



REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 30 August – 2 September 2016

The OIE Biological Standards Commission met at the OIE Headquarters from 30 August to 2 September 2016. Dr Monique Eloit, Director General of the OIE, welcomed the Members of the Commission, Dr Beverly Schmitt, President, Dr Franck Berthe and Dr Hualan Chen, Vice-Presidents, and Dr Peter Daniels and Dr Anthony Fooks, members of the Commission. The remaining member of the Commission, Dr Mehdi El Harrak, could not attend.

Dr Eloit informed the Commission that a proposed new procedure for selecting experts for nomination for election to the OIE Specialist Commissions and Working Groups, and for creating a database of suitable experts who could participate in *ad hoc* Groups is under development and would be presented for discussion to the OIE Council at its meeting in late September. The objectives are to have clear criteria to ensure that the selection process is transparent and defensible, based on the competence of the experts while broadening the geographical range of their origin. It is expected that the system will be operational in time for the next round of elections in 2018.

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

1. 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. *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.

2.1. Review chapters currently in Part 3 *Specific Recommendations* and identify any that should be moved to Part 1 *General Standards*

The Commission agreed that Part 3 *Specific Recommendations* of the *Terrestrial Manual*, which includes among others recommendations for validation of diagnostic tests and for the manufacture of vaccines, would more logically follow Part 1 *General Standards* as many of the chapters elaborate themes addressed in the chapters in Part 1. Part 3 should thus be moved to follow Part 1, and renumbered Part 2. This change would mean that the current Part 2 *OIE Listed Diseases and Other Diseases of Importance* would become renumbered as Part 3. This restructuring is similar to that of the *Terrestrial Animal Health Code (Terrestrial Code)* where Volume I contains general provisions and Volume II contains recommendations applicable to OIE Listed diseases and other diseases of importance to international trade.

2.2. Update from February meeting: proposal to include in the *Terrestrial Manual* oral vaccination of dogs against rabies

At its last meeting in February 2016, the Commission had received from a commercial company a study it had undertaken to immunise dogs against rabies using oral vaccination. The company requested that the Commission consider amending the *Terrestrial Manual* chapter on rabies to include the principle of oral vaccination of dogs as currently the *Terrestrial Manual* only provides for parenteral vaccination of dogs and the references for oral vaccination are applicable only to wildlife. The Commission had sought the advice of the OIE Reference Laboratory experts.

Reviewing the replies received there was a consensus among the experts that oral vaccination of dogs should indeed be included in the *Terrestrial Manual* chapter. The Commission identified two of the OIE Reference Laboratory experts who could prepare a text. Once drafted and agreed upon by the remaining experts, the text could be added to the chapter, which would then be included in the 2017/2018 review cycle, aimed at proposing the update for adoption in May 2018.

The Commission noted a WHO¹ document entitled *Oral vaccination of dogs against rabies: Guidance for research on oral rabies vaccines and field application of oral vaccination of dogs against rabies*. Once the *Terrestrial Manual* chapter includes text on oral vaccination of dogs against rabies, the Commission recommended that the OIE request the WHO to replace its document with reference to the OIE standard.

2.3. Update from February meeting: suitability of the complement fixation test for diagnosis of glanders

At its last meeting, the Delegate of Singapore had asked a number of questions regarding the consequences of the inability of the CFT² for glanders to differentiate serologically between *Burkholderia mallei*, the disease that causes glanders, and *B. pseudomallei*, the disease that causes melioidosis. The Delegate pointed out the need for diagnostic tests that differentiate *B. mallei* from *B. pseudomallei* and the necessity to include both agents in the *Terrestrial Manual* chapter on glanders (see Agenda Item 2.9 of the report of the meeting of the Biological Standards Commission, February 2016). The Commission had sought the advice of the OIE Reference Laboratory experts.

Reviewing the replies, the Commission welcomed the news that the OIE is funding a study entitled *Validation study of a western blot technique and ELISAs³ for serological diagnosis of glanders in equids for the purpose of certifying freedom from infection in individual animals for trade or movement*. The preliminary results should be available in December 2017. The Commission supported this study and requested a project outline and progress reports. The Commission also supported a proposal from the OIE Reference Laboratory in the United Arab Emirates to develop a *B. pseudomallei* ELISA and to undertake an infection trial in equids.

Until the studies are complete, the experts advised that as there is no test that can differentiate serologically between *B. mallei* and *B. pseudomallei*, the CFT remains the best test and cannot yet be replaced. Furthermore, the experts advised that it is now acknowledged that *B. mallei* and *B. pseudomallei* are the same species, and would strongly recommend including melioidosis in the glanders chapter. The Commission supported this proposal and would request that the experts update the chapter accordingly.

Finally the experts asked those OIE Member Countries that are endemic for both diseases to provide the OIE with data on the prevalence of melioidosis in horses. Although they have encountered melioidosis in camels, the OIE Reference Laboratory experts have not yet encountered a melioidosis positive equid.

¹ WHO: World Health Organization

² CFT: complement fixation test

³ ELISA: enzyme-linked immunosorbent assays

2.4. Adding date of adoption and last amendment to *Code* and *Manual* chapters

The Commission was informed that, following a request from a Member Country, the OIE Headquarters had agreed to add the following sentence to the end of all chapters in the Codes and the Manuals: “NB: first adopted in YEAR; Most recent updates adopted in YEAR”. Welcoming this development, the Commission proposed that from May 2017, the date of each update be added to the chapters.

2.5. Request to delete the target animal batch safety test from OIE Guidelines on veterinary vaccine production

In September 2015, the EPAA⁴ held an international workshop on *Harmonization of 3Rs in Biologicals*. One of the conclusions of the workshop was that scientific evidence that the TABST⁵ contributes to the safety of veterinary vaccine production and release is lacking. On that basis, the workshop recommended that all references to this test be deleted from OIE Guidelines, and thus the EPAA requested that the OIE revise all Standards that still stipulate the use of TABST.

As the EPAA had not provided any data to support the claim, the Commission decided to ask those OIE Collaborating Centres involved in veterinary vaccine production if they agreed with the conclusions of the EPAA’s report. The Centres would also be asked their opinion on the use of animals in veterinary vaccine production and general advice on how to progress issues of animal welfare in relation to vaccine production.

2.6. Review of validation dossiers of diagnostic tests for two bee diseases with the aim of including them in the *Terrestrial Manual*

The OIE Reference Laboratory for bee diseases in France had submitted validation dossiers for diagnostic tests for two bee diseases: Small hive beetle infestation (*Aethina tumida*) and *Tropilaelaps* infestation of honey bees (*Tropilaelaps* spp.), with the request that the Commission approve the tests for inclusion in the *Terrestrial Manual* chapters.

The Commission noted that the number of samples included in the validation procedures was low, but concluded that this was related to the difficulty of working with bees. Although the tests would need further validation, the Commission agreed to include them in the chapters, ranking the PCR⁶ “++” for all the purposes given in Table 1. *Test methods available and their purposes*. (This Table is included in all disease chapters of the *Terrestrial Manual*; diagnostic tests available and in use for the disease are graded against the six purposes for which diagnostic tests may be carried out given in Chapter 1.1.6 *Principles and methods of validation of diagnostic assays for infectious diseases*.) The grading “++” means the test is a suitable method but may need further validation. The morphological identification tests could be ranked +++, which means recommended method, validated for the purpose shown.

