Report on Activities of the Biological Standards Commission 2016–2017

Beverly Schmitt

President
Biological Standards Commission (BSC)

**Members**

- Beverly Schmitt (USA) – President
- Franck Berthe (France) – Vice-President
- Hualan Chen (China [PPR]) – Vice-President
- Tony Fooks (UK) – Member
- Mehdi El Harrak (Morocco) – Member
- Peter Daniels – (Australia) – Member
Biological Standards Commission

- **Formal meetings:**
  - 30 August to 2 September 2016
  - 7 to 10 February 2017

- **Email communications**
Activities in brief

- OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
- OIE Reference Centres (for terrestrial animals)
- Ad hoc Groups
- International Standardisation/Harmonisation
  - Standardisation programme
  - OIE Register of diagnostic kits
- Liaison with other Commissions
Activities

About the *Terrestrial Manual* update

- Member Country comments are compiled by the OIE Secretariat
- The Consultant Editor reviews them and brings issues to the BSC
- The BSC approves changes or refers for further editing or input from subject matter experts
- 21 chapters and the glossary are being proposed for adoption
Chapters proposed for adoption

- Glossary
- 1.1.5 Quality management in veterinary testing laboratories
- 1.1.9. Tests for sterility and freedom from contamination of biological materials intended for veterinary use
- 2.1.6. Echinococcosis (infection with *Echinococcus granulosus* and with *E. multilocularis*)
- 2.1.8. Foot and mouth disease (infection with foot and mouth disease virus)
- 2.1.20 Trichinellosis (infection with *Trichinella* spp.)
- 2.2.5. Infestation with *Aethina tumida* (small hive beetle)
- 2.2.6. Infestation of honey bees with *Tropilaelaps* spp.
Chapters proposed for adoption

- 2.3.8. Duck virus hepatitis
- 2.2.13. Marek’s disease
- 2.4.4. Bovine genital campylobacteriosis
- 2.4.12. Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- 2.4.14. Lumpy skin disease
- 2.5.1. African horse sickness (Infection with African horse sickness virus)
- 2.5.9. Equine rhinopneumonitis (infection with equid herpesvirus-1 and -4)
Chapters proposed for adoption

- 2.7.1. Border disease
- 2.7.2. Caprine arthritis/encephalitis & Maedi-visna
- 2.7.13. Sheep pox and goat pox
- 2.8.9. Teschovirus encephalomyelitis
- 2.9.3. Infection with Campylobacter jejuni and C. coli
- 2.9.9. Toxoplasmosis
- 2.9.11. Zoonoses transmissible from non-human primates
Corrections to chapters proposed for adoption

- Lumpy skin disease: After chapter was sent to Member Countries as the version to be proposed for adoption, Reference Laboratory experts recommended that a reference to a real-time polymerase chain reaction (PCR) protocol be added.

- Foot and mouth disease: vaccine section, reference to the use of the bovine tongue epithelium method will not be removed pending further consideration.
Ad hoc Group on the *Terrestrial Manual* chapter on rabies

- Oral vaccination of dogs to be included in chapter on rabies
- AHG to expand section on the oral vaccination of dogs including manufacturing methods and bait requirements
- Review section on diagnostic techniques and incorporate new tests and delete obsolete tests
Glanders chapter

- Two OIE Reference Laboratory experts recommended that meliodiosis should be included in chapter on glanders
- BSC requested experts work together to prepare the draft text
- Chapter will be included in 2017/2018 review cycle
- Experts also advised no assay exists that differentiates between *Burkholderia mallei* and *B. pseudomallei*, therefore, complement fixation is still best test
Other *Terrestrial Manual* issues

- European Partnership for Alternative Approaches to Animal Testing (EPAA) recommended all references in OIE guidelines to target animal batch safety test (TABST) be eliminated; BSC decided not to eliminate but to note that prescribed TABST can be eliminated when other quality control measures are in place.

- Following Member Country advice, the BSC agreed to add adoption dates to the end of each chapter.

- The BSC continues to eliminate unnecessary animal inoculation techniques from the *Terrestrial Manual* in line with OIE’s animal welfare policy.
Activities

2. Reference Laboratories and Collaborating Centres
## OIE Reference Laboratories and Collaborating Centres in 2016

<table>
<thead>
<tr>
<th></th>
<th>Reference Laboratories</th>
<th>Collaborating Centres</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number</strong></td>
<td>260</td>
<td>51</td>
<td>311</td>
</tr>
<tr>
<td><strong>Countries</strong></td>
<td>39</td>
<td>26</td>
<td>45*</td>
</tr>
<tr>
<td><strong>Diseases/Topics</strong></td>
<td>119</td>
<td>46</td>
<td>-</td>
</tr>
<tr>
<td><strong>Experts</strong></td>
<td>188</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

*Countries hosting both Reference Laboratories and Collaborating Centres are not counted twice.*
World Distribution of OIE Reference Laboratories

