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REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 11–12 September 2014

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The OIE Biological Standards Commission (the Commission) met at the OIE Headquarters from 11 to 12 September 2014. Dr Bernard Vallat, Director General of the OIE, welcomed the Members of the Commission: Prof. Vincenzo Caporale, President, Dr Hualan Chen, Vice-President, Dr Rodolfo Rivero, Vice-President, Dr Beverly Schmitt, Dr Paul Townsend and Dr Peter Daniels, Members of the Commission.

Referring to the OIE global network of 296 Reference Laboratories and Collaborating Centres, Dr Vallat expressed the OIE's commitment to ensuring the excellence of the services provided and compliance with quality standards so as to ensure that the network continues to contribute to the OIE's scientific integrity and to support the global community. The newly proposed laboratory visits will help to monitor the performance of the Reference Centres to verify that they are fulfilling the mandate and achieving the expected standard. For developing countries, and even for other Member Countries, tools such as the PVS[1] Pathway: Laboratory Mission and Methodology, the OIE Twinning Programme, and Focal Points for Veterinary Laboratories will contribute to building national capacities. National governments need to support their national reference laboratories to ensure appropriate diagnostic capacity and so that OIE Reference Centre status could be achieved in a greater number of countries.

Updating the Commission on news from the OIE Headquarters, Dr Vallat introduced Dr Brian Evans, newly appointed Deputy Director General of the OIE and Head of the Scientific and Technical Department, also overseeing the International Trade Department and the Animal Health Information Department. This will improve internal coordination between these departments and harmonisation of the standard-setting process to produce better global standards.

Other modernising activities that the OIE is engaging in include the new project to incorporate information on genetic sequences into the OIE WAHIS[2] database. The Reference Centre network is key to the success of this initiative, which will be presented by the President of the Commission at the Third Global Conference of the OIE Reference Centres, Seoul, Korea (Rep. of), 14–16 October 2014.

In response to a comment from Prof. Caporale that the Commission would like to be involved in issues such as the Laboratory Focal Point training, Dr Vallat pointed out that the Terms of Reference for Focal Points for Veterinary Laboratories include the task of preparing comments for the Delegate on all relevant OIE draft standards or guidelines, in particular standards to be published in the *Terrestrial Manual*, and to advise the Delegate on the national implementation of adopted standards as well as on topics relating to OIE Reference Laboratory activities. To assist the Focal Points, the OIE will organise information sessions in all five OIE regions and members of the Commission from the region concerned could be invited to participate in these sessions. Prof. Caporale welcomed the proposal. He believed that it is essential for the Commission to liaise with these Focal Points for the benefit of the Reference Centre network.

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1 PVS: Performance of Veterinary Services
2 WAHIS: World Animal Health Information System

Finally Dr Evans addressed the Commission. He said that the work of the three departments he oversees focuses on scientific excellence, the backbone of the OIE standards. He foresees an increasing role for the Commission in areas such as emerging and priority diseases, diagnostics, antimicrobial resistance, vaccines, training of Focal Points for Veterinary Laboratories, and the PVS Laboratory missions. In the year leading to elections of the Specialist Commissions, Dr Evans stressed the necessity of having the commitment of members of the Commission to ensure that the work is done in a timely manner. The support provided by the OIE to the Commission must be reciprocal. The legacy of this Commission would be, amongst others, the advances made in the area of new technologies.

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 *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*), Prof. Steven Edwards.

2.1. Decision on proposals of the Enlarged Bureau Group

The Commission reviewed the outcome of the Enlarged Bureau Group (EBG) meeting, which was held on 10 September 2014. The Commission approved the EBG Group's proposals (see Annex 3). Twelve chapters and the glossary were approved for circulation to Member Countries for first-round comment and eventual proposal for adoption by the Assembly in May 2015.

The new chapter 1.1.8 on *Minimum requirements for vaccine production facilities* (which had been renamed as *Recommendations for manufacturing sites for veterinary vaccines*) was put on hold for further consultation with the authors. The latter would to be requested to separate the information into requirements for manufacturing sites (chapter 1.1.8) and quality control of vaccines (chapter 1.1.9)

Both the EBG and Commission members agreed to review Chapter 1.1.3 *Biosafety and biosecurity in the veterinary microbiology laboratory and animal facilities* and to send their comments to the OIE by the end of October 2014. The chapter will be amended accordingly for review at the January 2015 meeting with the aim of sending it for second-round comment and eventual proposal for adoption by the Assembly in May 2015

A new draft chapter entitled *Standards for high throughput sequencing, bioinformatics and computational genomics* was put on hold. This text is a blueprint for the Commission's future work in this area. The concept will be discussed at the Global Conference of OIE Reference Centres (Korea, October 2014; see item 7.1) and the *ad hoc* Group will then further elaborate the text.

Chapter 2.9.12 *Zoonoses transmissible from non-human primates* was amended. It would be sent for first-round Member Country comment while further consultation with the OIE Scientific Commission for Animal Diseases and the Terrestrial Animal Health Code Commission was also sought.

All remaining chapters that had not been identified for update since at least 2010 along with Chapter 1.1.4 *Quality management in veterinary testing laboratories* were added to the list of chapters identified for proposal for adoption in May 2016.

2.2. Use of different chapter names in the *Terrestrial Code* and the *Terrestrial Manual*

Member Countries had continued to comment that the disease names used in the *Terrestrial Animal Health Code* texts (*Terrestrial Code*) follow the format "Infection with [pathogen name]" while the *Terrestrial Manual* does not follow this format. The Consultant Editor has prepared a text, endorsed by the Commission, explaining the Commission's position: this discrepancy arises from the fact that the

Terrestrial Manual covers diseases rather than infections. The text would be provided to the Council with the request to allow the different approaches to be maintained while providing a cross-reference key between the two systems. The document can be found at Annex 4 for information.

2.3. Possibility of posting draft *Terrestrial Manual* chapters on the OIE website for all interested parties

The European Commission had commented that the draft *Terrestrial Manual* chapters are the only OIE standards not publicly available on the OIE website at draft stage before adoption. The Commission was in favour of posting the draft texts on the OIE website, but acknowledged that the final decision should be taken by the OIE.

2.4. Adding the European Directorate for the Quality of Medicines to the mailing list for comment on draft *Terrestrial Manual* chapters

The European Directorate for the Quality of Medicines (EDQM) had requested that it be added to the mailing list to receive draft *Terrestrial Manual* chapters for comment as one of several proposals for improving cooperation between it and the OIE. The EDQM and the OIE have shared interests in the area of quality control of pharmaceutical products for veterinary use and the harmonisation of regulatory requirements. Again, the Commission was in favour of posting the draft texts on the OIE website, but acknowledged that the final decision should be taken by the OIE.

3. OIE Reference Centres

In view of the growing number of OIE Reference Laboratory applications and designations, the President of the Commission stressed the importance of assessing and monitoring the performance of the laboratories. He proposed that all future applicants should already be a national reference laboratory for the disease in question, before submitting an application for OIE Reference Laboratory status. Applicants should already be active in the region organising training programmes or conferences. Where there are existing OIE Reference Laboratories for the same disease, these could be consulted during the review process.

Given that quality management systems are essential, the Commission agreed that all OIE Reference Laboratories must be accredited to ISO 17025 or equivalent. This requirement would apply to all new applicants; existing OIE Reference Laboratories that are not yet accredited would be given a 3-year deadline to achieve this standard. Laboratories would be asked in the annual report to upload a copy of their accreditation certificates.

The *Guidelines for applicants for OIE Reference Laboratory status* amended to take account of these proposals, would be reviewed by the Commission at its next meeting and, if approved by the Commission and then by the Council, would be uploaded onto the OIE website.

3.1. Applications for OIE Reference Centre status

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

OIE *Reference Laboratory for Tularemia*
Laboratory of Zoonotic Bacteriology and Mycoplasmology, Institute for Veterinary Medical Research, Centre for Agricultural Research, Hungarian Academy of Sciences, Hungária krt. 21, Budapest 1143, HUNGARY
Tel.: (+36-1) 467.40.60; Fax: (+36-1) 467.40.76
E-mail: m.gyuranecz@gmail.com; gyuranecz@vmri.hu
web: www.vmri.hu/index_eng.htm
Designated Reference Expert: Dr Miklós Gyuranecz.

An application had been received from a European country for the designation of two OIE Reference Laboratories: for bovine spongiform encephalopathy (BSE) and for scrapie. The Commission requested more information on the laboratories' international activities, evidence of their provision of training and consultancy services internationally, and proof of their accredited quality management system. Another application had been received from a European country for the designation of an OIE Reference Laboratory for Infectious equine anaemia. The Commission requested more information on

publications in peer-reviewed journals on the disease in question, on the laboratory's international activities, evidence of provision of training and consultancy services internationally, and copies of its ISO 17025 accreditation certificates.