In the meantime, the Commission agreed to submit the dossiers to two validation experts with the request that they review them and propose ways to improve the validation process for tests for bees.

2.7. Review of two validation dossiers for diagnostic tests for rabies with the aim of including them in the *Terrestrial Manual*

A group of experts, including OIE Reference Laboratory experts, had submitted the validation dossier for a direct immunohistochemical test for rabies diagnosis with the request that it be included in the *Terrestrial Manual* chapter. The Commission had a few technical questions for the group, but overall agreed that the test would be a useful addition to the *Terrestrial Manual* and would request that the group provide a test protocol for inclusion in the chapter. In the meantime, the Commission agreed to submit the dossier to the validation experts for review.

⁴ EPAA: European Partnership for Alternative Approaches to Animal Testing

⁵ TABST: target animal batch safety test

⁶ PCR: polymerase chain reaction

A second group of experts, also including OIE Reference Laboratory experts, had submitted a similar request for conventional and real-time RT-PCR⁷ assays for the detection of lyssaviruses. Again, the Commission agreed to include the tests in the *Terrestrial Manual* chapter upon receipt of suitable protocols. And again, the dossier would be submitted to the validation experts for review.

Earlier in the meeting, the Commission had decided that oral vaccination of dogs should be included in the *Terrestrial Manual* chapter on rabies (see Agenda Item 2.2 of this report). Once all the texts requested are received (on oral vaccination of dogs, protocol for the direct immunohistochemical test and protocols for the conventional and real-time RT-PCR), the draft chapter will be reviewed by the Commission with the aim of approving it for the 2017/2018 review cycle.

2.8. Review of draft chapters received and their endorsement for circulation for Member Country comment

Of the 30 chapters that the Commission had previously identified for update, a small number (six) had been commissioned but had not been received. The Commission identified alternative experts who could assist with the revisions. In the case of OIE Reference Laboratory experts who did not respond to requests from the Headquarters, the Commission requested that a letter be sent from the Director General reminding them of their mandated obligations.

The Commission decided that the experts who had contributed chapters adopted in 2012 and 2013 be asked if their chapters needed to be updated and added to the 2017/2018 review cycle.

Noting that publication of the 2016 edition of the *Terrestrial Manual* would be delayed, the Commission proposed that the Headquarters consider producing a CD-ROM for users who have unreliable internet access.

The Commission reviewed 20 draft chapters and the glossary and approved them all 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 2017. One chapter, *Tests of biological material for sterility and freedom from contamination*, had been sent for first-round comment in October 2015 but had received so many comments that it was put on hold pending further review. The Commission agreed that the experts at the OIE Collaborating Centre for Laboratory Capacity Building in Geelong, Australia, had fully addressed the comments and approved the chapter for circulation for second-round comment. Chapters for second-round comment are sent to Member Countries following the Commission's February meeting.

The Commission noted that the disease, duck virus hepatitis (DVH) is caused by three different viruses: DVH type I is caused by duck hepatitis A virus, a member of the genus *Avihepatovirus*, of the family *Picornaviridae*; DVH type II is caused by duck astrovirus type 1, and DVH type III is caused by duck astrovirus type 2, both members of the *Astroviridae* family. The Code Commission was informed of this development as it may require changing the name of the *Terrestrial Code* chapter.

The Commission continues its efforts to eliminate unnecessary animal inoculation techniques from the *Terrestrial Manual* in line with the OIE's animal welfare policy. The Commission thus proposed deleting the mouse inoculation test from the chapter on African horse sickness, and the authors of the chapters on DVH, equine rhinopneumonitis and toxoplasmosis would be asked if animal inoculation was justified.

The expert who contributed the revised chapter on bovine genital campylobacteriosis pointed out that certain parts of the chapter on serological tests and on vaccines had remained unchanged for many years from earlier editions. He asked if he could send out a short questionnaire with the chapter to ascertain if that specific information was of use to users of the *Terrestrial Manual*. The Commission agreed to this request.

⁷ RT-PCR: reverse-transcription PCR

The Commission reiterated the OIE policy not to name specific commercial kits or reagents in the *Terrestrial Manual* unless there is no alternative.

The Commission agreed to maintain the name sheep pox and goat pox when referring to the disease. However when referring to the viruses, the official ICTV⁸ nomenclature – sheeppox virus and goatpox virus – would be used.

The *Terrestrial Manual* disease chapter template currently includes a section on zoonotic potential and biosafety and biosecurity requirements, but the section is not systematically filled in by the authors, nor is there consistency among the statements about risk analysis and biosafety and human health in veterinary laboratories. The Consultant Editor agreed to check and amend, if necessary, those chapters on zoonotic diseases. In the current batch these include the chapters on *Campylobacter jejuni* and *C. coli* and on toxoplasmosis.

Finally, so as to be able to work between meetings, the Commission requested that the OIE IT (Information Technology) Department make available a document sharing software tool. Members could comment on documents such as the draft *Terrestrial Manual* chapters in advance of meetings.

3. OIE Reference Centres

3.1. Further review of the approval and maintenance of Reference Centre status procedures: development of standard operating procedures

As agreed at the February 2016 meeting, the Commission further discussed the procedures for the approval and maintenance of Reference Centre status, and reviewed a first draft of the standard operating procedures for designation of OIE Reference Laboratories.

The Commission further discussed and defined the criteria and procedure for de-listing of laboratories. In addition to the two critical points identified in February: i) lack of submission of an annual report and ii) no progress or explanation provided on achievement of accreditation to the ISO 17025 or equivalent quality management system in their diagnostic laboratories, identified at its last meeting, the Commission added the following points:

- No response to requests from the OIE Headquarters for scientific expertise (e.g. revision of the *Terrestrial Manual* chapters)
- A pattern revealing lack of diagnostic activity or production and supply of reference material related to the disease or pathogen

The Commission discussed in-depth the timeline and different steps in the process of de-listing an OIE Reference Laboratory.

First, the Commission acknowledged and appreciated that the majority of OIE Reference Centre experts respected the deadline for submission of their annual reports and fulfilled the Terms of Reference (ToR) to the OIE through the online reporting system.

According to the current cycle, submission of annual reports of OIE Reference Centre activities during the previous year is due by the end of January of the following year; this deadline is usually immediately prior to the February meeting of the Commission. After this meeting, laboratories that have not submitted their annual reports will be sent a letter of reminder, with the Delegate of the corresponding Member Country in copy, to submit the report by an extended deadline. For laboratories that have still not submitted an annual report by the end of March, a forceful reminder will be addressed to the Delegate, with the expert in copy, giving a 2-week deadline to reply to the OIE with an explanation of the situation or circumstances that may have prevented the laboratory from fulfilling this ToR. Further communication by letter or direct discussion during the General Session may be considered, if needed, prior to the final recommendation to de-list the laboratory, which would be taken by the Commission at the September meeting. This procedure could also be applied to laboratories falling under one of the three other above-mentioned de-listing criteria.

