming laboratories, it is equally important to identify and encourage laboratories that are performing well, engaging with other laboratories and providing their expertise and services to the OIE and its Member Countries.

To this end, the Commission identified six questions¹¹ from the annual Reference Laboratory report template that they believe are good indicators of the international activities and commitment of laboratories to work on behalf of the OIE. The members agreed to divide the annual reports for 2017 amongst themselves and to analyse the answers to these six questions. This task would provide an overall picture of the engagement of the OIE Reference Laboratory network, identifying strengths and weaknesses. The exercise should reveal suitable candidates (leaders) who could be asked to consider leading the establishment of a network (see item 4.7 below). It could also lead to re-wording of some of the questions in the template, or to the provision of more explanatory notes should it seem that the questions are misinterpreted by the experts.

The analysis would be reviewed at the next meeting in February 2019.

¹⁰ PANVAC: Pan African Veterinary Vaccine Centre of the African Union

¹¹ The six questions are:

- 9. Did your laboratory provide expert advice in technical consultancies on the request of an OIE Member Country?
- 18. Did your laboratory organise scientific meetings on behalf of the OIE?
- 19. Did your laboratory participate in scientific meetings on behalf of the OIE?
- 20. Did your laboratory exchange information with other OIE Reference Laboratories designated for the same pathogen or disease?
- 22. Did your laboratory collaborate with other OIE Reference Laboratories for the same disease on scientific research projects for the diagnosis or control of the pathogen of interest?
- 24. Did your laboratory place expert consultants at the disposal of the OIE?

- **Collaborating Centres**

4.6. Defining steps for the implementation of the new procedures for designation of OIE Collaborating Centres: examining the list of existing Centres against the list of main focus areas and specialties

In May 2018, the *Procedures for designation of OIE Collaborating Centres* (the SOPs) were adopted by Resolution of the Assembly and made available online (see [9 au-dessus](#)). The Commission next needs to define the steps to be followed for the implementation of these new procedures, along with a timeline for completion of each stage, bearing in mind that this implementation phase should be flexible.

The first step would be to write to all the existing OIE Collaborating Centres to officially inform them of the adopted SOPs and of the Commission's intention to identify their core activities within the list of main focus areas and specialties (available online¹²) and of communicating their proposal to the Centres in the future. Some Centres will retain their designation unchanged, some may need to redefine their focus, and some will need to form consortia with Centres having the same specialty in the same region.

An external consultant had reviewed the annual reports of the Collaborating Centres' activities in 2017 and had identified their activities in relation to the list of main focus areas and specialties. The Commission determined that the external consultant should continue this analysis and mapping exercise by proposing into which focus areas and specialties the existing Collaborating Centres fall. This draft proposal would be prepared for the Commission for discussion at the next meeting in February 2019.

Following the February 2019 meeting, the proposed designation or re-designation (according to the 'map' analysis) would be sent to each Collaborating Centre for consideration and feedback for the September 2019 meeting.

At the September 2019 meeting, the Commission would review the responses received from the Centres. Three possibilities are envisaged:

- i) Centres for which there will be no or only a slight change of title and discipline: these Centres will be requested to submit, for review at the February 2020 meeting, a proposal for their activities for the forthcoming 5 years.
- ii) Centres for which there is evidence of overlapping activities with other Centres in the same region: these Centres will be requested to consider how they can come together to operate as consortia, for example by signing MoU¹³ or other such arrangement, that define the respective responsibilities of the entities and the operating procedures. In some cases, one existing Centre may qualify to form more than one consortium when its current activities cover more than one specialty. Whilst discussions are taking place on the formation of consortia, partners would also need to consider what activities they would propose to undertake in the forthcoming 5 years.
- iii) Centres for which the core activities do not easily fit into the identified specialties: these Centres will be asked to provide more information to assist the Commission in finding where best to assign them. Some Centres may choose to modify their specialty.

At the February 2020 meeting, the Commission will:

- i) Review and endorse the proposals for activities for the forthcoming 5 years submitted by the Centres that fall into the first group.
- ii) Review and endorse the proposals for consortia from those Centres that fall into the second group; candidates will be asked to submit proposals for their activities for the forthcoming 5 years.

¹² http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/A_List_of_focus_areas_and_specialties_for_OIE_Collaborating_Centers.pdf

¹³ MoU: Memorandum of Understanding

- iii) Review the supplemental information requested of Centres that fall into the third group. Those that can be assigned to a focus area and specialty, will be asked to submit proposals for their activities for the forthcoming 5 years. In accordance with the adopted SOPs, the Commission may consider proposing delisting of a Collaborating Centre if the need for the specific topic activities is no longer required.