Following completion of a twinning project, an application had been received from a European country for an OIE Reference Laboratory for Brucellosis. The Commission would seek the advice of the parent laboratory. Evidence of the institute's accredited quality management system would also be sought.

An application had been received from a country in the Americas for the designation of an OIE Reference Laboratory for antimicrobial resistance. Since the new mandate had been adopted in May 2012, OIE Reference Laboratories were designated for named diseases only (the introductory text to OIE Reference Laboratories on the OIE webpages, which continues to mention "topics" would be corrected). The Commission recommended that the application would thus better fit the mandate of an OIE Collaborating Centre and invited the applicant to re-apply. As one of the existing Centres in the region also provides services in the area of antimicrobial resistance, the applicant will eventually be invited to form a consortium with this Centre. There is currently an OIE Reference Laboratory for Antimicrobial resistance in Europe, which had been designated before the new mandate. Although it had been agreed not to apply the new mandate retroactively, this laboratory would also be invited to apply for OIE Collaborating Centre status and to liaise with the existing OIE Collaborating Centre for Veterinary Medicinal Products in France with the aim of forming a consortium.

At a previous meeting, a European country had submitted an application for a Reference Laboratory for Q fever. The application was put on hold pending receipt of more information on research and international activities and a full list of its recent publications. Reviewing the supplementary information that had been received, the Commission felt that there was a lack of evidence of leadership: all applicants should demonstrate that they are a reference point for the disease in the region in question, they should organise rather than just participate in proficiency tests, and they should be providing confirmatory diagnostic services, reference materials, etc., internationally. Until the applicant could provide such evidence, and of course, evidence of their accredited quality management system, the Commission could not approve the application.

An application that had been received from a country in the Asia, the Far East and Oceania Region for a Reference Laboratory for Equine piroplasmosis had been put on hold by the Commission at a previous meeting awaiting information on the laboratory's compliance with an internationally recognised quality management system (ISO 17025 or equivalent). The Commission reviewed the supplementary information received; although the laboratory has begun to implement a quality management system, it does not yet comply with nor is it accredited to such a system. The Commission agreed that once it achieves accreditation, it could be designated as an OIE Reference Laboratory; the time line envisaged is 3–5 years.

Following completion of a twinning project, two applications had been received from an African country for Reference Laboratories for African horse sickness and Bluetongue. The Commission requested more information on the laboratories' international activities and quality management system. Since the last meeting, the Commission had received assurances from the Parent laboratory of the proficiency and performance of the laboratories and agreed that both laboratories could be designated as OIE Reference Laboratories once it receives evidence of accreditation to an internationally recognised quality management system (ISO 17025 or equivalent).

Applications had been received from a country in the Asia, the Far East and Oceania Region for OIE Reference Laboratories for cysticercosis and for trichinellosis. The Commission reviewed the information it had requested on the laboratories' international activities, on their ability to receive samples from abroad, their quality management system, and on their legal and budgetary provisions specifically for the fulfilment of the OIE mandate. The Commission noted that although the institution had begun to implement a quality management system, it does not yet comply with nor is it accredited to such a system. The Commission agreed that once the institution achieves accreditation to ISO 17025 or equivalent, they could be designated as OIE Reference Laboratories.

3.2 Changes of experts at Reference Centres

The Delegate of the Member Countries concerned had submitted to the OIE the following nomination for a change of expert at two OIE Reference Laboratories. The Commission recommended their acceptance:

Contagious agalactia
Dr Roger Ayling to replace Dr Robin Nicholas at the Animal Health and Veterinary Laboratories Agency (AHVLA) in Weybridge, UNITED KINGDOM.

Anaplasma spp. and *Babesia* spp.
Dr Juan Joel Mosqueda Gualito to replace Dr Fernando Parrodi López at the Centro Nacional de Servicios de Constatación en Salud Animal (CENAPA) en Morelos, MÉXICO.

3.3. Specific issues related to Reference Centres: laboratory visits

At its last meeting, the Commission developed a structured approach to monitoring Reference Centres so that under-performing or other problematic ones could be dealt with in a fair, timely, and coherent manner. The decision tree on how to evaluate and react to under-performing or problematic OIE Reference Centres, based on the Terms of Reference, was appended to the report of the last meeting, and endorsed by the Director General.

The next task was to draw up the practical details of how these laboratory visits would take place. Following discussions, the Commission agreed that the:

- visits should be carried out by a maximum of two experts;
- visits should be a maximum of 3 days long;
- laboratory's quality management system along with the specific issues identified using the decision tree would be the main focus.

As this procedure could only be followed for laboratories that were already experiencing difficulties, the Commission proposed that random laboratory visits could also be carried out in association with the biennial conferences of the OIE Regional Commissions: one or two laboratories in the region could be chosen at random, an audit could be carried out and the results reported back to the Regional Commission at its Conference. This specific proposal would be submitted to the Council.

3.4. Feedback on Reference Laboratory quality management systems

Dr Min-Kyung Park, Scientific and Technical Department of the OIE, joined the meeting for this agenda item.

Upon analysis of the reports of OIE Reference Laboratory activities in 2013, a number of laboratories that did not have an internationally recognised quality management system and were not in the process of acquiring one were identified. At its last meeting in February 2014, the Commission drafted a letter requesting that these laboratories confirm that they accept the concept of compliance with an appropriate laboratory quality management system.

The Commission reviewed the replies, and agreed to further follow-up these laboratories: laboratories that indicated that they have the equivalence of ISO 17025 from a national or regional accreditation body would be requested to submit the certificates so the Commission could verify the competence of the accreditation body; laboratories that have indicated that they are in the process of achieving ISO 17025 or equivalent would be allowed 3 years to achieve accreditation.

In the next reporting cycle, all OIE Reference Laboratories that indicated that they have ISO 17025 accreditation or equivalent though a national or regional accreditation body, would be requested to upload their certificates. Those laboratories that are not able to meet these requirements within 3 years may lose their OIE Reference Laboratory designation as they would not be quality assured to an appropriate standard.

The importance of a quality management system, the inclusion of uploading the certificates in the on-line annual reporting system, and the proposal to delist those Reference Laboratories that do not maintain a quality system would be highlighted at the Third Global Conference of the OIE Reference Centres (see also item 7.1).

3.5. Review of new and pending applications for laboratory twinning projects

Dr Gounalan Pavade, Scientific and Technical Department of the OIE, updated the Commission on the OIE Laboratory Twinning programme. As of August 2014, 19 projects have been completed, 32 are underway and 15 are approved due to start based on fund availability. Nine Candidate Laboratories have applied to become OIE Reference Laboratories and five of these have been approved.

Three twinning proposals, namely between the United Kingdom and India for rabies, between France and Yemen for honey bee diseases, and between the United Arab Emirates and India for camelpox were presented for the Commission's technical input.

The Commission observed that training related to the laboratory quality management system, namely ISO 17025 or equivalent, should be integral to all twinning projects. On the honey bee disease project, the Commission observed that the main aim of the project is for the capacity building of the Yemen laboratory and sustainability should be guaranteed after the twinning project is completed.

4. *Ad hoc* Groups

- **Past *ad hoc* Group meetings: reports for adoption**

4.1. Report of the Meeting of the *ad hoc* Group on Diseases of Camelids, 1–3 April 2014

The Commission adopted the report, which can be found at Annex 5 of this report.

One of the parallel sessions that will be held during the Third Global Conference of the OIE Reference Centres (see also item 7.1) will be on diseases of camelids.

- **Future *ad hoc* Groups: scheduling and drafting ToRs**

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

Prof. Caporale presented a *Pilot Project for the Creation of an OIE Platform for the Collection and Management of Genomic Sequences in Animal Health*. The principal objective is to develop a comprehensive approach and an *open access* database to collect, store and share sequence information relating to animal diseases and food safety. Sequence data, in particular those referring to the whole genomes, are very relevant not only to epidemiological analysis but also to infection pathogenesis and immunity. It can be envisaged that genome sequence databases of pathogens of animal health significance will have an ever-increasing role in veterinary medicine, especially if enriched by related metadata. The pilot project also includes the development of standards for the management of HTS-BCG for inclusion in the OIE *Terrestrial Manual*.

In drafting the document, Prof. Caporale consulted the OIE Administration, Logistics and Publications Department and the OIE Animal Health Information Department, and the OIE Collaborating Centre for Viral Genomics and Bioinformatics, University of Glasgow Centre for Virus Research, United Kingdom. The Commission approved the pilot project. Once the OIE approves it, the project will be presented at the Third Global Conference of the OIE Reference Centres (see also item 7.1), as it is envisaged to use the network's competence and expertise in developing policies and practices for the management and use of sequence information. The platform must be of use to the network's needs so their input is essential in this, the developmental stage. The OIE Reference Laboratories for aquatic diseases will also be included in the project.