⁸ ICTV: International Committee on Taxonomy of Viruses

For those laboratories that have not achieved accreditation to ISO 17025 or equivalent quality management system by the end of 2017, the Commission proposed suspending their OIE Reference Laboratory status with the possibility to be reinstated within 2 years should they achieve accreditation in that time. Laboratories that have still not achieved accreditation 2 years after suspension would have to re-apply for OIE Reference Laboratory status.

The Commission mentioned that this timeline with explanatory text would be added to the draft standard operating procedures.

The Commission took the opportunity to emphasise the importance of the timely submission of annual reports by OIE Reference Centres.

3.1.1. Review of the current Reference Laboratory network system

The Commission reviewed a document on the current OIE Reference Laboratory network system with the aim of developing a strategic plan for its future role. The document was forwarded to the Aquatic Animals Commission for input as this is an area of mutual interest. The Commissions would find a means to work together, and with staff from the OIE Headquarters with responsibilities in the area, to develop and evolve this document before presenting it to the Assembly.

3.2. **Update on Reference Laboratory quality management systems: progress towards ISO 17025 or equivalent accreditation and procedure for handling laboratories that do not intend to get towards ISO 17025 or equivalent accreditation**

The Commission reviewed information received from the 16 OIE Reference Laboratories that are currently not accredited to ISO 17025 or equivalent quality management system. Ten of the 16 indicated that they have a quality management system or are in progress to achieve ISO 17025 or an equivalent system; six laboratories did not provide a reply, mentioned a system that was not equivalent to the requirement or indicated their lack of interest in achieving this goal explaining their circumstances (e.g. primary activities of the laboratory was research or academics and not diagnostics). Some laboratories stated that they were accredited by a national accreditation body and were willing to provide the Commission with the supporting documents to demonstrate this equivalence. In favour of maintaining the valuable scientific expertise of these OIE Reference Laboratories, the Commission would review these documents at its next meeting along with the analysis of the annual reports. The Commission recognised nevertheless that numerous laboratories have made progress to achieve ISO 17025 or an equivalent quality management system, and stressed that those laboratories that do not meet this requirement by the deadline (end of 2017) would be de-listed through the procedure detailed in Agenda Item 3.1 of this report.

The procedures proposed by the Biological Standards Commission would be submitted for input and approval by the Aquatic Animal Health Standards Commission, which is responsible for aquatic animal laboratories, as both Commissions would need to apply the same commonly agreed practices.

Finally, the Commission explored and discussed different options to maintain the valuable expertise and active role of those laboratory experts who risked being de-listed: the proposal to have two different lists of OIE Reference Laboratories was not supported, but maintaining a database of expertise that could be linked to the one mentioned by Dr Eloit in her welcoming address, is a viable option that the Commission would further explore at its next meeting.

3.3. **Necessity of maintaining laboratories for caprine arthritis/encephalitis and for maedi-visna**

The OIE Reference Laboratories for small ruminant lentiviruses (caprine arthritis/encephalitis and maedi-visna) had very few activities to report in 2015. The expert stated that there appears to be a decreasing need for international testing or reagent exchange, and asked if the Commission wished to maintain these OIE Reference Laboratories and if a 'negative' report with few activities but with accompanying explanations was acceptable.

The Commission would accept such a report as valid, and would like to maintain these laboratories and their expertise. At the same time the Commission also invites applications from Member Countries where expertise exists in these small ruminant diseases.

3.4. Other topics related to Reference Centre status: Reference Laboratories on antimicrobial resistance

Although OIE Reference Laboratories are designated for a named disease, there remains an exception to this rule: the OIE Reference Laboratory for antimicrobial resistance in the United Kingdom. This OIE Reference Laboratory would better fit the mandate of an OIE Collaborating Centre. As the activities of such a new OIE Collaborating Centre may overlap with those of the OIE Collaborating Centre for Veterinary Medicinal Products in Fougères, France, the Commission recommended that the UK Centre contact the French Centre with the view to forming a consortium with it.

3.5. Applications for OIE Reference Centre status

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

OIE Reference Laboratory for classical swine fever

Animal Health Research Institute (AHRI), Council of Agriculture, 376 Chung-Cheng Rd., Tansui District, New Taipei City 25158, CHINESE TAIPEI
Tel.: (+886-2) 26.21.21.11 ext. 343; Fax: (+886-2) 26.22.53.45;
E-mail: cychang@mail.nvri.gov.tw; Website: <http://eng.nvri.gov.tw/>
Designated Reference Expert: Dr Chia-yi Chang.

OIE Reference Laboratory for classical swine fever

China Institute of Veterinary Drug Control (IVDC), No.8 Zhongguancun South Street, Haidian District, Beijing 100081, CHINA (PEOPLE'S REP. OF)
Tel.: (+86-10) 62103670; Fax: (+86-10) 62103671;
E-mail: ncsfri_ivdc@163.com, wq551@vip.sina.com
Designated Reference Expert: Dr Qin Wang.

An application had been received for recognition of an OIE Reference Laboratory for duck virus hepatitis. The Commission noted that the certificate of accreditation to ISO 17025 was out of date and also that the applicant mentioned that the laboratory was accredited for numerous tests for hog cholera and pseudorabies but not for duck virus hepatitis. The applicant also stated that the laboratory neither organises nor participates in inter-laboratory proficiency tests, which is one of the mandated Terms of Reference for OIE Reference Laboratories. The applicant would be asked for clarification of these points.

An application had also been submitted for designation as an OIE Collaborating Centre for Diagnosis and control of emerging and re-emerging swine diseases in Europe. OIE Collaborating Centres are designated for cross-cutting issues relating to the management of general questions on animal health issues. The Commission found that the activities and services proposed in the application fitted more with those of OIE Reference Laboratories for various swine diseases. Although Collaborating Centres with similar titles had been adopted in the past, the Commission would not like to continue that practice but to maintain a clear distinction between the roles of Reference Laboratories and Collaborating Centres. The applicant would be asked to apply for OIE Reference Laboratory status for diseases for which it has expertise and where there is not already an OIE Reference Laboratory in the country.

Finally, the Commission deferred a review of an application for OIE Reference Laboratory status to the February meeting as the application arrived during the meeting. The Commission reminds the OIE Member Countries that the deadline for receipt of applications is 45 days before the meeting.

The Commission noted that the following OIE Reference Laboratory had asked to be removed from the lists: OIE Reference Laboratory for bee diseases in Germany following the retirement of the designated expert; and the OIE Reference Laboratories for caprine arthritis/encephalitis and for maedi-visna in France following reorganisation of the institution and discontinuation of activities on these two diseases.

3.6. Changes of experts at OIE Reference Centres

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

Highly pathogenic avian influenza and low pathogenic avian influenza (poultry) and Newcastle disease

Dr Isabella Monne to replace Dr Giovanni Cattoli at the Istituto Zooprofilattico Sperimentale delle Venezie, Padova, ITALY.