At the September 2020 meeting, the Commission will review any remaining proposals for consortia and activities for the forthcoming 5 years.

The OIE Council and Regional Commissions will be involved in all stages of this process, and the Assembly will be updated annually at the General Session of all progress made throughout this process of implementation of the SOPs.

- **Reference Centres**

- 4.7. **Development of procedures for the establishment and maintenance of OIE Reference Centre networks**

Following the adoption of the procedures for approval and maintenance of Reference Laboratory status and of Collaborating Centre status, the Commission turned its attention to the development of procedures for functioning networks among OIE Reference Centres.

Given the discussion and proposal on how to implement the SOPs for Collaborating Centres (see item 4.6 above), which would naturally lead to the establishment of networks in the form of consortia in the coming years, the Commission agreed to first consider Reference Laboratory networks.

The OIE currently has a small number of Reference Laboratory networks (FMD, OFFLU, bluetongue and non-tsetse transmitted animal trypanosomoses), each operating according to its own model, and *Guidance for the Management of OIE Reference Centre Networks* (<http://www.oie.int/en/scientific-expertise/reference-laboratories/reference-centre-networks/>), which were drafted with the purpose of allowing flexibility rather than constraining potential interested applicants.

The main object for the OIE and the Commission in establishing networks is to attract experts from beyond the OIE Reference Laboratory network: experts from national reference laboratories, experts from laboratories in low- and middle-income countries, experts who are or were involved in the OIE Twinning Programme and experts who are knowledgeable on a disease but are not necessarily working in a laboratory, etc. To succeed in establishing such networks, the Commission agreed that it is important to identify those OIE Reference Laboratories that would be motivated to take the lead, along with initial objectives and tasks.

To progress this project, the members of the Commission agreed to identify, when undertaking the analysis of those questions in the annual report template that reveal international activities undertaken on behalf of the OIE (see item 4.5 above) suitable candidates (leaders) and partner Reference Laboratories who could be asked to consider establishing a network and at the same time to propose initial priority issues for the network to address. The list would be reviewed at the February 2019 Commission meeting, after which these leaders and partners could be approached. The OIE could provide an IT platform for exchange of information, which is an essential aspect of a functioning network.

Once candidate networks on issues have been identified, the Commission would focus on elaborating the current guidance into SOPs for eventual proposal for adoption by the Assembly.

5. *Ad hoc* Groups

- **Update on activities of past *ad hoc* Group meetings**

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

Dr Glen Gifford from the Science and New Technologies Department of the OIE updated the Commission on the ongoing OIE project to replace the OIE's International Standard Bovine Tuberculin (ISBT).

An OIE *ad hoc* Group of bovine tuberculosis (bTB) experts is coordinating a project to develop and evaluate a replacement for the OIE's ISBT. The ISBT is used as a reference standard for quality control tests for purified protein derivative (PPD) bovine tuberculins that are used in bTB surveillance, diagnosis, and export certification. The current reference standard was produced in 1986 and stocks are becoming depleted.

In the studies, two candidate tuberculins will be tested in guinea-pigs and cattle, in comparison with the current ISBT, to evaluate and calibrate the candidate tuberculins' potency and specificity, as well as their overall 'fitness for purpose'. A preliminary evaluation (PE) in guinea-pigs has now been completed with satisfactory results, and a larger international collaborative study that is scheduled for September 2018 to June 2019 where the performance of the two candidate tuberculins will be further assessed in guinea-pigs as well as experimentally infected cattle and naturally sensitised 'reactor' cattle to further evaluate 'fitness for purpose'.

When the tests are completed, provided the data are satisfactory, the *ad hoc* Group will prepare a summary report and submit it for approvals/endorsement through the OIE governance processes including adoption by Member Country Delegates at the OIE General Session, and a report will be submitted for publication in a peer-review journal. The NIBSC¹⁴ could then begin distributing the new ISBT.

5.2. *Ad hoc* Group on Veterinary Biobanking

Dr Antonino Caminiti from the Science and New Technologies Department of the OIE updated the Commission on the progress that had been made with the project to develop an OIE Virtual Biobank. He informed the Commission that the Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia (Brescia, Italy), OIE Collaborating Centre for Veterinary Biologicals Biobank, is currently drafting the project plan for the development of the system in collaboration with the OIE. The project plan will include, among other things, the budget and the timeframe. Once finalised, the project plan will be shared with the Commission, which represents the project's Internal Advisory Board according to the project governance scheme. One of the Commission's members will be invited to the first meeting of the project's Steering Committee as a representative of the Internal Advisory Board

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

Dr Caminiti updated the Commission on the progress that had been made with the project to develop an OIE Pathogen Genomic Platform. Funding applications had not been successful so far and new funding sources were being considered to advance the project. Nevertheless, the Commission supported the idea of a web-based system for the collection of genetic sequences of pathogens to be combined with the information gathered from OIE Member Countries through WAHIS¹⁵. The Commission also supported the inclusion of national reference laboratories among potential sequence providers in addition to the OIE's Network of Reference Laboratories. The Commission encouraged the OIE to continue searching for new funding opportunities.

