WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

Original: English
September 2015

REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 1–3 September 2015

_____

The newly elected OIE Biological Standards Commission met at the OIE Headquarters from 1 to 3 September 2015. Dr Monique Eloit, elected Director General of the OIE from January 2016, welcomed the Members of the Commission, Dr Beverly Schmitt, President, Dr Franck Berthe, Vice-President, and Dr Peter Daniels, Dr Mehdi El Harrak and Dr Anthony Fooks, members of the Commission. Dr Chen Hualan, second Vice-President, could not attend the meeting.

Dr Eloit congratulated the elected and re-elected Members and wished them every success. She informed the Commission that the Sixth Strategic Plan had been adopted by the World Assembly of Delegates to the OIE (Assembly) at the General Session in May this year. The Plan details the OIE priorities for the 5-year period 2016–2020, which corresponds to Dr Eloit's mandate as Director General. The Plan emphasises the need to improve the scientific excellence of the OIE. She mentioned that the pool of experts called upon for advice would need to be enlarged, and OIE staff would be dedicated to providing better support to the Specialist Commissions. The work of the OIE Specialist Commissions would also need to be better coordinated through joint meetings to ensure commonality of objectives and output and to avoid duplication. The OIE Member Countries had specifically requested more transparency in the OIE's working procedures, and improved communication. Dr Eloit stated that the OIE Headquarters would develop a structured work programme detailing the practical implementation of the Strategic Plan for endorsement by the Assembly. She invited the members of the Commission to submit any proposals they may have to improve procedures, and to preserve the credibility of the OIE and its accountability to its Member Countries.

Dr Brian Evans, Deputy Director General and Head of the OIE Scientific and Technical Department, agreed with Dr Eloit that the OIE Specialist Commissions are the backbone of the OIE, responsible for ensuring that the work identified by the Council and the Assembly is successfully accomplished. Procedures to improve cooperation among the Commissions would be developed and put in place so that Commissions can proceed collectively to undertake priority work. Dr Evans also proposed that transparent procedures be put in place for those tasks that are the responsibility of the Biological Standards Commission, such as verifying that OIE Reference Centres comply with an appropriate quality management system. He would encourage the Commission to consider its involvement in other OIE activities, such as training of national Focal Points for Veterinary Laboratories.

Following adoption of a Resolution at the General Session in May this year, the OIE Headquarters was developing a framework for evaluating the performance of the Specialist Commissions, which would be submitted to the Council for approval. It is envisaged that this framework would be in place after the General Session in May 2016.

Finally, Dr Evans emphasised the reciprocal nature of the relationship between the OIE Specialist Commissions, the Council and the Assembly. Information needs to flow between all three bodies, and the Assembly is the decision-making body of the OIE.

In light of the comments regarding improved and transparent procedures and output, Dr Schmitt proposed that the agenda of the next meeting in February 2016 include an in-depth discussion on the Commission's activities, *modus operandi* and working procedures. Foremost among the items for discussion would be an extensive review of the structure of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*). Recognised by the World Trade Organization as an International Standard, the scope and content of the *Terrestrial Manual* chapters must be rigorously reviewed, taking account of the Commission's, the Council's and the Assembly's vision and requirements. The second theme that needed comprehensive review by the Commission is the OIE Reference Centres, including the procedure for reviewing new applications for OIE Reference Centre status and for monitoring activities of designated Centres. Given the importance of these discussions, the next meeting would be extended by 1 day.

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 *Terrestrial Manual*, Prof. Steven Edwards.

Dr Schmitt informed the Commission that the Enlarged Bureau Group, which had been formed to review the draft chapters and propose them to the Commission for circulation or further revision, had not been convened prior to the current meeting. She felt that this task is a fundamental responsibility of and should be undertaken by the Commission. External experts could be invited to future meetings if their expertise is needed; the decision would be taken on a case-by-case basis. This topic would be part of the in-depth review of the *Terrestrial Manual* that will take place at the February 2016 meeting.

2.1. Overall structure and review process for the *Terrestrial Manual*

For the benefit of the newly elected members, Prof. Edwards briefed the Commission on the structure and review process for the *Terrestrial Manual*.

Each year, a set of chapters is identified that are in need of priority revision. As a general rule, the OIE Reference Laboratory experts are requested to provide a consensus document. Once approved by the Commission at its September meeting, the chapters are circulated for first-round comment. At its February meeting, the Commission reviews any amendments to the chapters made according to the comments and approves the chapters for circulation a second time as the final version that will be presented for adoption by the Assembly at the General Session in May of each year. If adopted, the web version of the *Terrestrial Manual* is updated.

2.2. Prospect of a printed edition of the *Terrestrial Manual* in 2016

Given that the web edition of the *Terrestrial Manual* is the most up-to-date version, the Commission questioned both the necessity of continuing to publish a printed edition, and its "legal" status. The Commission recognised however, that certain countries have problems maintaining internet access and thus that is may be too soon to abandon the printed edition. It would be useful to have feedback from the Focal Point Veterinary Laboratory training on this issue. The final decision rests with the OIE Headquarters.

2.3. Harmonising the chapter titles in the *Terrestrial Manual* and the *Terrestrial Code* revisited

During the General Session, a Member Country had noted the continuing discrepancy in naming chapters between the *Terrestrial Animal Health Code* (*Terrestrial Code*) and the *Terrestrial Manual*. In September 2014, the Consultant Editor had 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 (see Annex 4 of the report of the Biological Standards Commission, September 2014).

Before taking a decision, the Commission sought an explanation for the rationale underpinning the title format of disease-specific chapters in the *Terrestrial Code* (see Item 8.1). This topic would also be part of the in-depth review of the *Terrestrial Manual* that will take place at the February 2016 meeting.

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

The Commission reviewed 21 draft chapters and one guideline 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 2016.

The batch of draft chapters includes two new chapters: Chapter 1.1.8 *Minimum requirements for the organisational management of a vaccine manufacturing facility*, and Chapter 1.1.9 *Minimum requirements for the production and quality control of vaccines*. The Commission is aware that these chapters are very detailed and asked for Member Country comment on the necessity for this level of detail in an OIE Standard. The Commission asks if the chapters would better fit the format of a guideline. Finally, the Commission is also aware that there may be overlap between the information given in these chapters and the information in the existing vaccine chapters (Chapter 1.1.6 *Principles of veterinary vaccine production*, Chapter 1.1.7 *Tests for sterility and freedom from contamination of biological materials*, and Chapter 1.1.10. *Vaccine banks*). A member of the Commission was appointed to review the contents of the chapters and advise the Commission on suitable actions.

Chapter 1.1.10 *Vaccine banks* had been sent for Member Country review in October 2014. As it had received a large volume of comments, an *ad hoc* Group had been convened to review these comments and amend the chapter accordingly. The Group had extensively revised and updated the draft. The Commission agreed to treat the chapter as a new update and to send it out for comment.

Comments had been submitted by the OIE Working Group on Wildlife on Chapter 2.9.12 *Zoonoses transmissible from non-human primates*. The Commission expressed its gratitude for the constructive proposals and identified experts who could further develop the text.

2.5. Proposal to move the chapter on Nipah and Hendra virus diseases to multispecies section

The Commission agreed to move Chapter 2.9.6 *Nipah and Hendra virus diseases* from the Section 2.9 *Other diseases* to Section 2.1 *Multiple species* of the *Terrestrial Manual*.

2.6. Proposal to develop a form for submission of new test methods and validation data

The OIE Headquarters regularly receives requests for the form that needs to be filled in when submitting a new test method for consideration for inclusion in the *Terrestrial Manual*. At present no such form exists. Dr François Diaz proposed to draft one based on Chapter 1.1.5 *Principles and methods of validation of diagnostic assays for infectious diseases* and the existing form that is part of the procedure for the registration of diagnostic kits. The Commission would review the draft at its next meeting.

3. OIE Reference Centres

3.1. Applications for OIE Reference Centre status

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

OIE *Reference Laboratory for Avian chlamydiosis*
Anses (Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'Environnement et du Travail), Animal Health Laboratory, Bacterial Zoonoses Unit, 14 rue Pierre et Marie Curie, 94701 Maisons-Alfort Cedex, FRANCE
Tel.: (+33-1) 49.77.13.00; Fax: (+33-1) 49.77.13.44
E-mail: karine.laroucau@anses.fr
Designated Reference Expert: Dr Karine Laroucau.

OIE *Reference Laboratory for Enzootic abortion of ewes* (*ovine chlamydiosis*)
Anses, Animal Health Laboratory, Bacterial Zoonoses Unit, 14 rue Pierre et Marie Curie, 94701 Maisons-Alfort Cedex, FRANCE
Tel.: (+33-1) 49.77.13.00; Fax: (+33-1) 49.77.13.44
E-mail: karine.laroucau@anses.fr
Designated Reference Expert: Dr Karine Laroucau.