Following the Conference, the *ad hoc* Group could then meet at the OIE Headquarters to begin to work on some of the components of the project. The provisional date for the meeting is November 2014.

5. International Standardisation/Harmonisation

- **Diagnostic tests**

5.1. OIE Register of diagnostic kits: update and review of applications

Dr François Diaz, Scientific and Technical Department of the OIE, presented the abstract sheet of the validation data of the Newcastle Disease Virus antibody detection ELISA, which was included in the OIE register following the vote of the World Assembly of Delegates in May 2014. The abstract sheet was drafted in collaboration with the diagnostic kit manufacturer, and was endorsed by the Commission and will be put on the OIE website on the page dedicated to the OIE register.

He updated the Commission on the current status of the dossiers submitted according to the OIE Procedure for Registration of Diagnostic Kits. In particular, he informed the Commission that a new application form for a diagnostic kit had been submitted to the OIE. The Commission proposed experts for the future panel in charge of the evaluation.

He informed the Commission that the evaluation of the dossier on "BOVIGAM® *Mycobacterium bovis* Gamma interferon test kit for cattle" had been completed. Based on the final report from the expert evaluation panel, the Commission provided a favourable opinion for the inclusion in the OIE register of this diagnostic kit with the following purposes:

BOVIGAM® *Mycobacterium bovis* Gamma interferon test kit for cattle is fit for the detection of cell mediated immune response to infection with *Mycobacterium bovis* and other mycobacteria belonging to the tuberculosis complex on analysis of whole blood specimens in cattle, buffalo (*Syncerus caffer*), goat and sheep (provisionally) for the following purposes:

1. Historical freedom;
2. Re-establishment of freedom after outbreaks;
3. Certify freedom from infection or agent in individual animals or products for trade/movement purposes;
4. Eradication of infection from defined populations;
5. Confirmatory diagnosis of suspect or clinical cases (includes confirmation of positive screening test);
6. Estimate prevalence of infection to facilitate risk analysis (surveys/herd health schemes/disease control);
7. Ancillary test for eradication of tuberculosis.

Further to the decision of the OIE Director General, this would be proposed for adoption by the World Assembly of Delegates at the General Session in May 2015.

5.2. Standardisation programme: future directions

During the Third Global Conference of the OIE Reference Centres (see also item 7.1), two presentations will be given on the Commission's standardisation programme: one, to be given by Dr Maura Ferrari of the OIE Collaborating Centre for Veterinary Biologicals Biobank in Brescia, Italy, on the results of a survey to determine the biological resources and standard reference reagents held in OIE Reference Centres that can be shared among the OIE Member Countries, and the second, to be given by Dr Paul Townsend, Member of the Biological Standards Commission, on the challenges faced by the Reference Laboratories fulfilling their mandate to produce and supply International reference material. The Commission will set priorities based on the outcome of discussions from the Conference.

5.3. Follow-up request to validate C-ELISA for epizootic haemorrhagic disease

Following a request from the Scientific Commission for Animal Diseases, the Commission had asked the OIE Reference Laboratory for epizootic haemorrhagic disease (EHD) to coordinate a study with the Reference Laboratories for Bluetongue to validate the competitive enzyme-linked immunosorbent assay (C-ELISA) for EHD. The expert had responded that he had already worked on validating the assay and had provided the validation data. At its last meeting the Commission requested that these data be given to the OIE Reference Laboratories for Bluetongue for an opinion.

The Commission reviewed the responses received from the OIE experts and determined that the assay was not yet fully validated according to the OIE standard. The EHD expert would be asked to continue to work on validating the assay in coordination with the OIE Reference Laboratories for Bluetongue.

5.4. Update on African horse sickness ring trial

Dr Susanne Munstermann, Chargée de projet, Scientific and Technical Department of the OIE, informed and sought the advice of the Commission about a ring trial that is being organised by the OIE Reference Laboratories for African horse sickness (AHS) to generate validation data on polymerase chain reaction protocols from the *Terrestrial Manual*.

The Commission stated that this activity is important; it is useful to have reproducibility. Proficiency testing is also an integral part of the mandate for OIE Reference Laboratories. The Commission proposed that the panels used in the trial be enlarged to be made less homogenous so that specificity could also be assessed. The members of the *ad hoc* Group on Validation of Diagnostic Assays could peer review the validation data for all the protocols once available.

6. Follow-up from the General Session

6.1. Follow-up from the General Session

The Commission noted that the three resolutions it had proposed had been adopted unanimously by the World Assembly at the General Session in May 2014:

- Resolution No. 27: Adoption of the new or revised texts for the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
- Resolution No. 29: Register of Diagnostic Kits Validated and Certified by the OIE
- Resolution No. 41: Designation of OIE Reference Laboratories for terrestrial animal diseases

A fourth resolution, Resolution No. 28: Designation of OIE Collaborating Centres, had also been adopted.

The Commission noted the discussions that took place following Prof. Caporale's presentation on the activities of the Commission during the past year.

7. Conferences, Workshops, Meetings

7.1. Third Global Conference of the OIE Reference Centres, Seoul, Korea (Rep. of), 14–16 October 2014

The Conference was now in the final stages of preparation. The programme had been finalised and is available on the Conference website, which is accessible to invited experts. The abstract book is near completion. There would be parallel sessions on: New diagnostic technologies, Aquatic animal diseases, Horse diseases, Animal welfare, and Diseases of camelids. The Commission approved preliminary programmes for the parallel sessions along with items proposed for the Conference's final recommendations.

7.2. GMI (Global Microbial Identifier) project

Prof. Vincenzo Caporale has been nominated as the OIE Representative on the GMI Steering Committee. He had been invited to the 7th Global Microbial Identifier (GMI) meeting in Sand Hutton, York, United Kingdom from 11 to 12 September 2014, but presided over the OIE Biological Standards Commission instead. One of the founding members of GMI would participate in the parallel session on New diagnostic technologies that would be held during the Third Global Conference of the OIE Reference Centres (see also item 7.1); the OIE could thus be updated on the outcome of the GMI meeting.

7.3. WAVLD[3], 15–18 June 2015, Saskatoon, Canada: 1-day OIE Seminar on diagnostics: Wednesday 17 June 2015

The Commission proposed that the theme of the 1-day OIE Seminar that would be held during the WAVLD Symposium would be: *New Diagnostic Technologies and International Standard Stetting*. The Commission would review the proposed programme and speakers at its next meeting.

8. Liaison with other Commissions

8.1. Gaps identified in WAHIS: harmonisation of definitions for all types of vaccines currently in use

Dr Paula Cáceres Soto, Head of the OIE Animal Health Information Department, joined the meeting. She explained the need to harmonise terminology used in the OIE documentation (guidelines for annual disease information reports, the *Terrestrial Code*, the *Terrestrial Manual*, etc.), for example the definitions of the types of vaccines currently in use. The Commission stated that it is currently reviewing the *Terrestrial Manual* chapters on vaccines including the classification of vaccine types. Based on this work, the Commission would cooperate to harmonise this terminology.

8.2. Scientific Commission for Animal Diseases (Scientific Commission)

Matters from the Scientific Commission to the Biological Standards Commission

8.2.1. Report of the Meeting of the *ad hoc* Group on MERS-CoV Infection in Animals, 15–17 July 2014

The Commission noted the report of the Meeting of the *ad hoc* Group on MERS-CoV Infection in Animals. This *ad hoc* Group had reached the same conclusion as the *ad hoc* Group on Diseases of Camelids. The Commission agreed to take the opportunity offered by the Third Global Conference of the OIE Reference Centres to urge OIE Reference Laboratories for certain diseases such as rabies, brucellosis, tuberculosis, etc., to collaborate to develop reliable diagnostic tests for camelids.

[3] WAVLD: World Association of Veterinary Laboratory Diagnosticians

8.2.2. Report of the Meeting of the *ad hoc* Group on Diseases of Camelids, 1–3 April 2014 (reply to SCAD re: tuberculosis)

Previously, the Scientific Commission had forwarded two questions to the *ad hoc* Group on Diseases of Camelids regarding the inclusion of camelids in the *Terrestrial Code* chapter as species of epidemiological significance for tuberculosis, and the exclusion of camelids from the *Terrestrial Code* chapter as there is no validated or prescribed test in the *Terrestrial Manual.*

The *ad hoc* Group was of the opinion that only New World camelids should be included as species of epidemiological significance for tuberculosis in the *Terrestrial Code.* Regarding the validation of diagnostic tests, the *ad hoc* Group stated that to date no test method has been validated in New World camelids and concluded that, even if the New World camelids are species of epidemiological significance for tuberculosis, they should be excluded for the present for trade purposes in the *Terrestrial Code* chapter on tuberculosis.