¹⁴ NIBSC: National Institute for Biological Standards and Control (United Kingdom)

¹⁵ WAHIS: World Animal Health Information System

6. International Standardisation/Harmonisation

- **Diagnostic tests**

6.1. OIE Register of diagnostic kits

6.1.1. Update and review of applications

Dr François Diaz from the Science and New Technologies Department of the OIE presented the SOPs for the OIE Procedure for Registration of Diagnostic Kits to the newly elected Commission.

Dr Maria Szabo from the Science and New Technologies Department of the OIE updated the Commission on the status of the applications under current review.

6.2. Standardisation programme

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

Dr Caminiti updated the Commission on the progress that had been made with the project to extend the list of OIE-approved reference reagents.

The Commission was presented with the results of the proficiency test conducted on candidate reagents for trichinellosis for inclusion in the list of OIE-approved International Standards, which were submitted by the OIE Reference Laboratory for trichinellosis in Italy. One member of the Commission was designated to review and evaluate the results of the proficiency test in combination with the datasheet previously submitted by the OIE Reference Laboratory. The analysis would be presented to the Commission at the next meeting in February 2019.

6.2.2. Serum products: re-review of ESPA¹⁶ proposal to develop international trade standards for animal serum products used in culture media

At the previous meeting in February 2018, the Commission had received a request from the ESPA that the OIE develop international trade standards for a specific category of serum products, namely the “animal serum products used in culture media”. At that meeting, the Commission considered that OIE *Terrestrial Manual* Chapter 1.1.9. *Tests for sterility and freedom from contamination of biological materials intended for veterinary use* already took into account the concerns raised by the association, and that the specific issues related to traceability of serum products could be addressed in the next update of the chapter instead of creating a new chapter.

Since February, the ESPA sent further communications to the OIE, with the same request, backed with a completed study undertaken by the United States (of America) Department of Agriculture entitled “*Assessment of the Risk to U.S. Livestock Health through the Importation of Bovine Serum Products into the United States (2017)*”.

The Commission reviewed the letters and risk analysis, and found no new evidence for changing their conclusion: that the *Terrestrial Manual* Chapter 1.1.9 satisfactorily covered the concerns raised, and specific issues related to traceability of serum products could be addressed in the next update of the chapter.

¹⁶ ESPA: European Serum Product Association

7. Resolutions for 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 3.2, 3.3 and 3.5).

8. Conferences, Workshops, Meetings

- **Future Conferences, Workshops, Meetings**

8.1. Update on laboratory focal points and engagement from the Commission members

Ms Jennifer Lasley from the OIE Programmes Department presented an update from the second cycle of regional seminars of the National Focal Point Programme for Veterinary Laboratories. The seminars in the second cycle are composed of four main topics – transport of specimens, biological risk analysis, quality management, and systems-based approach to laboratory networking – and the theme of the seminar is “Towards a culture of safety and quality”. Members of the Commission were requested to attend the regional seminars planned in 2018 and 2019.

8.2. 19th WAVLD¹⁷ Symposium, 19–22 June 2019, Chiang Mai, Thailand: 1-day OIE Seminar (Friday 21 June) theme, programme, speakers

The Commission proposed that the 1-day OIE Seminar that would be held during the 19th WAVLD Symposium could be divided into two parts: the morning session on quality management systems provisionally entitled *The Cost of Quality* and the afternoon session on *Biobanking and Reference Materials*.

The Commission developed a preliminary programme for the OIE Seminar, which would be further refined before the February meeting. Proposed speakers would need to be identified and contacted.

8.3. 7th meeting of the International Expert Group of Biosafety and Biosecurity Regulators in Ottawa, Canada 18–20 September 2018

Ms Lasley informed the Commission about Dr Ana Maria Nicola’s planned attendance at and presentation to the International Expert Group of Biosafety and Biosecurity Regulators, to be held in Ottawa, Canada 18–20 September 2018. Dr Nicola will present the updated standards for veterinary laboratories and the OIE tool for the evaluation of performance of veterinary services (including laboratory critical competencies and the PVS¹⁸ Sustainable Laboratories Tool).