OIE *Reference Laboratory for Foot and mouth disease*
Division of FMD, Animal and Plant Quarantine Agency (QIA), Ministry of Agriculture, Food and Rural Affairs, 175 Anyang-ro, Manan-gu, Anyang-si, Gyeonggi-do, 430-757, KOREA (REP. OF)
Tel: (+82-31) 467.17.19; Fax: (+82-31) 467.45.16
Web site: http://www.qia.go.kr/eng/index.asp
E-mail: parkjhvet@korea.kr
Designated Reference Expert: Dr Jong-Hyeon Park.

OIE *Reference Laboratory for Q fever*
National Veterinary Research Institute, Department of Cattle and Sheep Diseases, Al. Partyzantow str. 57, 24-100 Pulawy, POLAND
Tel: (+48-81) 887.32.64; Fax: (+48-81) 886.25.95
Web site: http://www.piwet.pulawy.pl
Email: kniem@piwet.pulawy.pl
Designated Reference Expert: Dr Krzysztof Niemczuk.

OIE *Reference Laboratory for Brucellosis* (Brucella abortus *and* B. melitensis)
National Institute of Animal Health, 50/2 Kasetklang, Ladyao, Chatuchak, Bangkok 10900, THAILAND
Tel: (+66-2579) 89.08 to 14 ext. 232; Fax: (+66-2579) 89.18/19
Web site: http://niah.dld.go.th
Email: monayae@dld.go.th
Designated Reference Expert: Dr Monaya Ekgatat.

An application had been received from a country for an OIE Reference Laboratory for Avian influenza and Newcastle disease. Point 5 of the current Guidelines for applicants for OIE Reference Laboratory status requests: *Experience in diagnostic testing for the disease according to the OIE Standards*. The Commission believes that an OIE Reference Laboratory for these two diseases should be undertaking molecular pathogenicity testing and would request information on this activity from the applicant before taking a final decision on the application.

Another country had previously submitted an application for an OIE Reference Laboratory for Avian infectious bronchitis. The Commission sought assurances that the laboratory undergoes external audits as part of its quality management system. The institution informed the Commission that it would immediately start to implement a quality management system and plans to get certified within 3 years. The Commission took note of this news and looks forward to receiving a new application once the accredited quality management system is in place.

Finally, the Commission reviewed supplementary information that had been requested regarding applications for the designation of two OIE Reference Laboratories: for bovine spongiform encephalopathy (BSE) and for scrapie. Given that there is a high density of OIE Reference Laboratories for these two diseases in the region concerned, along with the fact that fewer and fewer cases are being diagnosed, the Commission felt that the decision on this designation was an OIE policy decision and as such referred it to the OIE Council.

3.2. Changes of experts at OIE Reference Laboratories

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

Bluetongue
Dr Debbie Eagles to replace Dr Peter Daniels at the Australian Animal Health Laboratory (AAHL), CSIRO Livestock Industries, Geelong, Victoria, AUSTRALIA.

Bovine brucellosis
Dr Moon Her to replace Dr Suk-chan Jung at the Animal and Plant Quarantine Agency (QIA), Ministry of Agriculture, Food and Rural Affairs (MAFRA), Gyeonggi-do, KOREA (REP. OF).

Chronic wasting disease and Scrapie
Dr Gordon Mitchell to replace Dr Aru Balachandran at the Canadian Food Inspection Agency, Ottawa Laboratory (Fallowfield), Nepean, Ontario, CANADA.

Foot and mouth disease
Dr Andrea Pedemonte to replace Dr Eduardo Maradei at the Laboratorio de Fiebre Aftosa de la Dirección de Laboratorios y Control Técnico, SENASA, Buenos Aires, ARGENTINA.

Heartwater
Dr Nathalie Vachiéry to replace Dr Dominique Martinez at CIRAD (Centre international en recherche agronomique pour le développement), Montpellier, FRANCE.

Hendra and Nipah virus diseases
Dr Kim Halpin to replace Dr Peter Daniels at the Australian Animal Health Laboratory (AAHL), CSIRO Livestock Industries, Geelong, Victoria, AUSTRALIA.

Lumpy skin disease and Sheep pox and goat pox
Dr Pip Beard to replace Dr Eeva Tuppurainen at the Pirbright Institute, Surrey, UNITED KINGDOM.

Marek's disease
Dr John R. Dunn to replace Dr Aly Fadly at the United States Department of Agriculture (USDA), Agriculture Research (ARS), Avian Disease and Oncology Laboratory, East Lansing, Michigan, UNITED STATES OF AMERICA.

3.3. 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 2015, 26 projects have been completed, 34 are underway and 10 are approved and due to start based on fund availability.

Seven twinning proposals were presented to the Commission for technical review.

- ***Italy – Thailand*** for West Nile fever: the Commission observed that the West Nile fever is not a priority disease in Thailand and there are no significant animal health and public health consequences reported in the country. Before it could take a decision, the Commission requested more justification on the rationale for this project.

- ***Italy – Brazil*** for bluetongue: the Commission would like to get more information on the diagnostic facilities and research activities of the Brazilian laboratory for bluetongue and how this twinning project would help to improve the existing facilities.

- The Commission commented that the ***Italy – United Arab Emirates*** (UAE) twinning proposal for collaboration on camel diseases is strategically an important project. The Commission would like to see the full technical programme of the project once it has been developed by the laboratories involved.

- ***Argentina – Ecuador*** for foot and mouth disease (FMD): the Commission supports this project believing that increasing laboratory capacity in Ecuador is an important endeavour.

- The Commission approved the technical work programme of the ***Argentina – Tanzania*** twinning project for brucellosis.

- The Commission approved the technical contents of the ***France – Cameroon*** twinning project for veterinary medicinal products. As the proposal only mentions the overall objective, the Commission asked that the detailed specific objectives of the project also be specified under the overall objectives.

– The Commission approved the work programme of the ***Japan – Mongolia*** twinning project proposal. As the project also included work on other transboundary animal diseases in addition to FMD, the Commission asked that these be reflected in the objectives of the twinning programme.

The Commission was informed that a technical and financial audit had been conducted on two twinning projects. The Commission was interested in receiving the report on the outcome of the audited projects.

From the next meeting, the Commission asked for an overview of the implementation of the twinning programme, including the aquatic twinning projects, and the status of those "pipeline" twinning projects that had been approved and are ready to start subject to availability of funding.

3.4. Mission to candidate laboratory in Vladimir, Russia

For some time, visits to potential OIE Reference Laboratories have been seen as increasingly necessary to ensure the good quality of their facilities and services, and the institute's commitment to fulfilling the mandate of an OIE Reference Laboratory. To this end, the Commission was informed that an expert mission had been organised to evaluate the facilities at the Federal Centre for Animal Health (FGBI-ARRIAH), Vladimir, Russia, which had applied to be recognised as OIE Reference Laboratories for Avian influenza and Newcastle disease following a twinning project with the Istituto Zooprofilattico Sperimentale delle Venezie, Padua, Italy.

The Commission proposed that the Terms of Reference for this mission could be used as the basis for future missions. The report of the mission would be closely reviewed at the next Commission meeting.

3.5. Specific issues related to Reference Centres: guidelines for applicants

At its last meeting in January 2015, the Commission had proposed amendments to the *Guidelines for applicants for OIE Reference Laboratory status* (see Annex 4 of the report of the Biological Standards Commission, January 2015). Subsequently to that meeting, the Council had amended the Commission's proposal, and the Commission did not fully agree with the Council's changes. This topic would be part of the in-depth review of OIE Reference Centres that will take place at the February 2016 meeting, so discussion was deferred to then.

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

At the Third Global Conference of the OIE Reference Centres, held in October 2014 in Seoul, Korea (Rep. of), Dr Maura Ferrari of the OIE Collaborating Centre for Veterinary Biologicals Biobank, gave a presentation 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. One of the recommendations of the Conference was to further develop the concept of establishing a virtual OIE biobank taking into account the need to harmonise the system with other existing initiatives.

Dr Ferrari and colleagues met at the OIE Headquarters in May 2015 to discuss ways to advance this project. The Commission reviewed and amended a draft questionnaire that had been prepared by the Collaborating Centre. It was finally proposed to send a shortened questionnaire to those Reference Centres that had indicated that they have a biobank to collect information on their IT (information technology) systems, and also to collect any datasheets the Centres have for their biological resources.

To further progress the project, the Commission proposed that the Director General convene an *ad hoc* Group, and proposed draft Terms of Reference (ToR) for such a Group. The principal ToRs would be to identify which types of biological material, along with the metadata and quality assurance requirements, should be included in the OIE biobank, to review the IT options, and to prepare the technical specifications of the OIE biobank.