Trichinellosis

Dr Brad Scandrett to replace Dr Alvin Gajadhar at the Centre for Food-borne and Animal Parasitology, Canadian Food Inspection Agency, Saskatoon, CANADA.

Echinococcosis/hydatidosis

Prof. Michael Rogan to replace Prof. Philip Craig at the Cestode Zoonoses Research Group, University of Salford, UNITED KINGDOM.

Paratuberculosis

Dr Virginie Thibault to replace Dr Pascale Mercier at the Anses (Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail) laboratory, Niort, FRANCE.

3.7. Review of new and pending applications for laboratory twinning

Dr Tianna Brand, Head of the OIE Programmes Department, updated the Commission on the OIE Laboratory Twinning programme. As of 1 September 2016, 35 projects have been completed and 29 projects are underway and 11 are awaiting funding.

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

- **Australia – Vietnam** for enhanced diagnosis and characterisation of emerging infectious diseases of pigs in the South-East Asian Region: the Commission supported the technical contents of this project and stressed that the work programme should include training on quality assurance and risk management in all steps of the project.
- **Japan – Mongolia** for highly pathogenic avian influenza and low pathogenic avian influenza: the Commission supported the technical contents of this project and once again stressed that the work programme should include training on quality assurance and risk management in all steps of the project.

3.8. Follow-up from last meeting: Mission to avian influenza and Newcastle disease candidate laboratory in Vladimir, Russia

In February 2016, the Commission reviewed the report submitted by an expert following a mission to evaluate the facilities at an institute that had applied to be recognised as OIE Reference Laboratories for Avian influenza and Newcastle disease (see Agenda Item 3.7 of the report of the meeting of the Biological Standards Commission, February 2016). The report included a number of recommendations, which the Commission endorsed. Once the recommendations had been fully implemented, the institute would be in a position to submit a strengthened application for review.

Following the February meeting, the Delegate wrote to the OIE Director General to assure her that the recommendations in the mission report had been fulfilled and requesting that the institute be put forward for proposal for adoption as two OIE Reference Laboratories.

The Commission, in consultation with the expert, re-examined the mission report and its recommendations. In his report, the expert had stressed the importance of establishing facilities and protocols for the safe handling of H5 and H7 isolates in accordance with international norms, as also

described in the OIE *Terrestrial Manual* chapter on avian influenza, which states that “HPAI⁹ and H5/H7 LPAI¹⁰ are subject to official control. The viruses that cause HPAI and H5/H7 LPAI have the potential to spread from the laboratory if adequate levels of biosecurity and biosafety are not in place. Avian influenza viruses are classed at a minimum in Risk Group 2 for human and animal infection and should be handled with appropriate measures as described in Chapter 1.1.4 *Biosafety and biosecurity: Standard for managing biological risk in the veterinary laboratory and animal facilities*. Biocontainment measures should be determined by risk analysis as described in Chapter 1.1.4. The measures required may vary among the subtypes, with higher level containment (e.g. Risk group 3 or 4) being indicated for H5/H7 LPAI and HPAI viruses.”
(see: http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/2.03.04_AI.pdf)

Virulent H5 and H7 isolates are known human pathogens, with mortalities of up to 50% in infected individuals. In the Russian Federation all genotypes of avian influenza are currently classified as Class 2 pathogens. It is very important that the Russian Federation consider reviewing their biocontainment classification of HPAI (H5 & H7) with a view to alignment with the OIE recommendations, particularly if the laboratory is to act as an OIE Reference Laboratory with the responsibility to demonstrate best practice in respect of biosafety of its staff and in training scientists from other countries. The Commission concluded that the Delegate should reply to each individual point in the recommendations. His detailed reply would be reviewed at the next meeting in February 2017. Regarding the institute’s accreditation to GOST 17025-2019 standard, the Commission requested details of which tests for AI and ND will be accredited and accompanying documents.

4. *Ad hoc* Groups

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

4.1. *Ad hoc* Group on Replacement International Standard Bovine Tuberculin

Dr Simona Forcella from the OIE Status Department updated the Commission on the progress that had been made with the project to develop a replacement international standard bovine tuberculin. An action plan has been developed and instigated with the target date on proposing the new standard for adoption by the World Assembly in May 2019. The Plan has five milestone phases: donation of bulk material, preparation of candidate tuberculin, preliminary evaluation, international collaborative study, and finally adoption of the New International Standard Bovine Tuberculin. The OIE is soliciting financial support from public and private partnerships to support this important and urgent activity. The Commission advised that a contingency plan should be developed should the project run into difficulties.

4.2. *Ad hoc* Group on Vaccination

See Agenda Item 8.1.1.

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

Dr Neo Mapitse and Dr Lina Awada of the OIE World Animal Health Information and Analysis Department presented this Agenda Item. Dr Mapitse informed the Commission that following a call for tender, a private company will be contracted to design the specifications for the next version of the OIE WAHIS¹¹. A Project Manager will shortly be appointed to supervise the project, which should be complete by June 2019 and which will include linkages to the OIE Platform¹². Following the recommendations of the *ad hoc* Group on HTS-BCG, a Project Manager to define the technical specifications of the genomic platform has been appointed. He will work in collaboration with the WAHIS Project Manager. The specifications would be circulated to the *ad hoc* Group members at an early stage, so as to avail the OIE of their practical experience with such systems.

⁹ HPAI: High pathogenicity avian influenza

¹⁰ LPAI: Low pathogenicity avian influenza

¹¹ WAHIS: World Animal Health Information System

¹² OIE Platform Project: *Creation of an OIE platform for the collection and management of genomic sequences in animal health* to complement the epidemiological database within WAHIS

5. International Standardisation/Harmonisation

• Diagnostic tests

5.1. OIE Register of diagnostic kits

5.1.1. Update and review of applications

Dr François Diaz from the OIE Science and New Technologies Department of the OIE, updated the Commission on the OIE Procedure for Registration of Diagnostic Kits. He reminded the Commission that the two diagnostic kits adopted during the last General Session by the World Assembly of Delegates had been included in the OIE Register of diagnostic kits.

5.2. Standardisation programme

5.2.1. Update on progress on developing guidelines for the preparation and validation of antigen standards

Dr Anthony Fooks presented the latest version of the document *International Reference Standards for Antigen Detection Assays*. The Commission proposed that cross references to Chapter 3.6.2 *Development and optimisation of antigen detection assays* be added. Dr Peter Daniels agreed to thoroughly review the document and provide feedback to Dr Fooks. Once this review is complete, the document will be sent to the other members of the Commission for review before the next meeting in February 2017.

5.2.2. Update on progress on developing guidelines for the preparation and validation of reagents for molecular tests

The Commission agreed that once the format for the guidelines for the preparation and validation of antigen standards has been finalised (item 5.2.1), it would be sent to the OIE Reference Laboratory expert previously identified, who would be asked to prepare guidelines for the preparation and validation of reagents for molecular tests using this template.

5.2.3. Project to establish a virtual OIE Biobank: next steps

At its meeting in February 2016, the Commission was updated on the activities that had been undertaken since September 2015 on the project to establish a virtual OIE Biobank. The Commission had recommended that an *ad hoc* Group be convened and had proposed draft principal Terms of Reference for such a Group (see Agenda Item 5.2.3 of the report of the meeting of the Biological Standards Commission, February 2016).