9. Liaison with other Commissions

9.1. Horizontal issues among the Specialist Commissions

9.1.1. Request to propose a definition of “new strain” for the purpose of disease notification

The OIE World Animal Health Information and Analysis Department had identified the need for a definition of the term “new strain” to clarify Member Country obligations to report immediate disease events in accordance with the relevant Articles of chapter 1.1 of the OIE Codes.

The Biological Standards Commission advised that a new strain would relate to a phenotypic change corresponding to a genotypic change that can be diagnosed consistently. The Commission noted that the definition of new strain is somewhat addressed by the current definition of emerging disease provided by the *Terrestrial and Aquatic Codes*.

¹⁷ WAVLD: World Association of Veterinary Laboratory Diagnosticians

¹⁸ PVS: Performance of Veterinary Services

9.2. Scientific Commission for Animal Diseases

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

None at this meeting.

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. Feedback from agenda item 6.2.2

The Commission continued to be of the view that international trade standards for animal serum products used in culture media are not necessary and that existing standards in the *Terrestrial Manual* satisfactorily covered the concerns raised (see agenda item 6.2.2).

9.3.2. Questions from *ad hoc* Group on Avian Influenza

The *ad hoc* Group on Avian Influenza questioned the necessity of including in the *Terrestrial Code* chapter diagrams on the use and interpretation of diagnostic tests in surveillance (Article 10.4.33.) and proposed that they be moved to the *Terrestrial Manual*. The Commission reiterated¹⁹ its view that schematic representations of the application of laboratory tests for determining evidence of infection for various purposes **should** remain in certain disease-specific chapters of the *Terrestrial Code*. Generic terms **should** be used to designate the tests in these flowcharts, e.g. “serological test” rather than “ELISA”. In this way the focus of the *Terrestrial Manual* would remain as a standard on how to perform the tests described.

9.4. Aquatic Animal Health Standards Commission

None at this meeting.

10. Matters of Interest for Information

10.1. Update on OFFLU²⁰

Dr Pavade provided an update on the OFFLU activities. The Commission was briefed about the mission and objectives of the network and how it functions. Since it was established in 2005, OFFLU experts have shared and offered technical advice, training and veterinary expertise to Member Countries to assist in the prevention, diagnosis, surveillance and control of avian, swine and equine influenza. The experts have exchanged scientific data and biological materials (including virus strains) within the network, analysed molecular data, and shared such information with the wider scientific community. One of the main objectives of OFFLU is to collaborate with WHO on issues relating to the animal–human interface, including pandemic preparedness for early preparation of human vaccine. A significant amount of genetic and antigenic data on zoonotic avian influenza was shared with WHO at the February 2018 vaccine composition meetings. Animal health laboratories in 25 countries representing Africa, Asia, the Americas and Europe contributed sequence data for 168 H5, H7 and H9 and antigenic data for recent H5N1, H5N2, H5N6 and H5N8 viruses. In April 2018, OFFLU organised a technical meeting in Brighton, United Kingdom, in conjunction with the 10th International Symposium on Avian Influenza and 4th International symposium on neglected influenza viruses. More than 100 animal influenza experts participated in this meeting and exchanged research ideas. The experts were divided into separate technical working groups as avian, swine, equine and wildlife group,

¹⁹ See report of the meeting of the Biological Standards Commission, February 2016

²⁰ OFFLU: Joint OIE-FAO Network of Expertise on Animal Influenza

and each group finalised a 1- and 3-year work plan for the coming years. The Australian Animal Health Laboratory in Geelong is coordinating the next round (2018) 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 2018 to advise on a proposed revision to the chapter on avian influenza in the *Terrestrial Animal Health Code*. The OFFLU Secretariat held regular teleconferences among OIE and FAO Reference Centres and national laboratories to share updated situation reports and research data regarding avian influenza outbreaks.

10.2. Update on MERS-CoV²¹

Following approval of the proposal to convene an OIE *ad hoc* Group on MERS-CoV charged, among other tasks, to draft a *Terrestrial Manual* chapter, Dr Pavade requested that the Commission nominate a member to attend the meeting. The dates have yet to be finalised.

10.3. Follow up from the Consultation on Sustainable Biosafety and Biosecurity in Laboratories (1–2 March 2018)

Ms Lasley presented the report of the OIE Consultation on Sustainable Laboratory Biosafety and Biosecurity. In the framework of the Laboratory Focal Point seminars, Member Countries have stated that more technical assistance from the OIE in the implementation of the OIE standards is needed, especially for those Member Countries for which laboratory accreditation is not a mid- or long-term goal. The need of Member Countries remains, although the *ad hoc* Group was cancelled for unforeseen circumstances last September. The Commission recommended that the *ad hoc* Group be rescheduled and stated that such a tool for QMS implementation will allow all OIE Member Countries to better understand what is expected in the OIE Standards and to work continually towards quality management in their everyday work.