4. *Ad hoc* Groups

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

4.1. Report of the Meeting of the *ad hoc* Group on Vaccine Banks, 3–5 June 2015

The Commission adopted the report, which can be found at Annex 3 of this report. The Commission also approved the extensively revised Chapter 1.1.10 *Vaccine banks* for circulation to OIE Member Countries and proposal for adoption in May 2016 (see also Item 2.4).

- **Proposed future *ad hoc* Groups: scheduling and drafting ToRs**

4.2. *Ad hoc* Group on High Throughput Sequencing and Bioinformatics and Computational Genomics (HTS-BCG): implementation of the work plan

For this agenda item, Dr Antonino Caminiti, Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna, Brescia, Italy, gave a presentation entitled: *The increasing importance of sequence information in managing animal health information globally: OIE actions*. The presentation updated the new members of the Commission on the OIE *Platform for the Collection and Management of Genomic Sequences in Animal Health*, which already had the Commission's approval.

At its last meeting, the Commission had adopted the report of the *ad hoc* Group. To further progress the topic, the Commission proposed that the Director General re-convene the *ad hoc* Group, and proposed draft ToRs. The principal ToRs would be to review the draft work plan and assess the pilot project, and detail the steps needed for implementation of both.

4.3. *Ad hoc* Group on Replacement International Standard for Bovine Tuberculin

Prof. Steven Edwards briefed the Commission on the background to this agenda item.

The OIE Reference Laboratories for bovine tuberculosis had advised that current supplies of the International Reference Standard Bovine Tuberculin PPD[1] are running out, and there is an urgent need to develop a replacement. Given the complexity of the task, the Commission recommends that Dr Vallat establish an *ad hoc* Group to develop a protocol for evaluation and adoption of a new international standard bovine tuberculin, with participation from Reference Laboratories, tuberculosis experts, experts in international standardisation, members of the Commission and the *Terrestrial Manual* editorial team. Consideration should also be given to how this project could be funded, given that it involves potentially costly animal studies, and also the extent to which it is possible to minimise the number of animals used, by careful experimental design.

The Commission was also informed that the OIE had been approached by WHO[2] regarding this topic, and that relevant experts and observers from partner organisations will be invited to join the meeting of an *ad hoc* Group.

4.4. *Ad hoc* Group on a virtual OIE Biobank

See Item 3.6.

5. International Standardisation/Harmonisation

- **Diagnostic tests**

5.1. OIE Register of diagnostic kits

5.1.1. Update and review of applications

Dr François Diaz, Scientific and Technical Department of the OIE, updated the Commission on the current status of the dossiers submitted according to the OIE Procedure for Registration of Diagnostic Kits.

---

1 PPD: purified protein derivative
2 WHO: World Health Organization

He informed the Commission that evaluation of the dossier on "Pourquier® IIF *Taylorella equigenitalis*" 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:

Pourquier® IIF *Taylorella equigenitalis* is fit for the detection of *T. equigenitalis* bacterial bodies from the swabs of the reproductive tract of stallions and mares for the following purposes:

1. Certify freedom from infection or agent in individual animals or products for trade or movement purposes;
2. Estimate prevalence of infection to facilitate risk analysis (surveys, herd health schemes or disease control);
3. Control of infection in stallions and mares at the start of the breeding season.

Further to the decision of the OIE Director General, this would be proposed for adoption by the Assembly at the General Session in May 2016.

An abstract sheet of the validation data of the "Pourquier® IIF *Taylorella equigenitalis*" kit, drafted in collaboration with the diagnostic kit manufacturer and the expert evaluation panel, and endorsed by the Commission, is included at Annex 4 of this report.

5.1.2. Question regarding the recognition of a diagnostic test method when a diagnostic kit is recognised by the OIE

The question was raised regarding a kit that is recognised by the OIE and included in the OIE Register but for which the test method is not included in the *Terrestrial Manual,* and whether it should be added to the *Terrestrial Manual*. The Commission agreed to discuss this as part of the in-depth discussion on the *Terrestrial Manual* at its next meeting.

5.2. Standardisation programme

5.2.1. OIE-approved standard sera: datasheets for *Mycoplasma mycoides* subs. *mycoides* SC (small colony) antigen preparation for the complement fixation test for contagious bovine pleuropneumonia: follow up from last meeting

Following clarification from the OIE Reference Laboratory in Portugal concerning the international standard sera for the complement fixation test (CFT) for contagious bovine pleuropneumonia (CBPP) that it had prepared, the Commission agreed to adopt the standards. The Commission took note that the antigens are different from the already OIE-approved international standard sera for CBPP prepared by the OIE Reference Laboratory in Italy. The Portuguese standards would be added to the table of OIE-approved International Standard Sera (available on the OIE web site at: http://www.oie.int/en/our-scientific-expertise/veterinary-products/reference-reagents/).

5.2.2. EDQM[3] project: establishment of a biological reference preparation to allow testing of equine influenza vaccines for compliancy with the recommendations of the Expert Surveillance Panel on Equine Influenza Vaccine Composition

For this agenda item, Dr Marie-Emmanuelle Behr-Gross, EDQM, Council of Europe, Strasbourg, France, had been invited and gave a presentation entitled: *Project proposal for the establishment of a common OIE/Ph. Eur. standard antiserum against an equine influenza virus*.

Dr Behr-Gross presented the projects on equine influenza vaccine reference preparations that have been run under EDQM's Biological Standardisation Programme. So far, four biological reference preparations (BRP) have been developed under the common aegis of the OIE and the European Pharmacopoeia (Ph. Eur.). At its meeting on 6 March 2015, the OIE Expert Surveillance Panel on Equine Influenza Vaccine Composition advised that a complementary

[3] EDQM: European Directorate for the Quality of Medicines and HealthCare

BRP be prepared and established to allow testing of vaccine compliancy with the OIE 2014/15 Recommendations, and including A/eq/Richmond/1/2007-like viruses. The Biological Standardisation Programme Steering Committee of the EDQM endorsed this study proposal and nominated Dr Romain Paillot (Animal Health Trust, UK) as the Project Leader. Dr Behr-Gross requested permission for the project to be run under the aegis of both OIE and Ph. Eur. She said that the final report would be proposed for endorsement by both organisations. Should the project be successful, the reference standard would be granted OIE and Ph. Eur. BRP status.

The Commission agreed that this is essential work and endorsed the proposal. It would review any progress reports submitted at future meetings.

5.2.3. Update on progress on developing guidelines for antigen standards

Dr Peter Daniels reported that due to the complexity of the subject matter, he has run into difficulties completing these guidelines. He would send a draft to the members of the Commission highlighting the areas that need to be addressed.

5.2.4. *In-vitro* production of dourine antigen

A European laboratory informed the Commission that it was producing an antigen for the dourine (*Trypanosoma equiperdum*) complement fixation test in an *in-vitro* culture system to replace animal experiments (using rats). The laboratory requested information on how to confirm that the quality of the new antigen meets the criteria required for OIE approval. Given the complexity of developing a guideline for antigen production, there is currently no guidance, but the Commission is working on this issue (see Item 5.2.3). In the meantime, the laboratory would be asked to provide all the data on the manufacturing process and characteristics that they have on the antigen.

5.2.5. New skin test for bovine tuberculosis that allows DIVA[4] strategies

Information had been received concerning a new skin test for bovine tuberculosis that uses a reagent that does not cross react with animals that have been vaccinated with BCG[5] thus allowing DIVA vaccine strategies to be undertaken. The manufacturer would like their reagent to recognised as an international standard. The Commission agreed to request the advice of the proposed *ad hoc* Group on a Replacement International Standard for Bovine Tuberculin (see Item 4.3).

5.2.6. Guidelines on the preparation and validation of an OIE-approved tuberculin standard

See Item 4.3.

5.2.7. Validation of the real-time reverse-transcription polymerase chain reaction method for detection of African horse sickness virus

At present, there is an increased demand to facilitate the international movement of horses on a global scale. In this context, the availability of fully validated diagnostic tests for African horse sickness (AHS) is an absolute necessity for enabling safe international trade of horses, rapid detection of outbreaks and improved disease surveillance. The need for fully validated diagnostic reverse-transcription polymerase chain reaction (RT-PCR) methods for AHS has become a priority for the OIE, due to the demand from the equine industry and equestrian sports organisations for these diagnostic tests to be used for import or export protocols to or from AHS endemic countries.