8.2.3. Proposal to amend the *Terrestrial Manual* chapter on Foot and Mouth Disease (FMD)

At its last meeting, the Scientific Commission had forwarded a request from an *ad hoc* Group to amend the *Terrestrial Manual* chapter on FMD to include the requirement that vaccine manufactures provide, on request of the vaccine purchaser, post-vaccination sera produced during final product batch testing for potency. This could be used to calibrate the locally used tests for measuring population immunity.

The Biological Standards Commission had reviewed the expert opinion it received and decided to seek further input to find a way that the proposal could be practically implemented.

8.3. Terrestrial Animal Health Standards Commission

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

8.3.1. Infection with avian influenza viruses

The Code Commission had received a comment from a Member Country proposing that Chapter 10.4 Infection with avian influenza viruses of the *Terrestrial Code* should state that influenza A viruses has 17 haemagglutinin and 10 neuraminidase subtypes rather than 19 and 9 as currently stated.

The Biological Standards Commission agreed to seek the advice of one of the OIE Reference Laboratories for this disease.

Follow-up from last meeting for information

8.3.2. The removal of details on diagnostic tests and their use from the *Terrestrial Code* and inclusion in the *Terrestrial Manual*

At its last meeting, the Biological Standards Commission expressed its view that details on diagnostic tests and their use and interpretation should be included in the *Terrestrial Manual* only and should not be included in the *Terrestrial Code*.

The Code Commission agreed to remove any such text from the *Terrestrial Code* only once it had been adopted and included in the *Terrestrial Manual*.

Regarding the schematic representation of laboratory tests for determining evidence of FMD virus infection through or following serological surveys that is included in the chapter on FMD in the *Terrestrial Code*, the Biological Standards Commission determined that the information is also part of a surveillance scheme and thus might need to be in the *Terrestrial Code*. The Commission pointed out that the necessity to carry out confirmatory tests further calls into question the concept of prescribed tests.

Further discussions are necessary between the Specialist Commissions to determine what should be included in each of the publications.

8.3.3. Tests that can be used to define an infection with *Burkholderia mallei* (glanders)

The Biological Standards Commission agreed with the Scientific Commission that text in the draft chapter on glanders for the *Terrestrial Code* that included details of which diagnostic tests to use and how they should be interpreted to define a case of glanders, should rather be in the *Terrestrial Manual*. The text had been incorporated by the OIE Reference Laboratory experts into the chapter, defined as a *Diagnostic pathway to confirm a case of glanders* rather than as a case definition. The draft *Terrestrial Manual* chapter would be circulated to Member Countries for first-round comment and eventual proposal for adoption by the Assembly in May 2015.

9. Matters of Interest for Information

9.1. Update on OFFLU[4]

Dr Pavade updated the Commission on OFFLU. OFFLU held an Executive Committee meeting in April 2014 to review and coordinate the progress of ongoing technical activities. The Committee suggested to plan a strategy meeting in October 2014 to discuss and decide what OFFLU should do in the next 5 years.

At the February 2014 WHO[5] vaccine composition meeting, the OFFLU network contributed H5 sequences and H9 sequences to help WHO with pandemic preparedness.

In March 2014, the OFFLU swine influenza virus group experts gathered at the University of Minnesota, Minneapolis, USA for its fourth annual technical meeting. The experts exchanged research findings and data on the global influenza situation in swine.

In April 2014, OFFLU, in collaboration with STAR-IDAZ[6] developed a strategic agenda for animal influenza research. Sixty key experts from the field of influenza were invited to this consultation at the OIE Headquarters in Paris, where they provided inputs and identified the research priorities for their sectors.

The OFFLU annual newsletter for 2013, compiling the achievements for the year, was prepared and circulated widely.

9.2. OIE PVS Laboratory Mission Manual: final version of manual and implications for potential training programmes

The Commission agreed that this is an important topic and asked that it be brought forward to the next meeting. In the meantime, the members agreed that they would provide critical comments on the PVS Laboratory Mission Manual provided. The Commission requested some reports of completed laboratories missions along with the corresponding PVS mission reports.

9.3. Fourth International Conference on Bluetongue, Teramo, Italy, 5–7 November 2014

The Commission noted that this Conference was taking place.

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

5 WHO: World Health Organization

6 STAR-IDAZ: Global Strategic Alliances for the Coordination of Research on the Major Infectious Diseases of Animals and Zoonoses

10. Any Other Business

10.1. Work plan and activities (as of September 2014)

The updated work plan was agreed and can be found at Annex 6.

10.2. Shortcut for the registration of equine influenza vaccines

Prof. Caporale explained that at the meeting of the OIE Expert Surveillance Panel on Equine Influenza Vaccine Composition in March this year, the OIE Reference Laboratories agreed that information on the strains that should be put into equine influenza vaccines could be included in the *Terrestrial Manual* chapter. The *Terrestrial Manual* is an international standard.

10.3. EU project: "MediLabSecure" (2014–2017)

The Commission noted the project.

10.4. Correspondence re: nomenclature for BTV-25 (Toggenburg Orbivirus)

The Commission noted this correspondence.

10.5. Dates of the next Biological Standards Commission meeting

The Commission noted the dates for its next meetings: 27–29 January 2015.

11. Adoption of the Report

The report was adopted by the Commission.

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.../Annexes

Annex 1

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 11–12 September 2014

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Agenda

1. Adoption of the Agenda

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

2.1. Decision on proposals of the Enlarged Bureau Group
2.2. Use of different chapter names in the *Terrestrial Code* and the *Terrestrial Manual*
2.3. Possibility of posting draft *Terrestrial Manual* chapters on the OIE website for all interested parties
2.4. Adding the European Directorate for the Quality of Medicines to our mailing list for comment on draft *Terrestrial Manual* chapters

3. OIE Reference Centres

3.1. Applications for OIE Reference Centre status
3.2. Changes of experts at OIE Reference Centres
3.3. Specific issues related to Reference Centres: laboratory visits
3.4. Feedback on Reference Laboratory quality management systems
3.5. Review of new and pending applications for laboratory twinning

4. *Ad hoc* Groups

- **Past *ad hoc* Group meetings: reports for adoption:**

4.1. Report of the Meeting of the *ad hoc* Group on Diseases of Camelids, 1–3 April 2014

- **Future *ad hoc* Groups: scheduling and drafting ToRs**

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

5. International Standardisation/Harmonisation

- **Diagnostic tests**

5.1. OIE Register of diagnostic tests: update and review of applications
5.2. Standardisation programme: future directions (update on presentations from the Korea Conference)
5.3. Follow-up request to validate C-ELISA for epizootic haemorrhagic disease
5.4. Update on African horse sickness ring trial

6. Follow-up from the General Session

6.1. Follow-up from the General Session

7. Conferences, Workshops, Meetings

7.1. Global Conference of the OIE Reference Centres, Seoul, Korea, 14–16 October 2014
7.2. GMI (Global Microbial Identifier) project
7.3. WAVLD, 15–18 June 2015, Saskatoon, Canada: 1-day OIE Symposium on diagnostics: Wednesday 17 June 2015

8. Liaison with other Commissions

8.1. Gaps identified in WAHIS: harmonisation of case definitions and definitions for all types of vaccines currently in use

8.2. Scientific Commission for Animal Diseases

8.2.1. Report of the Meeting of the *ad hoc* Group on MERS-CoV Infection in Animals, 15–17 July 2014
8.2.2. Report of the Meeting of the *ad hoc* Group on Diseases of Camelids, 1–3 April 2014 (reply to SCAD re: tuberculosis)
8.2.3. Proposal to amend the *Terrestrial Manual* chapter on Foot and Mouth Disease (FMD)

8.3. Terrestrial Animal Health Standards Commission

8.3.1. Infection with avian influenza viruses
8.3.2. The removal of details on diagnostic tests and their use from the *Terrestrial Code* and inclusion in the *Terrestrial Manual*
8.3.3. Tests that can be used to define an infection with *Burkholderia mallei* (glanders)

9. Matters of Interest for Information

9.1. Update on OFFLU
9.2. OIE PVS Laboratory Mission Manual: final version of manual and implications for potential training programmes
9.3. Fourth International Conference on Bluetongue, Teramo, Italy, 5–7 November 2014

10. Any Other Business

10.1. Workplan and activities (as of September 2014)
10.2. Shortcut for the registration of equine influenza vaccines
10.3. EU project: “MediLabSecure” (2014–2017)
10.4. Correspondence re: nomenclature for BTV-25 (Toggenburg Orbivirus)
10.5. Dates of the next Biological Standards Commission meeting: 27–29 January 2015

11. Adoption of the report

Annex 2

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION
Paris, 11–12 September 2014

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MEETING OF THE ENLARGED BUREAU GROUP OF THE OIE BIOLOGICAL STANDARDS COMMISSION
Paris, 10 September 2014