At the current meeting, the Commission was informed that the Director General of the OIE was in favour of convening an *ad hoc* Group, and so the Commission revised the proposed Terms of Reference (ToR). It was decided to modify the first ToR to restrict the scope to OIE listed diseases:

- i) identify which types of biological material (for OIE listed diseases only) should be included in the OIE biobank;
- ii) define the quality requirements;
- iii) define the metadata attached to the biological material;
- iv) review the IT options and propose preferred option;
- v) propose standard MTA;
- vi) define the steps that are needed for implementation of the biobank database.

The Commission is aware of the need to facilitate the transport of materials to and from laboratories, which is linked to the CITES¹³ treaty, the Nagoya Protocol, IATA¹⁴ regulations, etc. It was felt however, that transport issues would be beyond the scope of this *ad hoc* Group. The Commission therefore recommended that a separate OIE *ad hoc* Group on transport of specimens be convened at a future date.

5.2.4. Update on progress on developing guidelines for the preparation and validation of reagents for molecular tests

Dr Dordor Vang presented to the Commission the list of OIE-approved standard reagents and other standard reagents developed by the OIE Reference Laboratories based on their 2015 annual reports. The Commission decided to contact those OIE Reference Laboratories that have developed standards to gather more information on the reagents and to see if they could be recognised as OIE-approved standard reagents. The Commission proposed to start with standard sera, as guidelines for their preparation have already been developed, and chose the following diseases as a starting point: African swine fever, bluetongue, highly pathogenic avian influenza and low pathogenic avian influenza, foot and mouth disease, lumpy skin disease, peste des petits ruminants, and Newcastle disease. The OIE Reference Laboratories for these diseases that indicated that they made standard sera would be contacted as a first step.

6. Follow-up from the General Session

The Commission noted that the three resolutions it had proposed had been adopted unanimously by the Assembly at the General Session in May 2016:

- Resolution No. 13: Amendments to the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
- Resolution No. 14: Designation of OIE Reference Laboratories for terrestrial animal diseases
- Resolution No. 15: Register of diagnostic kits validated and certified by the OIE

The Commission noted the discussions that took place following Dr Beverly Schmitt's presentation on its activities during the past year. The comment from the Delegate of Argentina on the need to pursue work on the development of validated and reliable diagnostic tools for glanders was being addressed (see Agenda Item 2.3 of this report).

7. Conferences, Workshops, Meetings

Past Conferences, Workshops, Meetings

7.1. **Update on seminars for National Focal Points for Veterinary Laboratories, the PVS Pathway Laboratory Tool and quality management**

Ms Jennifer Lasley from the OIE Programmes Department, and Dr François Diaz, presented this Agenda Item.

The National Focal Point Programme for Veterinary Laboratories is currently in its first cycle of implementation, and the programme has been met with appreciation and success. In the framework of the Regional Seminars for National Focal Points for Veterinary Laboratories, OIE Member Countries have provided feedback and indicated that four main topics are in need of further exploration and attention in the second cycle of the programme, to begin in mid-2017. These topics include: transport of specimens, biosafety and biosecurity, validation of diagnostic tests, and quality management. These issues will be the main pillars of the second cycle's curriculum.

¹³ CITES: Convention on International Trade in Endangered Species of Wild Fauna and Flora

¹⁴ IATA: International Air Transport Association

Member Countries have also stated that more technical assistance from the OIE in the form of interpretation and implementation of the OIE standards would be helpful, especially for those Member Countries for which accreditation is not a mid- or long-term goal. They stated that tools are needed for all OIE Member Countries, whereas current capacity building programmes only address more advanced laboratories (Twinning Programme).

To address the needs expressed during the Regional Seminars for National Focal Points for Veterinary Laboratories, the Commission agreed that there is a need to convene an *ad hoc* Group to address the development of quality management system implementation tools, including a stepwise, systematic, simple, clear and practical approach, especially targeted to smaller laboratories for which accreditation is not a mid- to long-term goal. Such a stepwise approach 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.

7.2. COMPARE¹⁵ project

COMPARE is a flexible information-sharing platform linked to the GMI initiative (see Agenda Item 7.3 below). It is a large European Union financed project with the intention to speed up the detection of and response to disease outbreaks among humans and animals worldwide through the use of new genome technology. The OIE is represented on two of its advisory panels. The Commission would be updated on developments at its next meeting in February.

7.3. GMI¹⁶ meeting, GMI9, 23–25 May 2016 at FAO¹⁷ premises in Rome, Italy

As the last GMI meeting took place at the same time as the OIE General Session, the OIE was not represented at it. However, the report of the meeting would be reviewed, particularly the GMI's proposed communication tool. The Commission would be updated at the next meeting in February 2017.

7.4. 4th OIE Global Conference on Veterinary Education

Dr Peter Daniels updated the Commission on the Global Conference on Veterinary Education. The OIE, through its normal processes of consultation, has developed a widely agreed set of competencies that graduating (Day 1) veterinarians are expected to possess, as a minimum, if the veterinary services are to function effectively. These in turn affect the recommended content of the veterinary curriculum.

The Commission reviewed the core competencies and noted that they do not mention the ability of a Day 1 veterinarian to request, interpret and use diagnostic test results. The Commission recommends that these skills be considered for inclusion in a future update of the OIE *recommendations on the Competencies of graduating veterinarians ('Day 1 graduates')* to assure National Veterinary Services of quality.

Future Conferences, Workshops, Meetings

7.5. 18th WAVLD¹⁸, 7–10 June 2017, Sorrento, Italy: 1-day OIE Seminar Friday 9 June: theme, programme, speakers

The Commission proposed that the 1-day OIE Seminar that would be held during the 18th WAVLD Symposium could be divided into two parts: the morning session on *Antimicrobial Resistance and Rapid Diagnostics* and the afternoon session on *Implementing new Biorisk Standards*.

Before developing a detailed programme and list of proposed speakers, the approval of these topics by both the WAVLD and the OIE Director General would be solicited.

¹⁵ COMPARE: Collaborative Management Platform for detection and Analyses of (Re-) emerging and foodborne outbreaks in Europe

¹⁶ GMI: Global Microbial Identifier

¹⁷ FAO: Food and Agriculture Organization of the United Nations

¹⁸ WAVLD: World Association of Veterinary Laboratory Diagnosticians

8. Liaison with other Commissions

8.1. Horizontal issues among the Specialist Commissions

8.1.1. Proposed *Terrestrial Code* chapter on vaccination: review of the chapter as developed by the *ad hoc* Group

Dr Franck Berthe presented the draft *Terrestrial Code* chapter on vaccination that had been developed by the *ad hoc* Group in accordance with the outline that had been approved previously by all the OIE Specialist Commissions. The approval of both the Code Commission and the Scientific Commission for Animal Diseases would also be sought.

The Biological Standards Commission has no specific comments but noted that the *ad hoc* Group should check cross references to *Terrestrial Manual* chapters as the numbers of these chapters had changed.