In 2013, the OIE asked the OIE Reference Laboratories for AHS for an opinion on the adoption of an RT-PCR diagnostic test for AHS as a prescribed test for international trade. It was clear at that time that there were a variety of suitable RT-PCR methods, and that before

[4] DIVA: detection of infection in vaccinated animals
[5] BCG: Bacillus Calmette–Guérin

adopting a common diagnostic procedure, it was necessary to perform a comparative study. OIE experts proposed that an international ring trial be undertaken to gather information on the performance variability of the different methods used in the main AHS diagnostic laboratories. This proposal was agreed by the Biological Standards Commission and the OIE *ad hoc* Group on International Horse Movement for Equestrian Sport.

The international comparative ring trial is now complete. Ten different RT-PCR protocols were compared and, because of its performance and widespread use, the study identified the Agüero method for full validation. The dossier was presented to the Commission for approval.

The Commission greatly appreciates the work of the experts and accepted the validation dossier. The OIE Reference Laboratory experts will be asked to update the *Terrestrial Manual* chapter to provide a more complete protocol for this test along with text explaining that the protocol had been identified in a comparative ring trial to be one among other top-ranking protocols. It had been selected for validation on the understanding that other protocols be validated in the future.

5.2.8. Info only: Second *Anti-Brucella ovis* International Standard Serum

The Commission noted this initiative to develop a second International Standard Serum to replace the existing OIE-approved International Sera for *Brucella ovis.*

- **Biosafety/Biosecurity**

5.3. Feedback from the Inaugural meeting of ISO/TC 212/JWG5, Laboratory Biorisk Management, London, UK, 13–14 January 2015

Dr Diaz informed the Commission that there was a joint project between ISO/TC 212 (Standardization and guidance in the field of laboratory medicine and *in vitro* diagnostic test systems) and ISO/TC 34 (Food products) intended to convert the CEN Workshop Agreement 15793 (CWA 15793) on Laboratory Biorisk Management to an ISO deliverable (ISO 35001 document) for all laboratories and related facilities that handle, store, transport, or dispose of biological agents or toxins, including veterinary laboratories. The next meeting to discuss and progress this issue is planned for November 2015. The OIE is invited to participate.

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 2015:

- Resolution No. 31: Adoption of the new or revised texts for the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
- Resolution No. 34: Register of Diagnostic Kits Validated and Certified by the OIE
- Resolution No. 32: Designation of OIE Reference Laboratories for terrestrial animal diseases

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

Finally the Commission noted Resolution No. 33: High Throughput Sequencing, Bioinformatics and Computational Genomics (HTS-BCG).

7. Conferences, Workshops, Meetings

7.1. Feedback on the 1-day OIE Seminar, 17 June 2015 (theme: *New Diagnostic Technologies and International Standard Stetting*) held during the WAVLD[6] Symposium 15–18 June 2015, Saskatoon, Canada

Dr Schmitt updated the Commission on the 1-day OIE Seminar.

The 11th OIE seminar, which was opened by Dr Martine Dubuc, OIE Delegate of Canada and Secretary General of the OIE Regional Commission for the Americas, comprised eleven presentations. The seminar was brought to a close by Dr Beverly Schmitt, who gave a short summary of the presentations noting that a spectrum of new tools had been discussed along with potential problems and challenges. These new technologies become even more robust when linked to epidemiological information. This OIE seminar was very well attended (approximately 100 participants) and the feedback was positive. Participants found the seminar to be interesting, practical, timely and of scientific importance. The presentations gave a perfect update on the targeted subjects, which triggered interesting questions. Many of the participants, including those from the private sector, asked questions about OIE projects and visited the OIE Stand discovering the OIE for the first time. The power point presentations and abstracts of the OIE seminar are available on the OIE Website at:
http://www.oie.int/eng/WAVLD2015/presentations.htm

Preparations are underway for the next WAVLD Symposium, which will be held in Sorrento, Italy from 7 to 10 June 2017. The OIE will continue its tradition of hosting a 1-day Seminar during the Symposium.

7.2. GMI[7] meeting, 11–13 May 2015, Beijing, China (People's Rep. of)

The Commission noted the report of the GMI meeting and reaffirmed its intention to continue its engagement in this project. Members of the Commission were identified who could participate in future GMI meetings to represent the OIE.

7.3. 4th Conference of ISOCARD[8]: Silk road camel: the camelids, main stakes for sustainable development, 8-12 June 2015 Almaty, Kazakhstan

Dr Mehdi El Harrak gave a brief presentation on this Conference. Dr El Harrak was one of the keynote speakers invited to represent the OIE and to give a presentation in the plenary session on the activities of the OIE *ad hoc* Group on Diseases of Camelids. There was much interest in the Group's activities from the participants who raised a number of points during the discussion, including: the choice of criteria for classifying priority diseases of camels; the possibility to prioritise other diseases, such West Nile fever and Rotavirus infection; the need for expertise on Bactrian camels; the role of laboratories in confirmation of diagnostic test results and the need for test validation, especially for brucellosis as a disease of priority; interest in and a progress report on the project to establish a laboratory network for diseases of camelids; and vaccination protocols for camelids.

8. Liaison with other Commissions

8.1. Horizontal issues among the Specialist Commissions

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

Dr Bonbon briefed the Commission on the background to the use of the disease name format "Infection with [pathogen name]" in the *Terrestrial Code* (see also Item 2.3). The original decision was linked to disease notification and country status and arose so that Member Countries could declare themselves free from rinderpest disease or free from rinderpest infection. The format also allows diseases to be listed in the same order alphabetically in all three official OIE languages. Its implementation has been progressive. Dr Bonbon acknowledged that the users of the *Terrestrial Manual* and the *Terrestrial*

---

6 WAVLD: World Association of Veterinary Laboratory Diagnosticians
7 GMI: Global Microbial Identifier
8 ISOCARD: The International Society of Camel Research and Development

Code are not always the same and that the chapter numbers do not correspond between the two publications, but he said that it would be helpful to have the same titles. The Biological Standards Commission would consider adopting this format but of adding the disease name in brackets.

Dr Bonbon went on to inform the meeting that the Code Commission is proposing that *Terrestrial Code* chapter 1.3 *Prescribed and alternative diagnostic tests for OIE listed diseases*, be deleted. The disease-specific chapters in the *Terrestrial Code* refer to diagnostic tests in the *Terrestrial Manual* without specifically identifying them as prescribed tests for international trade. Should this proposal be adopted by the Assembly in May 2016, the Biological Standards Commission would also remove the list from the *Terrestrial Manual*. For a number of years, each disease-specific chapter of the *Terrestrial Manual* that has been identified for update, has included a table that lists the diagnostic methods available for the disease in question alongside the purpose for which the assay has been validated. The purpose "Individual animal freedom from infection prior to movement" would be the equivalent of a prescribed test for trade.

Finally, Dr Bonbon asked the Biological Standards Commission to delete any case definition, if there are any, from the disease-specific chapters of the *Terrestrial Manual*. Case definitions are specifically linked to disease notification and thus should be included in the *Terrestrial Code* rather than the *Terrestrial Manual*. The Biological Standards Commission agreed to this request.

8.1.1. General discussion: distinction between OIE Standards and OIE Guidelines

The need had been identified to define the term 'OIE standard' recognising that the meaning of this term has been repeatedly sought in the WTO SPS Committee[9]. The legal implication of the definition also needs to be taken into consideration. The Code Commission proposed two definitions: one for OIE Standards and one for OIE Guidelines to distinguish between texts formally adopted by the Assembly and those endorsed without formal adoption. The Biological Standards Commission provided its comments on the proposals. The definitions would also be discussed by the Scientific Commission for Animal Diseases.

The Commission noted that the guidelines that comprise Section 3 of the *Terrestrial Manual* have been formally adopted by the Assembly and thus may need to be re-named. This topic would be added to the agenda of the in-depth discussion on the *Terrestrial Manual* at its next meeting.

8.1.2. Removal of details on diagnostic tests and their use from the *Terrestrial Code* and inclusion in the *Terrestrial Manual*

Previously, the Code Commission had agreed to remove from the *Terrestrial Code* text on diagnostic tests, etc., that was more suited for inclusion in the *Terrestrial Manual*, once it had been adopted and included in the *Terrestrial Manual*. The Code Commission was informed that this was now the case for the chapter on Zoonoses transmissible from non-human primates, an updated version of which had been adopted in May 2015.

In a number of the disease-specific chapters of the *Terrestrial Code* there are currently schematic representations of the application of laboratory tests for determining evidence of the infection in question for various purposes. The Biological Standards Commission agreed to discuss the necessity of including such flowcharts in the *Terrestrial Code* or the *Terrestrial Manual*, and the possibility of referring to the tests generically rather than specially ("serological test" rather than "ELISA"[10]) as part of the in-depth discussion on the *Terrestrial Manual* at its next meeting.