10.4. Veterinary para-professionals

Ms Lasley provided an update of the OIE's work on veterinary paraprofessionals (VPPs). She informed the Commission that pursuant to the plan to develop guidance for competencies and curricular requirements, the *ad hoc* Group developed a working draft of core curricula, and the OIE *Competency Guidelines for Veterinary Paraprofessionals* was published and presented to Members at the 86th General Session. It covers three tracks identified as important for VPPs working in the Veterinary Services: animal health field work, veterinary public health field work and laboratory diagnosis. The next meeting of the *ad hoc* Group's Special Session on Curricula Development will be convened from 3 to 7 December 2018 and will focus on the finalisation of the core curricula. The finalized document will be published and shared with the Assembly in May 2019.

10.5. Rinderpest (results of inspection reports for potential rinderpest holding facilities, another resolution is expected in May for designation and renewal of mandate, plus some other items)

An update on rinderpest post-eradication activities implemented since the last meeting was provided. The Global Rinderpest Action Plan (GRAP) will be jointly published by FAO and OIE in the fourth quarter of 2018. A prototype version of the GRAP was launched at the FAO-OIE Stakeholder Conference, held at the FAO headquarters, in Rome, Italy, 29–30 March 2018, after having the GRAP tested in two regional table-top exercises, in Nairobi, Kenya, 21–23 November 2017, and in Colombo, Sri Lanka, 13–15 March 2018. The Commission was informed that the modernisation of the Electronic Rinderpest Reporting System (ERRS), for OIE Members to do their annual reporting on rinderpest virus containing materials (RVCM), and the development of the Rinderpest Virus Tracking System, for Rinderpest Holding Facilities (RHF) to update their inventories in real time, has been successfully concluded. The "Sequence & Destroy" projects, taking place at two OIE Reference Laboratories for rinderpest, have already resulted in the destruction of significant amounts of RVCM, and safekeeping

²¹ MERS-CoV: Middle-East Respiratory Syndrome Coronavirus

of its genetic information, and will be concluded in March 2019. The FAO-OIE Joint Advisory Committee for Rinderpest (JAC) had its 13th meeting on 12–13 June 2018 at the headquarters of the International Atomic Energy Agency, in Vienna, Austria. In addition to discussing aforementioned subjects, the JAC issued a recommendation for OIE to propose for designation as RHF the two institutes whose application was pending, at the next General Session of the World Assembly of Delegates.

10.6. Follow up on the Guidelines on the investigation of suspicious biological events and subsequent workshop on bridging forensics and epidemiologists

Ms Tianna Brand, Head, OIE Programmes Department, provided an update, on behalf of Dr Christine Uhlenhaut, on the OIE *Guidelines on Investigation of Suspicious Events* drafted by an *ad hoc* Group and subsequently published in March 2018²² along with a workshop referred to as “Bridging Epidemiology and Forensics”²³ held in March 2018.

The guidelines were presented at the above-mentioned workshop to a group of experts from different regions and sectors, but consisted mostly of veterinary epidemiologists and law enforcement (e.g. the Head of the FBI laboratory in Quantico). The aim of the workshop was to assess if the guidelines had any gaps or needed any changes by working them through three different scenarios (small criminal case, bioterrorism, use of biological weapon of mass destruction in a hostile, state-sponsored act of aggression). According to the experts, the guidelines are well balanced and can be applied to a number of scenarios.

Since the publication of the guidelines, they have been presented at a number of international events involving the public health, law enforcement and security sectors. In doing so, interest in holding other workshops on the implementation of the guidelines has been expressed by United Nations agencies and by countries such as Malaysia, Brazil, Morocco and Tunisia to hold regional, multi-sectorial workshop. At this time, priorities are placed on other OIE activities that could include incorporating the guidelines. Having said that, the guidelines are publically available, thus can be used by anyone who wishes to do so, including for workshops that do not involve the OIE.

10.7. Update on VICH²⁴ activities

Dr Szabo gave a brief update on VICH-related activities and highlighted the importance of the dialogue between the Commission and the VICH Steering Committee to achieve harmonisation as far as possible between the OIE Standards and future VICH guidelines related to vaccines. She informed the Commission that two VICH Guidelines, 50²⁵ and 55²⁶, have been implemented in the United States of America and Japan. She stated that the OIE Biological Standards Commission had previously considered two of these guidelines and had concluded that, rather than completely eliminating all references to the TABST²⁷, references to the TABST in the *Terrestrial Manual* should be revised to include a note that the test could be eliminated in situations where other quality control measures are in place. The Commission had implemented this decision by modifying *Terrestrial Manual* Chapter 1.1.8 *Principles of veterinary vaccine production* and Chapter 3.7.2 *Minimum requirements for the production and quality control of vaccines* and amending all relevant disease chapters when they are updated.