Status of the chapters identified for update and proposal for adoption in 2015

No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
1.1.1.	Management of Veterinary Laboratories	**RECEIVED**	Amended and approved to be sent to Member Countries (MCs) for first-round comments	Agreed
1.1.3	Biosafety and biosecurity in the veterinary microbiology laboratory and animal facilities	**RECEIVED**	EBG and BSC to send their comments to OIE by end of October 2014. Chapter will be amended accordingly for review at January 2015 meeting.	Agreed
1.1.7.	Tests for sterility and freedom from contamination of biological materials	Not yet received	Awaiting text	
1.1.6.	Principles of veterinary vaccine production (re-write as a standard)	Collaborating Centre for Veterinary Medicinal Products has undertaken to draft the texts in collaboration with other OIE Centres working on vaccines: **RECEIVED 1.1.6 and 1.1.8; the latter incorporates chapter 1.1.9**	Amended and approved to be sent to MCs for first-round comments. Text referring to VICH to be reworded.	Agreed
1.1.8.	Minimum requirements for vaccine production facilities: renamed as *Recommendations for manufacturing sites for veterinary vaccines*		Approval deferred. Chapter authors to be requested to separate the information into requirements for manufacturing sites (chapter 1.1.8) and quality control of vaccines (chapter 1.1.9).	Agreed
1.1.9.	Quality control of vaccines		See above	
1.1.10.	International standards for vaccine banks	**RECEIVED**	Amended and approved to be sent to Member Countries (MCs) for first-round comments	Agreed (February 2014)
1.1.11	Standards for high throughput sequencing, bioinformatics and computational genomics	**RECEIVED**	On hold. Text is a blueprint for the Commission's future work in this area. Concept to be discussed at the Global Conference of OIE Reference Centres (Korea, October 2014) and the *ad hoc* Group will then further elaborate the text	Agreed
2.1.4.	Echinococcosis/Hydatidosis	Not yet received	Awaiting text	
2.1.6.	Heartwater	Not yet received	Awaiting text	

No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
2.1.12.	Q fever	**RECEIVED**	Amended and approved the diagnostic section to be sent to MCs for first-round comments. Vaccine section on hold	Agreed
2.1.19	Vesicular stomatitis	**RECEIVED**	Approved to be sent to MCs for first-round comments subject to clarification of some points by the authors	Agreed
2.2.1	Acarapisosis of honey bees	AHG revising bee disease chaps (coor. Ritter). Not yet received	Awaiting text	
2.2.3.	European foulbrood of honey bees	Not yet received	Awaiting text	
2.2.6.	*Tropilaelaps* infestation of honey bees (*Tropilaelaps* spp.)	Not yet received	Awaiting text	
2.2.7.	Varroosis of honey bees	Not yet received	Awaiting text	
2.3.5.	Avian mycoplasmosis (*M. gallisepticum, M. synoviae*)	Not yet received	Awaiting text	
2.3.9.	Fowl cholera	**RECEIVED**	Approved to be sent to MCs for first-round comments	Agreed (February 2014)
2.3.10.	Fowl pox	Not yet received	Awaiting text	
2.3.12.	Infectious bursal disease (Gumboro disease)	Received diagnostic section. Awaiting vaccine section	Awaiting text	
2.4.1.	Bovine anaplasmosis	**RECEIVED**	Approved to be sent to MCs for first-round comments	Agreed (February 2014)
2.4.5.	Bovine genital campylobacteriosis	Not yet received	Awaiting text	
2.4.7.	Bovine tuberculosis	Not yet received	Awaiting text	
2.4.8.	Bovine viral diarrhoea	Received diagnostic section. Awaiting vaccine section	Approved to be sent to MCs for first-round comments subject to clarification of some points by the authors	Agreed
2.4.10.	Dermatophilosis	Not yet received	Awaiting text	

No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
2.4.16.	Theileriosis	Intermediary version adopted May 2014. Further review to come	Awaiting text	
2.5.4.	Epizootic lymphangitis	Not yet received	Awaiting text	
2.5.9.	Equine rhinopneumonitis	Received diagnostic section. Awaiting vaccine section	Amended and approved the diagnostic section to be sent to MCs for first-round comments. Vaccine section on hold	Agreed
2.5.11.	Glanders	**RECEIVED**	Amended and approved to be sent to MCs for first-round comments	Agreed
2.7.9.	Ovine epididymitis (*Brucella ovis*)	**RECEIVED**	Amended and approved to be sent to MCs for first-round comments subject to clarification of some points by the authors	Agreed
2.8.7.	Porcine reproductive and respiratory syndrome	**RECEIVED**	Approved to be sent to MCs for first-round comments	Agreed
2.8.8.	Influenza A virus of swine	**RECEIVED**	Approved to be sent to MCs for first-round comments subject to clarification of some points by the authors	Agreed
2.8.10.	Teschovirus encephalomyelitis	Not yet received	Awaiting text	
2.8.11.	Transmissible gastroenteritis	Not yet received	Awaiting text	
2.9.4.	Cryptosporidiosis	**RECEIVED**	Under study	Agreed (February 2014)
2.9.6.	Nipah and Hendra virus diseases	**RECEIVED**	Approved to be sent to MCs for first-round comments subject to clarification of some points by the authors	Agreed
2.9.10.	Toxoplasmosis	Not yet received	Awaiting text	
2.9.11.	Verocytotoxogenic *Escherichia coli*	Not yet received	Awaiting text	
2.9.11.	Verocytotoxogenic *Escherichia coli*	Not yet received	Awaiting text	
2.9.12.	Zoonoses transmissible from non-human primates	**RECEIVED**	Amended and approved to be sent to MCs for first-round comments at the same time as consultation with the OIE Scientific Commission for Animal Diseases and the Terrestrial Animal Health Code Commission	Agreed

New chapters and chapters proposed for update in 2015
(i.e. for proposal for adoption in May 2016)

No.	Title
1.1.4.	Quality management in veterinary testing laboratories
2.1.x	Infection with *Brucella abortus, melitensis* and *suis*
2.1.7.	Japanese encephalitis
2.1.18.	Tularemia
2.3.8.	Duck virus hepatitis
2.3.13.	Marek's disease
2.3.15.	Turkey rhinotracheitis (avian metapneumovirus)
2.4.6.	Bovine spongiform encephalopathy
2.4.13.	Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
2.4.14.	Lumpy skin disease
2.6.2.	Rabbit haemorrhagic disease
2.7.1.	Border disease
2.7.3/4.	Caprine arthritis/encephalitis and Maedi-visna
2.7.13.	Scrapie
2.7.14.	Sheep pox and goat pox
2.9.3.	*Campylobacter jejuni* and *Campylobacter coli*
2.9.9.	Salmonellosis
Guideline 3.3.	The application of biotechnology to the development of veterinary vaccines
Guideline 3.4.	The role of official bodies in the international regulation of veterinary biologicals
Validation Guideline 3.6.8	Comparability of assays after minor changes in a validated test method

For information: chapters adopted since 2012

No.	Title	Year adopted
1.1.1	Collection, submission and storage of diagnostic specimens	May 2013
1.1.2.	Transport of specimens of animal origin	May 2013
1.1.3a	Standard for managing biorisk in the veterinary laboratory and animal facilities	May 2014
1.1.4.	Quality management in veterinary testing laboratories	May 2012
1.1.5.	Principles and methods of validation of diagnostic assays for infectious diseases	May 2013
2.1.1.	Anthrax	May 2012
2.1.2.	Aujeszky's disease	May 2012
2.1.3.	Bluetongue	May 2014
2.1.4x	Crimean–Congo haemorrhagic fever	May 2014
2.1.6x.	Epizootic haemorrhagic disease	May 2014
2.1.5.	Foot and mouth disease	May 2012
2.1.8.	Leishmaniosis	May 2014
2.1.9.	Leptospirosis	May 2014
2.1.10.	New and Old World screwworm (*Cochliomyia hominivorax* and *Chrysomya bezziana*)	May 2013
2.1.11.	Paratuberculosis (Johne's disease)	May 2014
2.1.14.	Rift Valley fever	May 2014
2.1.13.	Rabies (Vaccine section)	May 2013
2.1.15.	Rinderpest	May 2012
2.1.16.	Trichinellosis	May 2012
2.1.17.	*Trypanosoma evansi* infections (including surra)	May 2012
2.1.20.	West Nile fever	May 2013
2.2.2.	American foulbrood of honey bees	May 2014
2.2.4.	Nosemosis of honey bees	May 2013
2.2.5.	Small hive beetle infestation (*Aethina tumida*)	May 2013
2.3.1.	Avian chlamydiosis	May 2012
2.3.2.	Avian infectious bronchitis	May 2013
2.3.3.	Avian infectious laryngotracheitis	May 2014
2.3.4.	Avian influenza	May 2014
2.3.6.	Avian tuberculosis	May 2014
2.3.7.	Duck virus enteritis	May 2012
2.3.11.	Fowl typhoid and Pullorum disease	May 2012
2.3.14.	Newcastle disease	May 2012
2.4.1.	Bovine anaplasmosis	May 2012
2.4.2.	Bovine babesiosis	May 2014
2.4.9.	Contagious bovine pleuropneumonia	May 2014
2.4.11.	Enzootic bovine leukosis	May 2012