[9] WTO SPS Committee: Committee on Sanitary and Phytosanitary Measures of the World Trade Organization
[10] ELISA: enzyme-linked immunosorbent assay

8.1.3. Terms of reference for a proposed *Terrestrial Code* chapter on vaccination

The Biological Standards Commission was informed of a proposal to draft a *Terrestrial Code* chapter on vaccination to provide clear guidance on vaccination strategies. The OIE Director General would be requested to convene an *ad hoc* Group to draft this horizontal chapter with the participation of the relevant Specialist Commissions. First, the OIE Headquarters was requested to undertake a brainstorming session to develop appropriate Terms of Reference for the *ad hoc* Group. The draft ToRs were presented to the Code, Scientific and Biological Standards Commissions for comment. The Biological Standards Commission would welcome the opportunity to be involved in this *ad hoc* Group.

8.2. Scientific Commission for Animal Diseases (Scientific Commission)

Matters from the Scientific Commission to the Biological Standards Commission

8.2.1. Revision of the bovine spongiform encephalopathy (BSE) chapter of the *Terrestrial Manual* to include a description of the available tests to discriminate atypical from classical BSE

The Biological Standards Commission was informed that both the Scientific and Code Commissions had accepted the proposal that atypical bovine spongiform encephalopathy (BSE) should be differentiated from classical BSE in Chapter 11.4. of the *Terrestrial Code*, including its impact on BSE risk status recognition, maintenance and associated surveillance.

The Biological Standard Commission was asked to consider and agreed that the revision of the BSE chapter of the *Terrestrial Manual* should include descriptions of the available tests able to discriminate atypical from classical BSE. The OIE Reference Laboratory experts would be asked to update the chapter to include information on the suitable tests to be used to discriminate atypical from classical BSE. The chapter will then be circulated to Member Countries for first-round comment and eventual proposal for adoption in May 2016.

Follow-up from last meeting

8.2.2. Practicability of requiring FMD vaccine manufacturers to supply sera for test calibration

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 sought the advice of the OIE Reference Laboratories for FMD and those Collaborating Centres that deal with vaccine evaluation. Considering the responses, the Commission believed that it would be useful scientifically to have such sera and would request the OIE Reference Laboratories to update the *Terrestrial Manual* chapter to include this proposal.

8.2.3. Zoonoses transmissible from non-human primates: review of the *Terrestrial Manual* chapter by the Working Group on Wildlife

The OIE Working Group on Wildlife had provided a review of *Terrestrial Manual* Chapter 2.9.12 *Zoonoses transmissible from non-human primates.* The Biological Standards Commission was very grateful for the Working Group's input. The Commission identified experts who could further, update the chapter taking account of the review. Once a new draft is available, it would be submitted to the Working Group for review.

8.3. Terrestrial Animal Health Standards Commission

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

8.3.1. Discrepancies between the *Terrestrial Code* and *Terrestrial Manual* regarding collection and processing of bovine, small ruminant and porcine semen

The Code Commission had received a comment from a Member Country pointing out that there are discrepancies between the *Terrestrial Code* and *Terrestrial Manual* regarding collection and processing of bovine, small ruminant and porcine semen. The Biological Standards Commission decided to give the comments to the Consultant Editor of the *Terrestrial Manual* with the request that he review the chapters and the comments and advise the Commission on how to respond to the Code Commission.

8.3.2. Update on the meeting of the *ad hoc* Group on Equine Trypanosomoses

The Biological Standards Commission was informed that the *ad hoc* Group on Equine Trypanosomoses had met. One of the topics it had discussed was the impossibility of distinguishing between surra (*Trypanosoma evansi*) and dourine (*T. equiperdum*). The Group recommended that the *Terrestrial Manual* chapter on surra (*T. evansi*) include a PCR that differentiates *T. evansi* from *T. brucei*, and that this test be included in the table of test methods available for diagnosis of surra and their purpose. It also advised that both the surra and dourine chapters include a statement that treatment is possible for the bloodstream form of the diseases. The Group would provide a reference for this statement. The Biological Standards Commission agreed to these proposals.

9. Matters of Interest for Information

9.1. Update on OFFLU[11]

Dr Peter Daniels updated the Commission on OFFLU.

OFFLU organised a technical meeting in conjunction with the 9th International avian influenza symposium, Athens, Georgia, USA on 15 April 2015. The meeting discussed the strategic agenda as developed by combined meeting of the Steering Committee and Executive Committee in October 2014. Additionally the responsible experts presented the key achievements of OFFLU Technical Activities (TAs) since the previous Technical Meeting in 2012. These included the OFFLU contributions to the WHO VCM (Vaccine Composition Meetings), the vaccination technical meeting, the research agenda meeting with STAR-IDAZ[12], ring trail performance, the swine influenza virus (SIV) technical activities and the equine influenza (EI) technical activities including recommendations for changes in EI vaccine antigens.

New TAs proposed include epidemiology and surveillance, economic and social aspects, a wildlife group, a diagnostic TA incorporating current laboratory TAs, a one health TA including risk assessments for zoonotic potential and a TA for AI vaccine antigen review.

The OFFLU wildlife surveillance group was successfully formed and has convened the first teleconference among the experts.

OFFLU has compiled and analysed influenza data for the next WHO VCM meeting scheduled in St Jude Children's Research Hospital, Memphis, Tennessee, USA in September 2015.

---

[11] OFFLU: Joint OIE-FAO (Food and Agriculture Organization of the United Nations) Network of Expertise on Animal Influenza

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

Work is continuing on a project funded through the WHO Collaborating Centre for Influenza (St Jude) for the production of specialised antisera prepared in ferrets for the analysis of H5 antigens in support of the contributions to the WHO VCM.

Planning is advanced for the next OFFLU SIV group meeting in November 2015 at OIE Headquarters, which is being co-funded by the National Institute of Allergy and Infectious Diseases (NIAID) Centers of Excellence for Influenza Research and Surveillance (CEIRS) programme, for which OFFLU expresses its appreciation.

Dr Keith Hamilton who has served as the OIE focal point for OFFLU since its inception has left the OIE to accept a new position in North America. OFFLU expresses its appreciation to the sustained and high level inputs of Dr Hamilton to OFFLU and the control of influenza infections in animals over many years. Dr Hamilton has been replaced by Dr Tianna Brand as the OIE focal point for OFFLU.

9.2. Non-tsetse-transmitted animal trypanosomoses (NTTAT) network

The Commission was informed that an official OIE non-tsetse-transmitted animal trypanosomoses (OIE-NTTAT) network had been created. Prof. Philippe Büscher from the OIE Reference Laboratory for surra (*Trypanosoma evansi*), at the Institute of Tropical Medicine Antwerp, Belgium, had been appointed the Secretariat, and there are approximately 20 core members. The network's main objective is to develop a global control strategy for NTTAT. Seven research priorities have been identified. The Commission will receive annual reports on the network's activities.

9.3. Approved rinderpest holding facilities

At the General Session in May 2015, Resolution No. 25 *Designation of Facilities as Approved for Holding Rinderpest Virus Containing Material* was adopted. Four rinderpest holding facilities for storing rinderpest virus containing material, excluding vaccine stocks, and two rinderpest vaccine holding facilities for storing only manufactured vaccines, vaccine stocks and material solely for their production, were officially recognised. Member Countries having rinderpest virus containing material should destroy it or submit it to one of these facilities.

9.4. Research contracts awarded to laboratories under the OIE tender for research on selected equine diseases

The Commission was informed that six research projects on priority diseases of equines (African horse sickness, equine influenza and glanders) had been awarded funding following a call for tender. The Commission would receive progress reports on these projects

9.5. International Federation of Biosafety Associations Certification Body (IFBA): new certification in biological waste management

The Commission noted the report.

10. Any Other Business

10.1. Dates of the next Biological Standards Commission meeting

The Commission noted the dates for its next meetings: 2–5 February 2016; 30 August – 2 September 2016.

11. Adoption of the Report

The report was adopted by the Commission.