²² http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Guidelines_Investigation_Suspicious_Biological_Events.pdf

²³ http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/BTR/Bridging_Epidemiology_and_Forensics.pdf

²⁴ VICH: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products

²⁵ Biologicals: testing harmonisation of criteria to waive target animal batch safety testing for inactivated vaccines for veterinary use

²⁶ Harmonisation of criteria to waive target animal batch safety testing for live vaccines for veterinary use

²⁷ TABST: target animal batch safety testing

Dr Szabo informed the Commission that the VICH Steering Committee was working on a new guideline on *Harmonisation of criteria to waive Batch Safety Testing for veterinary vaccines: Laboratory Animal Batch Safety Testing* and continued the work on *Extraneous virus testing for Biologicals*. The plan is to use the existing VICH guidelines related to pharmacovigilance to develop minimum requirements for a pharmacovigilance/vaccinovigilance (OIE terminology) guideline in collaboration with HealthforAnimals (an active member of VICH, holding the VICH secretariat) and OIE Collaborating Centres.

Finally Dr Szabo mentioned that she would provide information not just after a VICH meeting but also when she considered that the information could be of interest to or have an impact on the Commission's work.

10.8. Second OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents in Animals: *Putting Standards into Practice*, Marrakesh, Morocco, 29 to 31 October 2018

Dr Elisabeth Erlacher-Vindel, Head of the OIE Science and New Technologies Department, updated the Commission on this important forthcoming OIE Global Conference. This Conference comes at a critical juncture in the fight against antimicrobial resistance (AMR). Member Countries have demonstrated an impressive commitment to developing national capacity in this effort in line with international standards. To build on and further inform this momentum, the event will bring together OIE Delegates and OIE National Focal Points for Veterinary Products, as well as experts, professionals, policy makers, international organisations and donors. The aim is to increase the understanding of the current global situation regarding AMR in animals, and to develop recommendations for future sustained control of AMR while ensuring animal health, animal welfare, veterinary public health, and food security. It will in particular provide a forum to examine how best to support Member Countries in continued fulfilment of the objectives of the OIE Strategy on AMR and the Prudent Use of Antimicrobials, and the Global Action Plan on AMR.

10.9. Update on OIE Project: Capacity building and surveillance for EVD²⁸: the EBO-SURSY project

Dr Sophie Muset from the OIE Programmes Department updated the Commission on this project. In December 2016, the OIE received a grant from the European Union to implement the project Capacity building and surveillance for EVD: the EBO-SURSY project. This 5-year project was launched on 15 January 2017 and aims to strengthen national and regional early detection systems in wildlife in West and Central Africa (10 focus countries) using a One Health multi-sectorial approach to better detect, differentiate and prevent future EVD outbreaks or outbreaks of other emerging zoonotic pathogens. To achieve its objectives the project will focus on three main areas:

1. Building institutional and One Health capacity through teaching and training;
2. Contributing to increasing the communities' awareness of zoonotic diseases;
3. Reinforcing zoonotic disease surveillance protocols through field investigations and improved diagnostic assays.

To implement the project, the OIE teamed up with three organisations: the Centre de coopération International en Recherche Agronomique pour le Développement (CIRAD), the Institut de Recherche pour le Développement (IRD) and the Institut Pasteur and its International Network (IP). The Governance of the Project will be supported by an Advisory Committee and a Programme Committee. The project is progressing well, partners' teams are now complete and are conducting field work as planned.

²⁸ EVD: Ebola virus disease

10.10. OIE Technical Standards for Manufacturing and Quality Control of Veterinary Vaccines: upcoming publication of new handbook/ebook of English/French/Spanish vaccine-related chapters from *Terrestrial Manual*

Dr Gifford updated the Commission on the upcoming publication entitled *OIE Technical Standards for Manufacturing and Quality Control of Veterinary Vaccines*. This publication is a compilation of the vaccine-related chapters from the *Terrestrial Manual*²⁹, and one chapter from the *Terrestrial Code*³⁰, and will be available in English, French, and Spanish as a paperback book or a downloadable pdf file. It is intended to serve as a readily accessible technical resource for vaccine manufacturers and regulatory officials, to advance global awareness and implementation of the established science-based standards for the quality, safety, and efficacy of veterinary vaccine.