8.2. Terrestrial Animal Health Standards Commission

For this agenda Item the Commission was joined by Dr Etienne Bonbon, President of the OIE Terrestrial Animal Health Code Commission.

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

8.2.1. Member Countries' comments on the hyphenation of 'foot-and-mouth disease

Following the Code Commission's decision to align the spelling of disease names with that of the ICTV, a Member Country had commented that the ICTV spells Foot-and-mouth disease virus with two hyphens, while the OIE does not. The Biological Standards Commission had already noted that there may be differences between the name of the virus and the name of the disease (see Agenda Item 2.8 of this report) and agreed to retain the name Foot and mouth disease without hyphens.

8.2.2. Collection and processing of *in-vitro* produced embryos/oocytes from livestock and horses (Chapter 4.8.)

A Member Country had pointed out that although Article 4.8.5 of *Terrestrial Code* Chapter 4.8 advises that oocytes, non-viable *in-vitro* produced embryos, and fluids used and generated during processing of *in-vitro* produced genetic material should be tested for pathogenic organisms, there is no detail in the *Terrestrial Manual* on what tests should be used in these cases. The Biological Standards Commission stated that there are currently no means to assess the risk of disease transmission in *in-vitro* produced embryos or oocytes, nor is there funding for such research. The Code Commission was requested to revise the Article to take account of this situation.

Follow-up from last meeting

8.2.3. Update on proposed definitions of OIE Standard and OIE Guideline

The Commission was informed that the proposed definitions of OIE Standard and OIE Guideline had been submitted to the OIE Council for discussion.

8.2.4. Expert advice on Member Country questions on the draft chapter on *Infection with bluetongue virus*

At its February meeting, the Biological Standards Commission was asked for comment on two points raised by Member Countries: 1) Are there any of bluetongue virus (BTV) strains that are considered to be non-pathogenic? 2) Is there scientific evidence for the continued exclusion of vaccine strains from the BTV case definition? The Commission consulted members of the *ad hoc* Group on Harmonisation of the three *Terrestrial Animal Health Code* Chapters on African horse sickness, bluetongue and epizootic haemorrhagic disease chapters. The scientific advice to the Code Commission is as follows:

- There was consensus among the experts that strains of BTV from live, attenuated BTV vaccines can replicate in vaccinated animals, infect vectors and be transmitted among ruminant hosts and that this may result in disease. Furthermore, genetic reassortment has been reported among such naturally transmitted vaccine strains and wild-type viruses, resulting in new strains of BTV that can also cause disease. These matters are reported in the scientific literature.
- Regarding exclusion of “non-pathogenic” strains of BTV from coverage under the *Terrestrial Code*, it was noted that there is not an identified molecular marker of virulence in BTV (such as is accepted for some viruses such as highly pathogenic avian influenza [HPAI] and Newcastle disease virus [NDV]). Lack of such a readily testable marker makes confident assignment of a BTV as “pathogenic” or “non-pathogenic” problematic. Furthermore there is not a standardised protocol of live animal testing to assess the relative pathogenicity of BTV strains. Reference laboratories routinely form their own assessments of pathogenicity of BTV through animal studies, but there is not a standardised protocol such as could be published in the *Terrestrial Manual* as a standard, as has been done for the poultry pathogens HPAI and NDV.

Based on these considerations the Biological Standards Commission advises that it is appropriate to retain reference to vaccine strains in the definition of BTV, and at the present time it is not possible to make definitive assessments of a BTV strain’s pathogenicity, even though epidemiological information may indicate lack of a disease problem associated with some BTV infections.

8.2.5. Expert advice on Member Country questions on the draft chapter on Infection with *Mycobacterium tuberculosis* complex

At its February meeting, Code Commission referred to the Biological Standards Commission Member Country comments that had been submitted on the new *Terrestrial Code* draft chapter 8.X Infection with *Mycobacterium tuberculosis* complex: 1) The rationale for listing New World camelids as “under study” in the case definition. 2) The appropriate isolation period prior to shipment for importation of bovids and cervids (90 days or 6 months or that the animals are tested more than twice, or with different techniques). The Biological Standards Commission sought the advice of the OIE Reference Laboratory Experts and Members of the *ad hoc* Group on Diseases of Camelids. The scientific advice to the Code Commission is as follows:

- New World Camelids are susceptible to the *M. tuberculosis* complex. The Commission recommends therefore deleting the words “under study” in the case definition.
- Regarding the isolation period, the experts advised that as clinical signs are rare, testing is therefore crucial. New World Camelids should be tuberculinised (single intradermal comparative tuberculin skin test) prescapularly and ideally serologically tested 10 to 30 days post-skin test to take advantage of the anamnestic antibody response that follows the tuberculin test in infected animals. A combination of two serological tests (e.g. ELISA and gamma-interferon assay) should be used following the tuberculin test, and *a priori* interpretation protocols established to maximise specificity or sensitivity, depending on the objectives. Such protocols offer superior risk management than isolation and clinical detection.

8.3. Aquatic Animal Health Standards Commission

8.3.1. For information: report of teleconference between the Presidents of the Aquatic Animal Health Standards and the Biological Standards Commissions

The Commission noted the report of the teleconference between the Presidents of the two OIE Specialist Commissions and the discussions on the proposed procedures for designation of OIE Reference Laboratories and on ISO 17025 accreditation (see Agenda Items 3.1 and 3.2 of this report). The Commissions would continue to collaborate on topics of mutual interest.

9. Matters of Interest for Information

9.1. Update on OFFLU¹⁹

Peter Daniels, Chair of the OFFLU Steering Committee (SC), and Tianna Brand, the OIE Contact Point for OFFLU, reported on the network's recent activities. It was noted that the SC and Executive Committee (EC) had not met in person for nearly 2 years, but that routine activities had continued. A combined meeting of the SC and EC is scheduled for the second week of September 2016 at the OIE Headquarters. The EC has continued to consult by email and by teleconferences, the most recent teleconference being in February 2016. Consistent with the OFFLU strategic directions meeting of October 2014, and with the agreement of WHO, contributions to the WHO 6-monthly vaccine strain selection meetings have continued of epidemiological information, sequence data and antigenic analyses of zoonotic avian influenza viruses reported or submitted by OFFLU contributors.

The core activities of OFFLU are organised in Technical Activities (TA) composed of networked groups of experts in the relevant subject matter from around the world. The Swine Influenza group has been active and was able to meet face to face thanks to the much appreciated funding support of CEIRS²⁰. This group monitors and reports on influenza infections in pigs, including those of human origin that in turn can reassert in swine populations and infect people in close contact with so-called variant viruses. The TA is also developing scientific systems to monitor such viruses for antigenic changes.

The equine influenza TA meets annually to review the global epidemiological situation regarding influenza infections in horses and to analyse data to detect changing antigenic profiles of these equine viruses. The results are communicated to interests producing and using equine influenza vaccines.

A new TA in epidemiology has been approved by the SC in accordance with the processes outlined in the OFFLU *modus operandi*. The EC will liaise with the designated leader of this Epidemiology TA to develop a work programme.