No.	Title	Year adopted
2.4.12.	Haemorrhagic septicaemia	May 2012
2.4.15.	Malignant catarrhal fever	May 2013
2.4.16.	Theileriosis	May 2014
2.4.17.	Trichomonosis	May 2012
2.4.18.	Trypanosomosis (Tsetse-transmitted)	May 2013
2.5.1.	African horse sickness	May 2012
2.5.2.	Contagious equine metritis	May 2012
2.5.3.	Dourine	May 2013
2.5.5.	Equine encephalomyelitis (Eastern & Western)	May 2013
2.5.6.	Equine infectious anaemia	May 2013
2.5.7.	Equine influenza	May 2012
2.5.8.	Equine piroplasmosis	May 2014
2.5.10.	Equine viral arteritis	May 2013
2.5.11.	Glanders	May 2013
2.5.13.	Venezuelan equine encephalomyelitis	May 2013
2.6.1.	Myxomatosis	May 2014
2.7.5.	Contagious agalactia	May 2013
2.7.6.	Contagious caprine pleuropneumonia	May 2014
2.7.7.	Enzootic abortion of ewes (ovine chlamydiosis)	May 2012
2.7.10.	Ovine pulmonary adenomatosis (adenocarcinoma)	May 2014
2.7.11.	Peste des petits ruminants	May 2013
2.8.1.	African swine fever	May 2012
2.8.2.	Atrophic rhinitis of swine	May 2012
2.8.3.	Classical swine fever (hog cholera)	May 2014
2.8.9.	Swine vesicular disease	May 2013
2.9.1.	Bunyaviral diseases of animals (excluding Rift Valley fever and Crimean–Congo haemorrhagic fever)	May 2014
2.9.2.	Camelpox	May 2014
2.9.5.	Cysticercosis	May 2014
2.9.8.	Mange	May 2013
2.9.7.	*Listeria monocytogenes*	May 2014
Guideline 3.1.	Laboratory methodologies for bacterial antimicrobial susceptibility testing	May 2012
Guideline 3.2.	Biotechnology in the diagnosis of infectious diseases	May 2012
Guideline 3.5.	Managing biorisk: examples of aligning risk management strategies with assessed biorisks	May 2014
3.6. Validation guidelines		
Guideline 3.6.1.	Development and optimisation of antibody detection assays	May 2014
Guideline 3.6.2.	Development and optimisation of antigen detection assays	May 2014
Guideline 3.6.3.	Development and optimisation of nucleic acid detection assays	May 2014
Guideline 3.6.4.	Measurement uncertainty	May 2014

No.	Title	Year adopted
Guideline 3.6.5.	Statistical approaches to validation	May 2014
Guideline 3.6.6.	Selection and use of reference samples and panels	May 2014
Guideline 3.6.7.	Principles and methods for the validation of diagnostic tests for infectious diseases applicable to wildlife	May 2014

MEETING OF THE ENLARGED BUREAU GROUP OF THE OIE

BIOLOGICAL STANDARDS COMMISSION

Paris, 10 September 2014

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

1.1. Update on progress since last meeting
1.2. Review of chapters proposed for first round of comments and eventual adoption in May 2015 [opinion and recommendations]
1.3. Identification of chapter for update in 2015 (i.e. for proposal for adoption in May 2016)

2. Outcome: recommendations of the Enlarged Bureau Group to the BSC (table from point 1.2 adapted according to discussions)

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MEETING OF THE ENLARGED BUREAU GROUP OF THE OIE

BIOLOGICAL STANDARDS COMMISSION

Paris, 10 September 2014

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Annex 4

Titles of chapters in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*

I have been asked to comment on the question of chapter titles in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*). As a number of Member Countries have mentioned, there is an increasing discrepancy with the *Terrestrial Animal Health Code* (*Terrestrial Code*) which is moving towards titles of the format "Infection with [disease agent]". The *Terrestrial Manual* retains the traditional nomenclature based on "Name of the disease". The Biological Standards Commission (BSC) has expressed its wish to retain this nomenclature. My comments are purely personal, from my perspective as consultant editor for the *Terrestrial Manual*, based also on my past experience as former President of the BSC and as Director of one of the world's largest veterinary laboratories.

The purpose of the *Terrestrial Code* (using words taken from its Foreword) is to set out standards for [*inter alia…*] safe international trade in terrestrial animals and their products. The … *Terrestrial Code* should be used ….. to provide for early detection, reporting and control of agents pathogenic to terrestrial animals and, in the case of zoonoses, for humans, and to prevent their transfer via international trade in terrestrial animals and terrestrial animal products….

The emphasis is therefore on the detection, reporting and control of pathogenic agents, which gives a certain logic to the chapter titles of the format "Infection with…", although it might be questioned whether this is appropriate to animal products, which may be contaminated with a pathogen but can hardly be described as "infected with". Infection is defined *[Dorland's Medical Dictionary]* as [1] "invasion and multiplication of micro-organisms in body tissues resulting in local cellular injury…." Or [2] "infectious disease". The word infestation is used in the case of parasites.

The *Terrestrial Manual* has the same overall aim as the *Terrestrial Code.* However the Foreword goes on to elaborate that *"The principal target readership is laboratories carrying out veterinary diagnostic tests and surveillance, plus vaccine manufacturers and regulatory authorities in Member Countries. The objective is to provide internationally agreed diagnostic laboratory methods and requirements for the production and control of vaccines and other biological products."* In the case of diagnostics, these laboratories carry out investigations and surveillance using tests that support a veterinary disease diagnosis, such diagnosis being a complex interpretation of clinical and epidemiological information together with laboratory data. The *Terrestrial Manual* has identified six broad groupings or "purposes" for which tests may be carried out. Some tests are more suited to certain purposes than others, and information on this is provided in the *Terrestrial Manual.* These six purposes cover a wider range of applications than the strict aims of the *Terrestrial Code*. In addition a number of chapters in the *Terrestrial Manual* provide a generic approach to certain disease complexes and may include more than one disease/infection from the OIE List, and in some cases unlisted diseases also. These are aspects that are highly valued by the laboratories that form the target readership for the *Terrestrial Manual*. In regard to the vaccine sections of the *Terrestrial Manual*, the standards set out requirements for vaccines that are used as part of disease control programmes. It could be argued that such vaccines equally are used to control infections, however many effective vaccines do not in fact provide total control of infection but rather provide a level of immunity that prevents disease manifestations.

The discussion could be argued either way, but there is a strong logic to retaining the use of disease titles for chapters in the *Terrestrial Manual*, as this is more relevant to the target readership. In addition allowance must be made for the fact there is not direct congruence between individual chapters in the *Terrestrial Code* or diseases/infections in the OIE List, and chapters in the *Terrestrial Manual*, for the reasons cited above. There would be some logic to providing a cross-reference key between the two systems, and also the list of Prescribed Tests in the *Terrestrial Manual* should refer to the nomenclature of the OIE List and the *Terrestrial Code.*

Dr Steven Edwards
August 2014

Annex 5

Original: English
April 2014

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON DISEASES OF CAMELIDS

Paris, 1–3 April 2014

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1. Opening

The OIE *ad hoc* Group on Diseases of Camelids met from 1 to 3 April 2014 at the OIE Headquarters in Paris, France. Dr Elisabeth Erlacher-Vindel, Deputy Head of the Scientific and Technical Department, welcomed the participants on behalf of the Director General of the OIE, Dr Bernard Vallat.

Dr Erlacher-Vindel presented the objectives of this meeting, which are reflected in the agenda.

Prof. Caporale, President of the OIE Biological Standards Commission, stated that the Commission expected the Group should identify priority diseases of camelids so that the corresponding chapter from the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*) could be reviewed.

The Group suggested inviting an expert on Bactrian camel diseases should another meeting be convened. Names of expert would be proposed by the Group to the OIE Headquarters.

2. Appointment of chairperson and rapporteur and adoption of agenda

The meeting was chaired by Dr Medhi El Harrak, and Dr Bernard Faye acted as rapporteur.

The adopted Agenda and List of Participants are presented in Appendices I and II of this report, respectively.