10.11. OIE Bulletin/Panorama: upcoming issue 2018-3 Bovine tuberculosis: A One Health Challenge

Dr Gifford informed the Commission on the preparation of an upcoming issue of the OIE Bulletin/Panorama online news magazine. The 2018-3 issue, which will comprise a collection of short 'news magazine' articles (approximately 300 words with graphics) on the topic *Bovine Tuberculosis: A 'One Health' Challenge*. Authors have been invited to contribute brief articles that highlight various aspects of bovine tuberculosis (bTB) control and eradication programmes from a 'One Health' perspective. The articles will cover topics such as OIE's project to replace the ISBT, the recently published Roadmap for Zoonotic Tuberculosis, Australia's successful eradication of bTB, and ongoing research into bTB epidemiology, vaccines, and diagnostics.

10.12. Evaluation of current equine influenza vaccination protocols prior to shipment

The Commission noted the study.

10.33. Evaluation on the availability and efficacy of available AHS vaccines and vaccine candidates

The Commission noted the study.

11. Any Other Business

11.1. Workplan

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

11.2. Dates of the next Biological Standards Commission meeting

The Commission noted the dates for its next meeting: 12–15 February 2019.

.../Annexes

²⁹ Chapter 1.1.8 *Principles of veterinary vaccine production*
Chapter 1.1.9 *Tests for sterility and freedom from contamination of biological materials intended for veterinary use*
Chapter 3.7.1 *Minimum requirements for the organisation and management of a vaccine manufacturing facility*
Chapter 3.7.2 *Minimum requirements for the production and quality control of vaccines*
Chapter 3.7.3 *Minimum requirements for aseptic production in vaccine manufacture*
³⁰ Chapter 4.7 *Vaccination*

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 3–6 September 2018

Agenda

1. **Welcome and orientation**
2. **Adoption of Agenda**
3. **Manual of Diagnostic Tests and Vaccines for Terrestrial Animals**
 - 3.1. Update from February 2018 meeting: review of a validation dossier for a quantitative real-time polymerase chain reaction method for detection of *Taylorella equigenitalis* directly from swabs
 - 3.2. Update from General Session – Chapter 2.5.11 Glanders and melioidosis
 - 3.3. Review of a validation study of a serological diagnostic assay with high specificity and sensitivity for glanders in equids
 - 3.4. Request to review the continued inclusion of the mallein test in the *Terrestrial Manual*
 - 3.5. Panaftsoa/VPH-PAHO/WHO initiative – ELISA for glanders diagnosis
 - 3.6. Update from General Session – use of the Frenkel method in the manufacture of FMD vaccines
 - 3.7. Comments from *ad hoc* Group on Evaluation of Member Country BSE Risk Status
 - 3.8. Review of draft chapters received and their endorsement for circulation for first-round Member Country comment
 - 3.9. Descriptions of test methods in the *Terrestrial Manual*: Commission's commitment to avoiding naming commercial products
 - 3.10. Review of a validation study of a serological diagnostic assay for AHS
 - 3.11. Discussion on the *Terrestrial Manual* chapter review process and the role of the Commission in the review cycle
4. **OIE Reference Centres**
 - 4.1. Applications for OIE Reference Centre status
 - 4.2. Changes of experts at OIE Reference Centres
 - 4.3. Review of new and pending applications for laboratory twinning
Reference Centre procedures
 - 4.4. Update on existing procedures for the establishment and maintenance of OIE Reference Centre
Reference Laboratories
 - 4.5. Follow-up February 2018 meeting: analysis of the annual reports of Reference Laboratory activities in 2017
Collaborating Centres
 - 4.6. Implementing the new procedures for designation of OIE Collaborating Centres: examining the list of existing Centres against the list of main focus areas and specialties
Reference Centre networks
 - 4.7. Development of procedures for the establishment and maintenance of OIE Reference Centre networks
5. **Ad hoc Groups**
Update on activities of past ad hoc Groups
 - 5.1. *Ad hoc* Group on Replacement of the International Standard Bovine Tuberculin (ISBT)
 - 5.2. *Ad hoc* Group on Veterinary Biobanking
 - 5.3. *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. Update and review of applications, future directions for the procedure
- 6.2. Standardisation programme
 - 6.2.1. Update on project to extend the list of OIE approved reference reagents
 - 6.2.2. Serum products: re-review of ESPA proposal to develop international trade standards for animal serum products used in culture media