OFFLU continues to produce its annual report, available on the OFFLU website. A presentation regarding the importance of OFFLU was presented by Dr Gounalan Pavade and Ms Tianna Brand to the Regional Commission for Asia, the Far East and Oceania and the Regional Commission for Africa, respectively, during the OIE General Session in May, emphasising to Delegates the importance of submitting sequence data and viral isolates to the designated Reference Laboratories. This "sharing" of material is critically important so that the Reference Laboratories may function effectively in analysing regional trends for the benefit of all countries in the region as well as meeting the public health obligations of the OIE and FAO in matters relating to zoonotic influenza and potentially pandemic influenza. In another activity at the "Human–Animal Interface" the Chair of the OFFLU EC, Dr David Swayne, together with OFFLU co-authors delivered a plenary paper to the recent Options IX Influenza Conference in Chicago, organised by ISIRV²¹.

9.2. Update on the Nagoya Protocol

Dr Margot Raicek briefed the Commission on the Nagoya Protocol, passed in October 2010 by the UN Convention on Biological Diversity, which mandates the terms of Access-and-Benefit-Sharing agreements between countries for any exchange of research samples containing genetic material. Potential concerns of its application to research on animal disease and development of new veterinary medicinal products were addressed. The Commission members were asked what experience they had had with organisational preparedness for the Protocol, and what effects of it, if any, they had heard of.

¹⁹ OFFLU: Joint OIE-FAO Network of Expertise on Animal Influenza

²⁰ CEIRS: Centers of Excellence for Influenza Research and Surveillance (of the U.S. Department of Health and Human Services, National Institute of Allergy and Infectious Diseases)

²¹ ISIRV: International Society for Influenza and Respiratory Viruses

As the Protocol has only recently been implemented in the national legislation of some signatory countries, knowledge of its effects remained limited. Some members of the Commission, specifically those from countries that are party to the Protocol, discussed experience with preparations for the Protocol made by their organisations. The Commission members agreed to enquire within their organisations on these preparations and any other positions relevant to animal health, and connect the OIE to these sources.

9.3. VICH²² document: Surveillance System for Animal Health Products, The Essentials for Veterinary Pharmacovigilance

Dr Maria Szabo of the OIE Science and New Technologies Department presented the VICH document for the Commission's information. The Commission agreed that the use of the term "pharmacovigilance" in the OIE Standards, as opposed to the term "vaccinovigilance" is preferable.

9.4. VICH Concept Paper for two VICH Guidelines: (1) general principles for detection of extraneous agents in veterinary vaccines and defining the testing of seeds and materials of animal origin (2) a list of extraneous agents that need to be covered

Dr Maria Szabo presented these VICH documents. The Commission advised that VICH should be aware of *Terrestrial Manual* Chapter 1.1.9 *Tests for sterility and freedom from contamination of biological materials intended for veterinary use*, which will be proposed for adoption in May 2017. Whereas the VICH document can include more details, it must not contradict this OIE Standard.

9.5. Update on Rinderpest

The Commission was informed that current tenure of the membership of the FAO/OIE Rinderpest Joint Advisory Committee (JAC) came to an end on 31 August 2016. However, in consideration of continuing post-eradication activities, the JAC will continue with five original members being re-appointed along with two new members for another 3 years starting 1 September 2016 until 31 August 2019. The Commission was also informed that the next JAC meeting will be held from 8 to 9 November 2016 at the OIE Headquarters.

The Commission was notified that one institute that applied to be a rinderpest holding facility (Category A – rinderpest virus containing material, excluding vaccines) in 2014 was inspected in July 2016. The report and the findings as to its appropriateness to be designated as a rinderpest holding facility (Category A) will be discussed during the JAC meeting in November. It was also reported that another facility is ready for its on-site inspection; however, the timing of the inspection is still to be determined. To date there are five rinderpest holding facilities in four countries as per Resolution No. 25 adopted in May 2015.

In May 2011, the Assembly adopted Resolution No. 18 *Declaration of Global Eradication of Rinderpest and Implementation of Follow-up Measures to Maintain World Freedom from Rinderpest*. An Appendix to this Resolution, *Global Rinderpest Eradication: Guidelines for Rinderpest Virus Sequestration*, indicates that all rinderpest holding facilities be biosafety level 3 (BSL3). The JAC noted that this criterion would create practical problems for vaccine manufacturers as some vaccine manufacturing facilities do not operate at BSL3. The JAC suggested that the guidance be amended and this proposal was accepted by the Biological Standards Commission in September 2013. However, it was not taken into account in an updated Resolution adopted by the Assembly in May 2014. The Scientific Commission will be asked at its forthcoming meeting (September 2016) to update the guidance with the view of presenting it for adoption by the Assembly in May 2017. The appropriate wording from the Biological Standards Commission's report of September 2013 will be provided to the Scientific Commission to assist in amending the guidance in Resolution No. 18 (adopted May 2011).

²² VICH: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products

Finally, the Commission was informed that there is a request, from at least one rinderpest holding facility, to change the definition of rinderpest virus containing material to exclude heat-inactivated sera. The definition of rinderpest virus containing material given in both Resolution No. 18 (adopted May 2011) and Chapter 8.15 of the *Terrestrial Code*, is purposefully broad to include all possibilities. Given the pronounced desire to keep the world free from rinderpest, there is a reluctance to support changes to the definition of such materials. The Scientific Commission will also be consulted on this matter.

9.6. Request for OIE view and strategy on time temperature indicators to validate cold chain for animal vaccines

The Commission received a request from a commercial company specialising in developing time temperature indicators (TTIs) to ensure that the *Terrestrial Manual* stresses the importance of the cold chain in veterinary vaccine production and delivery. The Commission noted that the section on *Implementation of the vaccination programme* in the new draft chapter on vaccination for the *Terrestrial Code* (see Agenda Item 8.1.1 of this report) includes the recommendation that vaccination campaigns should include standard operating procedures to: “establish, maintain and monitor the fixed and mobile components of the cold chain”, and agreed that this principle should be included in the relevant chapters of the *Terrestrial Manual*. The Commission also agreed that the topic could be added to *Terrestrial Manual* Chapter 1.1.3 *Transport of specimens of animal origin* when it is updated. Should the proposed *ad hoc* Group on Transport of specimens be convened (see Agenda Item 4.3 of this report), this task could be added to its Terms of Reference.

9.7. Ongoing World Bank activity aimed at capturing key constraints impacting the availability of quality livestock medicinal products, including vaccines

Dr Franck Berthe gave a presentation on a World Bank project entitled Enabling the Business of Agriculture (EBA): Comparing Regulatory Good Practices. EBA is a tool to inform policymaking and trigger reforms. Launched in 2012, its aim is to identify legal barriers for the business of agriculture and to quantify transaction costs of dealing with government regulations for over 60 countries around the world. Within the field of livestock, data are being collected on procedures for registering veterinary medicinal products, for importing, and the legal framework and requirements regarding labelling and sales. Preliminary data include analyses of the difference in registration times for VMPs throughout the countries, an analysis of countries with provision of legal timeframes for approving products and the differences between practice and legal timeframe, and differences in labelling requirements. Once the data have been validated and analysed, it is hoped to publish the report in January or February 2017. For more information see <http://eba.worldbank.org>

10. Any Other Business

10.1. Workplan

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

10.2. Dates of the next Biological Standards Commission meeting

The Commission noted the dates for its next meeting: 7–10 February 2017; 12–15 September 2017.