_____

.../Annexes

Annex 1

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 1–3 September 2015

_____

Agenda

1. Adoption of the Agenda

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

2.1. Overall structure and review process for the *Terrestrial Manual*
2.2. Prospect of a printed edition of the *Terrestrial Manual* in 2016
2.3. Harmonising the chapter titles in the *Terrestrial Manual* and the *Terrestrial Code* revisited
2.4. Review of draft chapters received and their endorsement for circulation for Member Country comment
2.5. Proposal to move the chapter on Nipah and Hendra virus diseases to multispecies section
2.6. Proposal to develop a form for submission of new test methods and validation data

3. OIE Reference Centres

3.1. Applications for OIE Reference Centre status
3.2. Changes of experts at OIE Reference Laboratories
3.3. Review of new and pending applications for laboratory twinning projects
3.4. Mission to candidate laboratory in Vladimir, Russia
3.5. Specific issues related to Reference Centres: guidelines for applicants
3.6. Project to establish a virtual OIE Biobank: next steps

4. *Ad hoc* Groups

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

4.1 Report of the Meeting of the *ad hoc* Group on Vaccine Banks, 3–5 June 2015

▪ Proposed future *ad hoc* Groups: scheduling and drafting ToRs

4.2. *Ad hoc* Group on High Throughput Sequencing and Bioinformatics and Computational Genomics (HTS-BCG): implementation of the work plan
4.3. *Ad hoc* Group on a Replacement International Standard for Bovine Tuberculin
4.4. *Ad hoc* Group on a virtual OIE Biobank

5. International Standardisation/Harmonisation:

▪ Diagnostic tests

5.1. OIE Register of diagnostic kits
  5.1.1. Update and review of applications
  5.1.2. Question regarding the recognition of a diagnostic test method when a diagnostic kit is recognised by the OIE

5.2. Standardisation programme
  5.2.1. OIE-approved standard sera: datasheets for *Mycoplasma mycoides* subs. *mycoides* SC (small colony) antigen preparation for the complement fixation test for contagious bovine pleuropneumonia: follow up from last meeting
  5.2.2. EDQM project: establishment of a biological reference preparation to allow testing of equine influenza vaccines for compliancy with the recommendations of the Expert Surveillance Panel on Equine Influenza Vaccine Composition
  5.2.3. Update on progress on developing guidelines for antigen standards
  5.2.4. *In-vitro* production of dourine antigen
  5.2.5. New skin test for bovine tuberculosis that allows DIVA strategies
  5.2.6. Guidelines on the preparation and validation of an OIE-approved tuberculin standard
  5.2.7. Validation of the real-time reverse-transcription polymerase chain reaction method for detection of African horse sickness virus
  5.2.8. Info only: Second *Anti-Brucella ovis* International Standard Serum

▪ **Biosafety/Biosecurity**

5.3. Feedback from the Inaugural meeting of ISO/TC 212/JWG5, Laboratory Biorisk Management, London, UK, 13–14 January 2015

6. Follow-up from the General Session

7. Conferences, Workshops, Meetings

7.1. Feedback on the 1-day OIE Seminar, 17 June 2015 (theme: *New Diagnostic Technologies and International Standard Stetting*) held during the WAVLD Symposium 15–18 June 2017, Saskatoon, Canada
7.2. GMI meeting, 11–13 May 2015, Beijing, China (People's Rep. of)
7.3. 4th Conference of ISOCARD: Silk road camel: the camelids, main stakes for sustainable development, June 8-12, 2015 Almaty, Kazakhstan

8. Liaison with other Commissions

8.1. Horizontal issues among the Specialist Commissions

8.1.1. General discussion: distinction between OIE Standards and OIE Guidelines
8.1.2. Removal of details on diagnostic tests and their use from the *Terrestrial Code* and inclusion in the *Terrestrial Manual*
8.1.3. Terms of reference for a proposed *Terrestrial Code* chapter on vaccination

8.2. Scientific Commission for Animal Diseases

8.2.1. Revision of the bovine spongiform encephalopathy (BSE) chapter of the *Terrestrial Manual* to include a description of the available tests to discriminate atypical from classical BSE
8.2.2. Practicability of requiring FMD vaccine manufacturers to supply sera for test calibration
8.2.3. Zoonoses transmissible from non-human primates: review of the *Terrestrial Manual* chapter by the Working Group on Wildlife

8.3. Terrestrial Animal Health Standards Commission

8.3.1. Discrepancies between the *Terrestrial Code* and *Terrestrial Manual* regarding collection and processing of bovine, small ruminant and porcine semen
8.3.2. Update on the meeting of the *ad hoc* Group on Trypanosomoses

9. Matters of Interest for Information

9.1. Update on OFFLU
9.2. Non-tsetse-transmitted animal typanosomoses (NTTAT) network
9.3. Approved rinderpest holding facilities
9.4. Research contracts awarded to laboratories under the OIE tender for research on selected equine diseases
9.5. International Federation of Biosafety Associations Certification Body (IFBA): new certification in biological waste management

10. Any Other Business

10.1. Dates of the next Biological Standards Commission meeting: 2–5 February 2016; 30 August – 2 September 2016

11. Adoption of the report

Annex 2

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 1–3 September 2015

List of participants

MEMBERS

Dr Beverly Schmitt
(*President*)
National Veterinary Services Laboratories, Diagnostic Virology Laboratory, P.O. Box 844, Ames, IA 50010
UNITED STATES OF AMERICA
Tel.: (1-515) 337.75.32
Fax: (1-515) 337.73.48
beverly.j.schmitt@aphis.usda.gov

Dr Peter Daniels
(*Member*)
25 Hermitage Road,
Geelong, Victoria 3220
AUSTRALIA
Tel: (61) 419.10.32.62
danielspeter19@gmail.com

Dr Franck Berthe
(*Vice-President*)
Head of the Animal and Plant Health Unit, Via Carlo Magno 1, Parma
ITALY
Tel.: (39-0521) 036 870
Fax: (39-0521) 036 8770
Franck.Berthe@efsa.europa.eu

Dr Mehdi El Harrak
(*Member*)
R&D Director, MCI Santé Animale, BP278 ZI SO, 28810 Mohammedia
MOROCCO
Tel.: +212- 662 88.33.78
elharrak_m@hotmail.com

Dr Hualan Chen
(*Vice-President*)
(*Invited but could not attend*)
National Avian Influenza Reference Laboratory, Animal Influenza Laboratory of the Ministry of Agriculture, Harbin Veterinary Research Institute, CAAS
427 Maduan Street, Harbin 150001
CHINA (PEOPLE'S REP. OF)
Tel.: (86-451) 8593.5079
Fax: (86-451) 8273.3132
hlchen1@yahoo.com

Dr Anthony Fooks
(*Member*)
Rabies and Wildlife Zoonoses Group
Virology Department, Animal and Plant Health Agency, New Haw, Addlestone
Surrey KT15 3NB
UNITED KINGDOM
Tel.: (44-1932) 35.78.40
Fax: (44-1932) 35.72.39
tony.fooks@apha.gsi.gov.uk

CONSULTANT EDITOR OF THE *TERRESTRIAL MANUAL*

Prof. Steven Edwards
c/o OIE 12 rue de Prony
75017 Paris, FRANCE
Tel.: (33-1) 44.15.18.88
Fax: (33-1) 42.67.09.87
steve-oie@cabanas.waitrose.com

OIE HEADQUARTERS

Dr Monique Eloit
Deputy Director General and Head, Administration, Management, Human Resources & Regional Actions Dept, OIE
12 rue de Prony
75017 Paris, FRANCE
Tel.: (33-1) 44.15.18.88
Fax: (33-1) 42.67.09.87
m.eloit@oie.int

Dr Brian Evans
Deputy Director General and Head, Scientific and Technical Dept (STD)
b.evans@oie.int

Dr Elisabeth Erlacher-Vindel
Deputy Head, STD
e.erlacher-vindel@oie.int

Ms Sara Linnane
Scientific Editor, STD
s.linnane@oie.int

Dr François Diaz
Chargé de mission, STD
f.diaz@oie.int

Dr Gounalan Pavade
OFFLU Coordinator, STD
g.pavade@oie.int

Dr Min Kyung Park
Chargée de mission, STD
m.park@oie.int

Dr Susanne Munstermann
Chargée de projet,
STD s.munstermann@oie.int

Annex 3

Original: English
June 2015

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON VACCINE BANKS

Paris, 3–5 June 2015

_____

1. Opening

The OIE *ad hoc* Group on Vaccine Banks met from 3 to 5 June 2015 at the OIE Headquarters to discuss and integrate comments received from Member Countries and individual reviewers on revised Chapter 1.1.10. *Vaccine banks* of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*).

Dr Bernard Vallat, Director General of the OIE, welcomed the participants and thanked the Group for supporting the OIE work on the revision of this important *Terrestrial Manual* chapter. He explained that the report would be presented to the newly elected Biological Standards Commission at its meeting in September 2015. If endorsed by the Commission, the report and chapter will be appended to the report of the Commission's meeting and circulated to Member Countries, which would have the opportunity to comment. The Biological Standards Commission will analyse any subsequent comments and take them into account at its meeting in February 2016. Eventually a revised chapter could be proposed for adoption by OIE World Assembly during the General Session in May 2016. Dr Vallat noted that the current chapter, adopted in 2008, had become out dated. He stressed that it was necessary to enlarge its scope to other animal diseases besides foot and mouth disease (FMD) and to encompass current concepts for vaccine banks. Dr Vallat highlighted the importance of well managed vaccine banks as a key tool for preventing diseases worldwide, and indicated that all situations should be considered, including national and regional (groups of countries) banks. He stated that the OIE manages a number of vaccine banks, such as the vaccine banks for FMD in South-East Asia and China (SEACFMD), as well as a vaccine bank for rabies, all of which have new specific characteristics that would also need to be provided for in the revised chapter. He explained that certain OIE mechanisms relating to vaccine banks had been introduced into different sections of the draft chapter, which might have confused Member Countries as the rationale may not have been sufficiently clear. He proposed clarifying the OIE approach to vaccine banks, and developing a separate specific section within the chapter for OIE vaccine bank mechanisms and conditions. Such a section would be useful, in particular for discussions with donors. The Director General clarified that the OIE World Animal Health and Welfare Fund is managing all OIE vaccine bank activities. In conclusion, Dr Vallat summarised the objectives of the *ad hoc* Group in the revision of the chapter on vaccine banks of the *Terrestrial Manual:*

- to enlarge the scope of the chapter to include diseases other than FMD;
- to consider standards for both national and regional vaccine banks; and
- to develop a specific section on requirements for OIE-managed vaccine banks.