3. Identification of the priority diseases of camelids for the consideration of the Biological Standards Commission

The Group discussed the identification of the priority diseases of camelids, mainly taking into consideration the criteria of Chapter 1.2. of the *Terrestrial Animal Health Code* (*Terrestrial Code*). It agreed on the following diseases:

Viral diseases: camelpox (Dromedary and Bactrian camels), rabies (all species), Rift Valley fever (Dromedary camels), bovine viral diarrhoea (New World camelids), and foot and mouth disease (Bactrian camels);

Bacterial diseases: anthrax (all species), brucellosis (all species), tuberculosis (Bactrian camels and New World camelids), and Johne's disease (all species);

Parasitic diseases: trypanosomosis (Dromedary and Bactrian camels).

The Group suggested having a chapter on surra in the *Terrestrial Code* as this is a disease of concern for camels.

Although mange was not included in this list, the Group considered that this disease was of concern for camelids and should therefore be considered by the Biological Standards Commission. The Group noted there had already been a chapter in the *Terrestrial Manual* on mange and decided to review it to check if camelids had been addressed.

4. Diagnostic test methods validated and recommended for the priority diseases, and international standard reagents and vaccines available

The Group developed a table for the selected priority diseases that included, for each disease, the susceptible species, the diagnostic test methods that could be used (identification of the agent and serological tests) with recommendations, and the available vaccines with recommendations on the vaccination strategy and on control measures for the disease.

The Group pointed out that to date no vaccine has been tested and validated for camelids, except for camelpox.

The table was based on the previous table ("*Infectious diseases of interest for camelids*") developed at the first meeting of the *ad hoc* Group on Diseases of Camelids and updated at the second meeting.

The table is given at Appendix III of this report.

The Group reviewed the relevant chapters from the *Terrestrial Manual* on the priority diseases and proposed amendments on some of them to reflect the fact that camelids are susceptible species.

5. Information on the spread and impact of brucellosis in camelids worldwide

Brucellosis is a serious disease in camelids, is wide spread in New World camelids and Old World camelids, and has a severe impact on public health.

Camelids do not seem to be the reservoir of either B*rucella abortus* or *B. melitensis*. Small ruminants and bovines are the main source of the infection in camelids, which can maintain the infection. Transmission between camelids is not clearly reported. The manifestation of the disease in camelids was found to be less severe (fewer clinical signs) than in cattle and small ruminants The environment (management system, i.e. intensive or extensive and cohabitation with other animal species) determines prevalence of the *Brucella* species in camelids (*B. melitensis* is predominant in Dromedaries and New World camelids while *B. abortus* is predominant in Bactrian camels).

All the diagnostic test methods available have been validated in cattle and small ruminants only. No vaccine has been developed and tested for camelids, however the vaccine *B. melitensis* Rev1 and *B. abortus* strain 19 might be used. Proper vaccination protocols and challenge tests should be done with this aim.

The lack of knowledge and information on brucellosis in camelids hampers the definition of the epidemiology and control strategy, as well as the definition of vaccination protocols. The Group therefore concluded that research on epidemiology and pathogenicity in these species was a priority.

Experimental infection has been performed in New World camelids (Gidlewski *et al*., 2000[1]). The Group was of the opinion that such infection should also be performed in pregnant Dromedaries to study pathogenicity and vaccine efficacy. A protocol would need to be elaborated for this purpose (e.g. infective doses, challenge strain, vaccine doses, pregnancy stages for infection).

Taking into consideration the difficulty in implementing such experimental infection, the Group suggested a collaborative approach.

The Group considered brucellosis as a priority disease in camelids and provided recommendations on diagnostic tests and vaccines (see Appendix III).

1 Gidlewski T., Cheville N.F., Rhyan J.C., Miller L.D. & Gilsdorf M.J. (2000). Experimental *Brucella abortus* induced abortion in a llama: pathologic effects. *Vet Pathol.*, **37** (1), 77–82. (http://www.ncbi.nlm.nih.gov/pubmed/10643984)

6. Update on the current disease situation and the epidemiology of the Middle East respiratory syndrome with regard to camelids in affected regions

Dr Peter Ben Embarek from the World Health Organization (WHO) gave a presentation on the current situation of the Middle East respiratory syndrome (MERS) in humans and Dr William Karesh presented the current MERS situation in animals.

MERS has not been demonstrated to threaten animal health. However as a zoonotic disease, the Group concluded that there is a need to conduct more research on virus shedding, potential transmission routes, pathogenicity and epidemiology in animals (in camels as a priority because they have been implicated through numerous surveillance studies as playing a role in the epidemiology of the disease, but also in bats and other relevant species).

1. The Group recommended experimental infections of camels with a human MERS CoV isolate to determine the pathogenicity of the human strain in camels and potential routes of transmission. This should include studies to determine pathogenesis, virus shedding (routes and length of virus shedding post-infection), viral presence in different organs and camel products (milk, meat, etc.), and seroconversion studies. Results should provide a better understanding of the behaviour of the virus in camels, potential implications for animal and public health, and the spread of the infection among camels and, potentially, to humans.

   The same experimental infection should be repeated with an isolate of camel origin.

   Before starting these experimental infections, the Group suggested, that to avoid duplication, information should be collected on ongoing similar experiments. The Group advised setting up an interdisciplinary expert group to develop a protocol for the experimental infection of animals with MERS CoV.

   The Group also recommended using this study to assess and, if possible, to validate the existing diagnostic test methods that are currently being used to carry out surveillance for MERS CoV in camels.

   There are a number of animal facilities that could carry out these infection studies safely and the Group suggested that the Central Veterinary Research Laboratory (OIE Reference Laboratory for camel pox and glanders, located in Dubai, United Arab Emirates) may be a suitable facility. The WHO representative stated that WHO would be able to provide support for these infection studies.

2. The Group further recommended the inclusion of veterinary counterparts in the investigation of human and animal MERS cases in the field. This should help to increase the opportunity to isolate virus strains from animals and to gain more comprehensive data for epidemiological studies.

3. Based on the surveillance data that were presented to the Group and from their knowledge of camel immunology, the Group suggested that juvenile camels were most likely to be infected with MERS and to shed MERS CoV (owing to the high prevalence of neutralising antibodies in the adult camel population in the region, adult camels were likely to be protected and neonatal camels were likely to be protected through maternally derived immunity). Juveniles could therefore be targeted in MERS virological surveillance.

4. The Group identified the need for additional surveillance in other key camel-rearing regions (48 countries in total), in particular in the Horn of Africa where more than two-thirds of the camel population are concentrated.

5. The Group further identified the need for additional studies to investigate a potential wildlife origin of MERS in wildlife populations overlapping with the distribution of the infection in camels.

7. Other matters

1. Request from the Scientific Commission for Animal Diseases

Following a question raised by the experts from the *ad hoc* Group on Tuberculosis during their meeting held from 9 to 11 April 2013, the Scientific Commission for Animal Diseases forwarded two questions to the *ad hoc* Group on Diseases of Camelids:

a. Should camelids (Dromedary camels, Bactrian camels and South American camelids) be included in the *Terrestrial Code* chapter as species of epidemiological significance for tuberculosis?

b. Should camelids be excluded for trade purposes from the *Terrestrial Code* chapter as there is no validated or prescribed test in the *Terrestrial Manual?*

The Group was of the opinion that only New World camelids should be included as species of epidemiological significance for tuberculosis in the *Terrestrial Code* chapter (Wernery U. & Kinne J., 2012[2]). Although tuberculosis has been reported in Dromedary and Bactrian camels (Kaleab *et al.*, 2012[3]; Alvarez *et al.*, 2012[4]), the disease is not epidemiologically significant in these two species.

Regarding the validation of diagnostic tests, some serological test methods have been used with success in Dromedary camels and in New World camelids. However, the Group stated that to date no test method has been validated in New World camelids. Therefore the Group concluded that, even if the New World camelids are species of epidemiological significance for tuberculosis, they should be excluded for the present for trade purposes in the *Terrestrial Code* chapter on tuberculosis.

2. Conferences

a) Third Global Conference of OIE Reference Centres, from 14 to 16 October 2014 in Incheon, Seoul, Korea (Rep. of)

The Group proposed a session be held during the conference to present the outcomes of this meeting and to discuss with the relevant OIE Reference Centres priority diseases identified during this meeting, to strengthen collaboration between laboratories and to initiate the validation of diagnostic tests.

b) Fourth Conference of the International Society of Camelid Research and Development, "silk road camel conference", from 2 to 6 June 2015, Almaty, Kazakhstan

Should another meeting of the *ad hoc* Group be needed, it was suggested that a side meeting of the Group could be organised during this conference.

3. Results of a vaccination trial of Dromedary camels with a rabies vaccine

Following the recommendations of the meeting of the OIE laboratory network on diseases of camelids held in Teramo, Italy, from 21 to 22 October 2011, a vaccination trial was conducted in Sudan in Dromedary camels with a bovine vaccine for rabies. Sera samples have been collected and need to be tested to assess the efficacy of the vaccination. The Group recommended to send the sera samples to the Collaborating Centre for Diseases at the Animal/Human Interface (Padova, Italy), which has already accepted to examine the sera.