7. Resolutions for the General Session

- 7.1. Excerpt from the Final Report: Comments from Delegates

8. Conferences, Workshops, Meetings

Future Conferences, Workshops, Meetings

- 8.1. Update on laboratory focal points and engagement from the Commission members
- 8.2. 19th WAVLD Symposium, 19–22 June 2019, Chiang Mai, Thailand: 1-day OIE Seminar (Friday 21 June): theme, programme, speakers: two sessions on quality management systems and on biobanking and reference materials
- 8.3. 7th meeting of the International Expert Group of Biosafety and Biosecurity Regulators in Ottawa, Canada 18–20 September 2018

9. Liaison with other Commissions

- 9.1. Horizontal issues among the Specialist Commissions
 - 9.1.1. Request to propose a definition of “new strain” for the purpose of disease notification
- 9.2. Scientific Commission for Animal Diseases
- 9.3. Terrestrial Animal Health Standards Commission
 - 9.3.1. Feedback from agenda item 6.2.2.
 - 9.3.2. Questions from *ad hoc* Group on Avian influenza
- 9.4. Aquatic Animal Health Standards Commission

10. Matters of Interest for Consideration or Information

- 10.1. Update on OFFLU
- 10.2. Update on MERS-CoV
- 10.3. Follow up from the Consultation on Sustainable Biosafety and Biosecurity in Laboratories (1–2 March 2018)
- 10.4. Veterinary para-professionals
- 10.5. Rinderpest (results of inspection reports for potential rinderpest holding facilities, another resolution is expected in May for designation and renewal of mandate, plus some other items)
- 10.6. Follow up on the Guidelines on the investigation of suspicious biological events and subsequent workshop on bridging forensics and epidemiologists
- 10.7. Update on VICH activities
- 10.8. Second OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents in Animals: *Putting Standards into Practice*, Marrakesh, Morocco, 29–31 October 2018
- 10.9. Update on OIE Project: Capacity building and surveillance for Ebola Virus Disease (EVD): EBO-SURSY
- 10.10. OIE Technical Standards for Manufacturing and Quality Control of Veterinary Vaccines: upcoming publication of new handbook/ebook of English/French/Spanish vaccine-related chapters from *Terrestrial Manual*
- 10.11. OIE Bulletin/Panorama: upcoming issue 2018-3 Bovine tuberculosis: A One Health Challenge
- 10.12. Evaluation of current equine influenza vaccination protocols prior to shipment
- 10.13. Evaluation on the availability and efficacy of available AHS vaccines and vaccine candidates

11 Any Other Business

- 10.1. Workplan
 - 10.2. Dates of the next Biological Standards Commission meeting: 12–15 February 2019
-

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION
Paris, 3–6 September 2018

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Work Programme for the OIE Biological Standards Commission

Subject	Issue	Status and Action
Updating the <i>Terrestrial Manual</i>	1) Circulate the chapters approved by the BSC to Member Countries for first-round comment	October 2018
	2) Remind authors of the chapters identified previously for update but not yet received	On-going
Collaborating Centres	3) Implementation of the adopted SOPs:	
	a) write to existing Collaborating Centres to explain new developments and to explain proposed BSC actions	October 2018
	b) finish mapping of existing Collaborating Centres to identify their main focus areas and specialties, and overlapping specialties based on the annual reports	From Feb 2019
	c) write to Centres to inform of outcome of discussions and propose a way forward: status quo or re-focus or form consortium.	From March 2019
	d) 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
Reference Laboratories	1) Write letter introducing new BSC and explaining proposed actions	October 2018
	2) In-depth review of annual reports based on a number of criteria concerning international activities and commitment to work on behalf of the OIE	February 2019
	3) Write to suspended labs reminding them that they can be reinstated by end 2019 if they provide a certificate of accreditation to ISO 17025 or equivalent	October 2018
Reference Centres	4) Develop SOPs for Networks	From September 2018
Standardisation/ Harmonisation	1) Project to extend the list of OIE approved reference reagents	On-going
	2) Project to develop Replacement International Standard Bovine Tuberculin	On-going, for 2020
	3) OIE Platform for the Collection and Management of Genomic Sequences in Animal Health	On-going
Ad hoc Groups	1) Replacement of the International Standard Bovine Tuberculin	Virtual meeting
	2) High Throughput Sequencing and Bioinformatics and Computational Genomics (HTS-BCG):	On hold awaiting funding
	a) Definition of business processes, operations and main technical specifications of the OIE platform	
	b) Development of sub-modules for the diseases that have been selected for the pilot phase of the OIE platform project	
	3) Veterinary Biobanking	TBD
	4) MERS-CoV	TBD
Conferences, Workshop, Meetings	1) WAVLD, June 2019: finalise programme and list of speakers	September 2018
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>	February 2019

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