2. Appointment of chairperson and rapporteurs, and adoption of the agenda

The Group appointed Dr Michel Lombard as the chairperson of the meeting and Dr Gaston Funes agreed to act as rapporteur.

The Agenda, adopted with minor changes, and the List of Participants can be found at Appendices I and III of this report, respectively.

3. Background to the meeting

Dr Elisabeth Erlacher-Vindel, Deputy Head of the Scientific and Technical Department, introduced Dr Alain Dehove, Coordinator of the OIE World Animal Health and Welfare Fund, who presented the rationale for the work carried out by the OIE on vaccine banks, in the light of potential input to be considered by the Group while revising the chapter.

Dr Dehove explained that vaccine banks help provide access by OIE Member Countries to high quality vaccines that comply with OIE standards for different diseases. The OIE supports Member Countries getting access to vaccines and establishing vaccine banks, as well as in setting up vaccine bank mechanisms that can be used by countries, or regional or international organisations; this may include involvement in vaccine bank management mechanisms. Although the OIE has developed the concept of regional (continental) as well as global vaccine banks, it wishes to avoid reference to the concept of vaccine "stockpiles". The review should consider all diseases suitable for the possible establishment of a vaccine bank, and not exclusively focus on viruses. In the OIE experience, a service contract approach would allow for larger vaccine banks (more eligible countries or as members of vaccine banks), that in turn would allow for better leverage. The OIE also highlights the benefits of vaccine banks in terms of harmonising the requirements for vaccines or the vaccination strategies used.

Other aspects considered by the OIE included financial mechanisms that facilitate replenishment of antigens; cost-related benefits (economies of scale); vaccine shelf life (mechanisms that allow vaccines to be used before their shelf life has expired or that ensure that vaccines with the longest possible shelf life are delivered); speed of delivery (including availability and logistics); multi-donors and multi-suppliers approach.

Dr Erlacher-Vindel clarified the difference between OIE Standards and OIE guidelines: OIE Standards are published in the *Terrestrial Manual*, the *Manual of Diagnostic Tests for Aquatic Animals* (*Aquatic Manual*) and the *Terrestrial Animal Health Code* (*Terrestrial Code*) and *Aquatic Animal Health Code* (*Aquatic Code*) adopted by the World Assembly of Delegates; OIE guidelines are complementary texts endorsed by Specialist Commissions that are sometimes made available on the OIE website only. She explained that a horizontal chapter on vaccination, for inclusion in the *Terrestrial Code*, was under discussion; if it is decided to go ahead, the development of this chapter would involve the contribution of the three OIE Specialist Commissions – the Terrestrial Animal Health Code Commission, the Scientific Commission on Animal Diseases, and the Biological Standards Commission.

The importance of maintaining within the chapter cross references to relevant chapters of the OIE *Terrestrial Code* and the OIE *Terrestrial Manual*, or the European Pharmacopeia and other documents was noted, and the Group kept relevant texts available for consultation during the deliberations.

The participants introduced themselves to the Group and presented relevant background information from their specific fields of expertise.

4. Review of the Terms of Reference for the *ad hoc* Group meeting

The Group reviewed the Terms of Reference for the meeting and agreed to add a second point to address the needs of OIE-managed vaccine banks: "2. To address the concepts of and mechanisms for vaccine banks for animal diseases, and address the specific requirements for OIE vaccine banks".

The adopted Terms of Reference can be found at Appendix II to this report.

5. Review of Member Country comments on Chapter 1.1.10. *Vaccine banks* of the OIE *Terrestrial Manual* and update of the chapter

Comments were received from Australia, the European Union, Ireland, New Zealand, the United States of America and individual reviewers. In their review of the draft chapter, the Group considered all comments received and accepted when considered relevant.

General considerations and recommendations with relevance to other OIE standards and texts

The Group recommended maintaining an introduction that explains different vaccination scenarios until a horizontal chapter on vaccination becomes available in the OIE *Terrestrial Code*.

In the context of revising Section D. *Quantities of vaccine required in a bank*, the Group noted that it might be useful to have a definition of the term "vaccination coverage" in the Glossary of the *Terrestrial Manual*.

When reviewing Section H. *Deployment planning*, the Group noted the importance of avoiding thermo-shock while reconstituting freeze-dried vaccines, and agreed that this would best be described in a horizontal chapter on vaccination.

Overall, the Group's revision aimed at making the chapter more universally applicable. To this end, disease-specific examples were removed, where possible, and listings of requirements that are defined in OIE Standards were removed and replaced by references to these standards. Terms defined in the glossary of the OIE *Terrestrial Code*, such as *Competent Authority*, were used to replace wording describing the same concepts. The description of the diseases caused by multiple strains and serotypes of a pathogen with significant differences in antigenicity was harmonised throughout the text.

When going through the different sections of the draft chapter, the Group had the following observations and proposed amendments.

INTRODUCTION

The Group revised the introduction to the chapter, which described different vaccination strategies of relevance when discussing vaccine banks, and clarified that the introduction should remain in place until the adoption of a horizontal chapter on vaccination.

The different types of vaccination were revised, including both routine vaccination and emergency vaccination.

SECTION A: DEFINITION OF A VACCINE BANK

The different types of mechanisms for reserves of vaccines and antigens were clarified, including the option of having both (antigens and vaccines) as components of a bank.

The Group agreed that pathogen seed is not a component of a bank.

The Group further clarified that the chapter should address reserves for different vaccination strategies, including both routine campaigns and vaccination in emergency situations.

A short explanation of each vaccine bank mechanisms was retained within the definition section.

SECTION B: TYPES OF BANKS

The Group agreed on the characterisation of both national and regional vaccine banks, including, for the latter, criteria for common risk and control strategies. Clarifications were added on the nature of the product maintained within a bank (antigen versus ready-to-use formulated vaccines).

The Group also clarified the concept of specifically dedicated facilities licensed to formulate the final vaccine to be considered in addition to manufacturers.

Other aspects discussed by the Group included the supply and storage of the antigens, formulation, timing of delivery, availability of reagents, logistics, location of antigens and administrative issues. Advantages and disadvantages of each type of bank were also addressed.

The Group decided that all references to the service contract mechanism, as well as to OIE managed vaccine banks, be grouped together in a specific section (Section I. *Considerations for vaccine banks managed by international organisations*).

SECTION C: SELECTION OF VACCINES FOR A BANK

The Group noted that regional situations regarding different diseases should be considered when prioritising strains for inclusion in a vaccine bank.

The Group revised the text on the selection of vaccines for a bank, providing clarification regarding the risk assessment that should be the basis of vaccine selection, as well as references to the WAHIS System and to Reference Laboratories as reliable source of relevant information for the selection of strains or vaccines for a bank.

The necessity to incorporate new strains into a bank to achieve a better match with circulating antigenic variations of a given pathogen or to develop and adapt them for vaccine production, when appropriate, was stressed and addressed.

The importance of confidentiality and restricting information on certain details pertaining to the vaccine bank (from Competent Authorities) taking into account the risk of bioterrorism, was also highlighted within the chapter.

SECTION D: QUANTITIES OF VACCINE REQUIRED IN A BANK

In consideration of relevant comments, the concept of epidemiological modelling as a tool for estimating the quantities of vaccines was included in the revised text. Other criteria considered useful when setting up a vaccine bank included the potential economic impact of the disease.

The Group further considered different factors regarding the diseases, the susceptible populations, logistics and resources, global, regional and national epidemiological situations, characteristics of the vaccine, and contingency planning in relation to the quantities of vaccines, and proposed amended wording. The text proposed further emphasised that post-vaccination strategies should also be considered when deciding on quantities of vaccines for a bank, as well as the need for cooperation between vaccine banks, encouraging the establishment of regional or international vaccine banks, which would result in availability of a larger number of doses.