2 Wernery U. & Kinne J. (2012). Tuberculosis in camelids: a review. *Rev. sci. tech. Off. int. Epiz*., **31** (3), 899–906.

3 Kaleab Z., Tesfaye T., Gezahegne M.,Yehualashet B. & Gobena A. (2012). Tuberculosis in dromedaries in eastern Ethiopia: abattoir-based prevalence and molecular typing of its causative agents. *Small Rum. Res*., **109** (2), 188–192.

4 Alvarez J., Bezos L., Juan L.D., Vordermeier M., Rodriguez S., Fernandez-de-Mera G., Mateos A. & Dominguez I. (2012). Diagnosis of tuberculosis in camelids: old problems, current solutions and future challenges. *Transbound. Emerg. Dis*., **59** (1), 1–10.

4. Collaborating Centre

The Group pointed out the need to have a Collaborating Centre for the diagnosis and control of diseases of camelids, and encouraged strongly the Member Countries concerned to submit applications for this topic.

8. Adoption of report

The Group adopted the report.

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…/Appendices

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON DISEASES OF CAMELIDS

Paris, 1–3 April 2014

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Agenda

1. Opening
2. Appointment of chairperson and rapporteur, and adoption of agenda
3. Identification of the priority diseases of camelids for the consideration of the Biological Standards Commission
4. Diagnostic test methods validated and recommended for the priority diseases, the international standard reagents and the vaccines available
5. Information on the spread and impact of brucellosis in camelids worldwide
6. Update on the current disease situation and the epidemiology of the Middle East respiratory syndrome with regard to camelids in affected regions
7. Other matters
8. Adoption of report

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Appendix II

MEETING OF THE OIE *AD HOC* GROUP ON DISEASES OF CAMELIDS

Paris, 1–3 April 2014

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Appendix III

PRIORITY DISEASES OF CAMELIDS FOR THE CONSIDERATION OF THE BIOLOGICAL STANDARDS COMMISSION

A) Viral diseases of camelids

Diseases	Species	Identification of the agent	Serological tests	Recommendations for diagnosis	Vaccines	Recommendations for vaccines / control of the disease
Camelpox (see Chapter 2.9.2. of the OIE *Terrestrial Manual* 2012)	Dromedary and Bactrian camels	TEM, virus isolation, IHC, PCR and qPCR	ELISA VNT	None	Several vaccines available (killed and attenuated)	Only homologous strains should be used for vaccine production. A global strategy for the eradication of the disease should be initiated.
Rabies (see Chapter 2.1.13. of the OIE *Terrestrial Manual* 2012)	All species	FAT, PCR and IHC	VNT	An ELISA need to be developed and validated for camelids	No vaccination protocol developed for camelids. Vaccination with cattle dose was used.	Vaccination protocols (taking into account duration of antibodies) with available vaccines need to be developed in camelids.
RVF (see Chapter 2.1.14. of the OIE *Terrestrial Manual* 2012)	Dromedary camels	Virus isolation and qPCR	C-ELISA VNT	Validation of an Ig M ELISA would be necessary	No vaccination protocol developed for camelids. Vaccination with cattle dose was used.	Vaccination protocol with the Clone-13 live attenuated virus vaccine needs to be developed in Dromedary camel.
BVD (see Chapter 2.4.8. of the OIE *Terrestrial Manual* 2012)	New World camelids. More investigation on Dromedary and Bactrian camels	Virus isolation, PCR, IHC and ELISA	C-ELISA VNT	1. Validation of serological tests in milk 2. Susceptibility of Dromedaries and Bactrian camels should be assessed	No vaccination protocol developed for camelids. Inactivated vaccine with sheep and goat dose is used.	Vaccination protocols with inactivated vaccines need to be developed in camelids.
FMD (see Chapter 2.1.5. of the OIE *Terrestrial Manual* 2012)	Bactrian camels	Virus isolation, PCR, and ELISA	NSP-ELISA, C-ELISA, VNT	Validation of ELISAs is needed	No vaccination protocol developed for Bactrian camels. Vaccination with cattle dose is used.	Vaccination protocol (taking into account duration of antibodies) with bovine vaccines needs to be developed in Bactrian camels.

B) Bacterial diseases of camelids

Diseases	Species	Identification of the agent	Serological tests	Recommendations for diagnostic	Vaccines	Recommendations for prevention
Anthrax (see Chapter 2.1.1. of the OIE *Terrestrial Manual* 2012)	All species	Immuno-fluorescence, PCR, culture and identification of *Bacillus anthracis*	None	None	No vaccination protocol developed for camelids. Live vaccine with cattle dose is used.	Vaccination protocols with live vaccine need to be developed in camelids.
Brucellosis (*B. melitensis* & *B. abortus*, depends on the environment) (see Chapters 2.4.3. and 2.7.2. of the OIE *Terrestrial Manual* 2012)	All species	Staining methods, culture and PCR	BBAT, CF, FPA, C-ELISA	BBAT, FPA and CF need to be validated (reference samples available)	No vaccination protocol developed for camelids. Live vaccines are used.	1. Vaccination protocols need to be developed 2. Challenges should be performed for *B. abortus* and *B. melitensis* 3. Vaccination of all the susceptible species living in the same area
Johne's disease (see Chapter 2.1.11 of the OIE *Terrestrial Manual* 2012)	All species	Culture, Immuno-chemistry and PCR	I-ELISA, AGID	Validation of the serological tests	No vaccination protocol developed for camelids. Inactivated vaccine with cattle dose is used.	Vaccination protocols with inactivated vaccine need to be developed in camelids. Eradication of positive animals and vaccination
Tuberculosis (see Chapter 2.4.7. of the OIE *Terrestrial Manual* 2012)	New World camelids	Direct identification, culture and PCR (diagnostic and typing)	ELISA, TB StatPak MAPIA	Validation of serological test	None	Eradication of positive animals

c) Parasitic diseases of camelids

Diseases	Species	Identification of the agent	Serological tests	Recommendations for diagnostic	Vaccines	Recommendations for prevention
Trypanosomosis (see Chapter 2.1.17 of the OIE *Terrestrial Manual* 2012)	Dromedary and Bactrian camels	Agent identification, PCR	CATT and I-ELISA (neither ELISA is commercially available)	I-ELISA can be used with anti-camel conjugates	None	1. Systematic control for animal trade 2. Treatment of positive animal 3. Need more investigations on drug resistance.

List of Abbreviations:

AGID:	Agar gel immunodiffusion
BBAT:	Buffered Brucella antigen test
BVD:	Bovine viral diarrhoea
CATT:	Card-agglutination trypanosoma test
C-ELISA:	Competitive enzyme-linked immunosorbent assay
CF:	Complement fixation
FAT	Fluorescent antibody test
FMD:	Foot and mouth disease
FPA:	Fluorescent polarisation Assay
I-ELISA:	Indirect enzyme-linked immunosorbent assay
IHC:	Immunohistochemistry
MAPIA:	Multi-antigen print immunoassay
NSP-ELISA:	Non-structural protein enzyme-linked immunosorbent assay
OIE:	World Organisation for Animal Health
OIE *Terrestrial Manual*:	OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
PCR:	Polymerase chain reaction
qPCR:	Real time Polymerase chain reaction
RVF:	Rift Valley fever
TEM:	Transmission electron microscopy
VNT:	Virus neutralisation test

Annex 6

BSC Work Plan: from September 2014 to January 2015

Topic/Issue	Responsible(s)	Deadline
Manual of Diagnostic Tests and Vaccines for Terrestrial Animals		
Circulate the chapters approved by the EBG and the BSC to Member Countries for first-round comment	**SL**	By end-October 2014
Remind authors of the chapters identified by the EBG and the BSC for adoption in 2015 but not yet received	**SL**	On going
Commission the chapters identified by the EBG and the BSC for proposal for adoption in 2016	**SL**	On going
Update all the disease-specific chapters of the *Manual* according to the new template	**BSC/SST**	Continuing implementation with the aim of finalising all these modifications for the publication of the paper version of the *Manual* in 2016
***Ad hoc* Groups**		
High throughput sequencing and bioinformatics and computational genomics (HTS-BCG)	**SST: EEV, SL, Member of the BSC who attended: VC, PD**	**Dates: provisional 13–14 November 2014**
Camelidae	**SST: EEV, FD, KH, Member of the BSC who will attend: VC**	**To be discussed at the January 2015 meeting**
Meetings		
Third Global Conference of the OIE Reference Centres, Seoul, Korea (Rep. of) 14–16 October 2014	**SST & BSC**	Recommendations programme in progress
Activities		
Pilot Project for the Creation of an OIE Platform for the Collection and Management of Genomic Sequences in Animal Health	SST, SALP, SIS & BSC	Present to Reference Centre network in October 2014