11. Adoption of the Report

The report was adopted by the Commission.

.../Annexes

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 30 August – 2 September 2016

Agenda

1. Adoption of Agenda

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

- 2.1. Review chapters currently in Part 3 *Specific Recommendations* and identify any that should be moved to Part 1 *General Standards*
- 2.2. Update from February meeting: proposal to include in the *Terrestrial Manual* oral vaccination of dogs against rabies
- 2.3. Update from February meeting: suitability of the complement fixation test for diagnosis of glanders
- 2.4. Adding date of adoption/last amendment to *Code* and *Manual* chapters
- 2.5. Request to delete the target animal batch safety test from OIE Guidelines on veterinary vaccine production
- 2.6. Review of validation dossiers of diagnostic tests for two bee diseases with the aim of including them in the *Terrestrial Manual*
- 2.7. Review of two validation dossiers for diagnostic tests for rabies with the aim of including them in the *Terrestrial Manual*
- 2.8. Review of draft chapters received and their endorsement for circulation for Member Country comment

3. OIE Reference Centres

- 3.1. Further review of the approval and maintenance of Reference Centre status procedures: development of standard operating procedures
 - 3.1.1. Review of the current Reference Centre system
- 3.2. Update on Reference Laboratory quality management systems: progress towards ISO 17025 or equivalent accreditation and procedure for handling laboratories that do not intend to get towards ISO 17025 or equivalent accreditation
- 3.3. Necessity of maintaining laboratories for caprine arthritis/encephalitis and for maedi-visna
- 3.4. Other topics related to Reference Centre status: Reference Laboratories on antimicrobial resistance
- 3.5. Applications for OIE Reference Centre status
- 3.6. Changes of experts at OIE Reference Centres
- 3.7. Review of new and pending applications for laboratory twinning
- 3.8. Follow-up from last meeting: Mission to avian influenza and Newcastle disease candidate laboratory in Vladimir, Russia

4. Ad hoc Groups

Update on activities of past ad hoc Groups

- 4.1. *Ad hoc* Group on a Replacement International Standard for bovine tuberculin
- 4.2. *Ad hoc* Group on Vaccination
- 4.3. *Ad hoc* Group on High Throughput Sequencing and Bioinformatics and Computational Genomics (HTS-BCG)

5. International Standardisation/Harmonisation

- 5.1. OIE Register of diagnostic kits
 - 5.1.1. Update and review of applications
- 5.2. Standardisation programme
 - 5.2.1. Update on progress on developing guidelines for the preparation and validation of antigen standards
 - 5.2.2. Update on progress on developing guidelines for the preparation and validation of reagents for molecular tests
 - 5.2.3. Project to establish a virtual OIE Biobank: next steps
 - 5.2.4. Project to extend the list of OIE approved reference reagents

6. Follow-up from the General Session

7. Conferences, Workshops, Meetings

Past Conferences, Workshops, Meetings

- 7.1. Update on seminars for National Focal Points for Veterinary Laboratories, the PVS Pathway Laboratory Tool and quality management
- 7.2. COMPARE project
- 7.3. GMI meeting, GMI9, 23–25 May 2016 at FAO premises in Rome, Italy
- 7.4. 4th OIE Global Conference on Veterinary Education

Future Conferences, Workshops, Meetings

- 7.5. 18th WAVLD, 7–10 June 2017, Sorrento, Italy: 1-day OIE Symposium Friday 9 June: theme, programme, speakers

8. Liaison with other Commissions

- 8.1. Horizontal issues among the Specialist Commissions
 - 8.1.1. Proposed *Terrestrial Code* chapter on vaccination: review of the chapter as developed by the *ad hoc* Group
- 8.2. Terrestrial Animal Health Standards Commission
 - 8.2.1. Member Countries' comments on the hyphenation of 'foot-and-mouth disease
 - 8.2.2. Collection and processing of *in-vitro* produced embryos/oocytes from livestock and horses (Chapter 4.8.)

Follow-up from last meeting

- 8.2.3. Update on proposed definitions of OIE Standard and OIE Guideline
- 8.2.4. Expert advice on Member Country questions on the draft chapter on *Infection with bluetongue virus*
- 8.2.5. Expert advice on Member Country questions on the draft chapter on Infection with *Mycobacterium tuberculosis* complex
- 8.3. Aquatic Animal Health Standards Commission
 - 8.3.1. For information: report of teleconference between the Presidents of the AAC and the BSC

9. Matters of Interest for Consideration or Information

- 9.1. Update on OFFLU
- 9.2. Nagoya Protocol
- 9.3. VICH document: Surveillance System for Animal Health Products, The Essentials for Veterinary Pharmacovigilance
- 9.4. VICH Concept Paper for two VICH Guidelines: (1) general principles for detection of extraneous agents in veterinary vaccines and defining the testing of seeds and materials of animal origin (2) a list of extraneous agents that need to be covered
- 9.5. Update on Rinderpest
- 9.6. Request for OIE view and strategy on time temperature indicators to validate cold chain for animal vaccines
- 9.7. Ongoing World Bank activity aimed at capturing key constraints impacting the availability of quality livestock medicinal products, including vaccines

10. Any Other Business

- 10.1. Workplan
 - 10.2. Dates of the next Biological Standards Commission meeting
-

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION
Paris, 30 August – 2 September 2016

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BSC Work Plan: from September 2016

<i>Manual of Diagnostic Tests and Vaccines for Terrestrial Animals</i>
Circulate the chapters approved by the BSC to Member Countries for first-round comment
Remind authors of the chapters identified previously for adoption in 2017 but not yet received
Commission the chapters for proposal for adoption in 2018 or 2019
Move current title of Part 3 <i>Specific Recommendations</i> to Part 2 (current Part 2 OIE Listed Diseases and Other Diseases of Importance becomes Part 3)
Review guidelines (now chapters) in Part 3 and identify which should be moved to Part 1
Activities
Laboratories: guidelines for applicants, SOPs for approval and maintenance of Collaborating Centre status
Further develop a strategic plan for the role of the OIE Reference Centre network, in liaison with the Aquatic Animals Commission
Review of annual reports of OIE Reference Laboratories to assess interpretation of the question asked and possible need to rephrase or refine the template
Contact identified OIE Reference Laboratories to ask if they agree to having their reference reagents evaluated with the view to becoming OIE-approved standards
Guidelines for the preparation and validation of reagents for molecular tests
Guidelines for the preparation and validation of antigen standards
Project to develop Replacement International Standard Bovine Tuberculin
OIE Platform for the Collection and Management of Genomic Sequences in Animal Health
<i>Ad hoc Groups</i>
Virtual OIE Biobank
Transport of specimens
Meetings
WAVLD, June 2017, Sorrento, Italy

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