SECTION E: REGULATORY CONSIDERATIONS

The Group discussed the appropriate location and title for this section, agreeing that regulatory aspects concerned all aspects of vaccine banks, including provisions regarding storage of vaccines and antigens, addressed in the following section of the draft under discussion.

The Group agreed to rename the section “Regulatory Considerations” and to move it to before Section F. *Acquisition of antigens of vaccines for a bank.*

SECTION F: ACQUISITION OF ANTIGENS OR VACCINES FOR A BANK

The Group considered issues related to the sourcing of vaccines and antigens, including quality management schemes, as well as regulatory concerns. References to OIE *Terrestrial Manual* Chapter 1.1.6. *Principles of veterinary vaccine production* and other relevant OIE Standards were included.

The Group considered that for the procurement process it would be important for the *Competent Authority* to request a comprehensive dossier with extensive “technical specifications” including all relevant information regarding the production and delivery capacity of the supplier of the bank and the quality of the vaccine. The Group further agreed on the importance of prioritising the quality of the antigens or vaccines, which should comply with a minimal technical specification or quality standards, rather than exclusively the lowest price. The text of the draft chapter was revised accordingly.

References to the official OIE disease status recognition procedures, for which vaccines used should comply with OIE Standards in the OIE *Terrestrial Manual* were also included.

SECTION G: STORAGE OF VACCINES OR ANTIGENS IN A BANK

The Group discussed the necessity for regular inspections or audits of both the vaccine-producing plants, as well as the storage facilities, to verify compliance with recognised quality standards.

The need for independence of a vaccine bank in relation to a production plant, when they are co-located and share facilities, was stressed. The need for biosecurity procedures, including positive air pressure, HEPA filtration at air inlets, and quarantine procedures, was also discussed.

The Group further discussed storage conditions for antigens or vaccines, including the appropriate storage depending on the form or type of the vaccine (frozen liquid; freeze-dried powder). The maintenance of appropriate temperature conditions was highlighted, as well as appropriate containers and labelling.

Monitoring procedures and periodic checks to verify the appropriateness of storage conditions were stressed, as were the importance of periodic checks to verify the integrity and stability of the antigens. Continuity of electricity power supply, as well as back up storage equipment and facilities, were considered key issues.

The Group revised the draft text in accordance with these considerations.

SECTION H: DEPLOYMENT PLANNING

Text clarifying the specific meaning of "deployment" was included within the section.

Reference to the direct involvement of the *Competent Authority* for requesting and deciding on the deployment of vaccines, in agreement with the governance and management of the bank was included.

Aspects related to all logistics, including cold chain, communication and simulation exercises for ensuring an appropriate deployment of vaccines were discussed in detail and incorporated into this section.

SECTION J: CONSIDERATIONS FOR VACCINE BANKS MANAGED BY INTERNATIONAL ORGANISATIONS (NEW SECTION)

The Group reflected on the involvement of donors in financing vaccine banks to prevent, control, eliminate and eradicate diseases, noting differences in approaches and acknowledging that some donors rely on projects.

The Group further considered the following aspects and proposed appropriate text for the chapter:

The multi-donor approach was reviewed, recognising that different donors might be interested in funding specific aspects of a vaccine bank, for instance some donors might accept to cover the infrastructure, functioning and fixed costs of a bank and others may prefer to cover the purchase of antigens or vaccines. Clear guidelines were considered to be important, notably to be used when discussing with beneficiary countries. Other benefits of a multi-donor funding approach are that it allows complementarity and enlarges the coverage (regional and country earmarking) both geographically and with regard to the amount of strains.

The Group agreed that a regional or global approach is sought for these vaccine banks, as a tool to support regional strategies. The need for eligibility criteria to define beneficiary countries was discussed.

Cost–benefit advantages were identified, including economies of scale, but also the delivery of small quantities, reduction of the risk of storage of vaccines, direct purchasing of vaccines, harmonisation of regional strategies, and reduction in the number of procurement procedures for beneficiary countries.

Collaboration between vaccine banks and regional organisations (e.g. REMESA[1] or SEACFMD[2]) was highlighted as a good way for agreeing different mechanisms that provide additional benefits for beneficiary countries.

[1] REMESA: Mediterranean Animal Health Network
[2] SEACFMD: South-East Asia and China Foot and Mouth Disease Campaign

Differentiation between virtual banks, rolling stocks and other specific replenishment mechanisms, delivery on demand, buy-back schemes, and a service contract approach were noted, and further clarifications on service contracts for vaccine banks, including specific provisions and specifications, were discussed.

The Group stressed that international vaccine banks are necessary for both emergency situations and routine vaccination programmes, and considered that international vaccine banks could have a leverage effect at the country level as an incentive for the implementation of disease control programmes.

6. Any other matters

None.

7. Finalisation and endorsement of the draft report

The Group adopted the report.

_____

…/Appendices

Appendix I

AD HOC GROUP ON VACCINE BANKS

Paris, 3–5 June 2015

_____

Agenda

1. Opening
2. Appointment of chairperson and rapporteur, adoption of the Agenda
3. Background to the meeting
4. Review of the Terms of Reference for the *ad hoc* Group meeting
5. Review of Member Country comments on Chapter 1.1.10. *Vaccine banks* of the OIE *Terrestrial Manual* and update of the chapter
6. Any other matters
7. Finalisation and endorsement of the draft report

_____

Appendix II

AD HOC GROUP ON VACCINE BANKS

Paris, 3–5 June 2015

_____

Draft Terms of Reference

1. To review Member Country comments on Chapter 1.1.10. *Vaccine banks* of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* and update the chapter accordingly.

2. To address the concepts of and mechanisms for vaccine banks for animal diseases, and address the specific requirements for OIE vaccine banks.

_____

Appendix III

AD HOC GROUP ON VACCINE BANKS

Paris, 3–5 June 2015

_____

List of participants

MEMBERS

Dr Steven Edwards
c/o OIE
12 rue de Prony
75017 Paris
FRANCE
Tel: (44-1981) 550944
steve-oie@cabanas.waitrose.com

Dr Michel Lombard
IABS
22 rue Crillon
69006 Lyon
FRANCE
Tel: (33-4) 78 93 90 89
lombard.family@wanadoo.fr

Dr Alf-Eckbert Fuessel
Act. Head of Unit, DG SANTE/G2
Rue Froissart 101-3/67
B-1040 Brussels
BELGIUM
Tel: (32-2) 295 0870
alf-eckbert.fuessel@ec.europa.eu

Dr Gaston Maria Funes
Counsellor for Agricultural Affairs
Embassy of the Argentine Republic
Avenue Louise 225 box 3
1050 Brussels
BELGIUM
Tel: (32-2) 640 33 33
gfunes@agricola-ue.org

Dr Somjai Kamolsiripichaiporn
(*invited but could not attend*)
National Institute of Animal Health
Department of Livestock Development
Pakchong
Nakhonratchasima 30130
THAILAND
Tel: +66 44 27.91.12 ext.105
somjaik@dld.go.th

Dr Hernando Duque
North American FMD Vaccine Bank
Foreign Animal Disease Research Laboratory
Plum Island Animal Disease Center
Animal and Plant Inspection Services (APHIS)
United States Department of Agriculture (USDA)
P.O. Box 848 Greenport, NY 11944, USA
hernando.duque@aphis.usda.gov

Dr Mokganedi Mokopasetso
Botswana Vaccine Institute
Broadhurst Industrial Site, Lejara Road
Private Bag 0031
Gaborone
BOTSWANA
Tel: (267) 391.27.11
mmokopasetso@bvi.co.bw

REPRESENTATIVE BIOLOGICAL STANDARDS COMMISSION

Dr Anthony Fooks
Rabies and Widlife Zoonoses Group
Virology Department
Animal and Plant Health Agency
New Haw, Addlestone
Surrey KT15 3NB
Weybridge
UNITED KINGDOM
Tel: (44-1932) 35.78.40
tony.fooks@apha.gsi.gov.uk

OBSERVERS

Marien Jansen
International Federation for Animal Health (IFAH)
1 rue Defacqz
B-1000 Bruxelles
BELGIUM
Tel: +32-2-541-0111
marien.jansen@merck.com

OIE HEADQUARTERS

Dr Bernard Vallat
Director General
12 rue de Prony
75017 Paris
FRANCE
Tel: (33-1) 44 15 18 88
oie@oie.int

Dr Elisabeth Erlacher-Vindel
Deputy Head
Scientific and Technical Department
e.erlacher-vindel@oie.int

Ms Barbara Freischem
Chargée de mission
Scientific and Technical Department
freischem@oie.int

Dr Alain Dehove
Coordinator of the World Animal Health
and Welfare Fund
a.dehove@oie.int

Ms Sara Linnane
Scientific Editor
s.linnane@oie.int

_____