- 1 to 3 OIE Reference Labs
- 4 to 10 OIE Reference Labs
- 11 to 20 OIE Reference Labs
- more than 20 OIE Reference Labs
- no OIE Reference Labs

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2016 OIE Reference Laboratory Activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Tests in use</td>
<td>95.7%</td>
</tr>
<tr>
<td>2a. Production of OIE recognised standard reference reagents</td>
<td>46.7%</td>
</tr>
<tr>
<td>2b. Supply of standard reference reagents</td>
<td>13.3%</td>
</tr>
<tr>
<td>3. Production/supply of diagnostic reagents other than OIE-approved</td>
<td>66.2%</td>
</tr>
<tr>
<td>4. Production of vaccines</td>
<td>3.8%</td>
</tr>
<tr>
<td>5. Supply of vaccines</td>
<td>3.3%</td>
</tr>
<tr>
<td>6. Development of new diagnostic methods</td>
<td>17.6%</td>
</tr>
<tr>
<td>7. Development of new vaccines</td>
<td>4.3%</td>
</tr>
<tr>
<td>8. Provision of diagnostic testing</td>
<td>50.0%</td>
</tr>
<tr>
<td>9. Provision of expert advice in technical consultancy</td>
<td>69.5%</td>
</tr>
<tr>
<td>10. Participation in international scientific collaborative studies</td>
<td>62.4%</td>
</tr>
<tr>
<td>11. Collection of epizootiological data</td>
<td>71.0%</td>
</tr>
<tr>
<td>12. Dissemination of epizootiological data</td>
<td>67.6%</td>
</tr>
<tr>
<td>13. Method of dissemination of information</td>
<td>91.0%</td>
</tr>
<tr>
<td>14. Provision of scientific and technical training</td>
<td>58.1%</td>
</tr>
<tr>
<td>15. Maintenance of quality management system according to int'l standards</td>
<td>81.9%</td>
</tr>
<tr>
<td>16. Accreditation by an international accreditation body</td>
<td>69.0%</td>
</tr>
<tr>
<td>17. Maintenance of biosafety and biosecurity</td>
<td>93.8%</td>
</tr>
<tr>
<td>18. Organisation of international scientific meetings</td>
<td>12.9%</td>
</tr>
<tr>
<td>19. Participation in international scientific meetings</td>
<td>66.2%</td>
</tr>
<tr>
<td>20. Exchange information with other OIE labs</td>
<td>36.2%</td>
</tr>
<tr>
<td>21. Proficiency testing with other OIE labs</td>
<td>35.3%</td>
</tr>
<tr>
<td>22. Collaboration with other OIE laboratories for same disease</td>
<td>61.4%</td>
</tr>
<tr>
<td>23. Proficiency testing labs other than OIE labs</td>
<td>36.2%</td>
</tr>
<tr>
<td>24. Provision of consultant expertise</td>
<td>36.2%</td>
</tr>
</tbody>
</table>
Activities of Collaborating Centres in 2016

2016 Collaborating Centre Activities

1. Activities within the sphere of competence 100.0%
2. International harmonisation of regulations 87.2%
3. Maintenance of a network in same specialty 85.1%
4. Maintenance of a network in other disciplines 68.1%
5. Provision of consultant expertise 93.6%
6. Provision of scientific and technical training 95.5%
7. Organisation of international scientific meetings 36.2%
8. Coordination of scientific and technical studies 95.7%
Applications should be submitted 45 days before the date scheduled for the meetings of the relevant Commission (Biological Standards Commission or Aquatic Animal Health Standards Commission).

Applications comprise the information requested in all 17 points in the guidelines for applicants.

Applications must be no longer than 15–20 pages in A4 format in one of the official languages of the OIE (English, French or Spanish).

Maintenance of quality management system certified according to Int’l Standards

Terrestrial Animals

2015

- ISO 17025: 73.76%
- In preparation to achieve ISO 17025: 13.86%
- System equivalent to ISO 17025: 2.97%
- No: 9.41%

*Total of 202 out of 209 reports submitted

2016

- ISO 17025: 80.48%
- In preparation to achieve ISO 17025: 12.86%
- System equivalent to ISO 17025: 2.38%
- No: 4.29%

*Based on reports submitted as of 5 May 2017 (204 out of 209 have submitted)
Procedure for the Designation of OIE Reference Laboratories

Finalised in 2017 by Biological Standards Commission in consultation with the Aquatic Animals Commission

Five performance criteria:

- lack of submission of an annual report
- no progress or explanation on achievement of accreditation to ISO 17025 or equivalent
- pattern revealing lack of diagnostic activity or production/supply of reference material
- no response to requests from OIE Headquarters for scientific expertise
- no response to OIE on administrative issues of transparency and confidentiality
Any OIE Ref. Lab. scoring negatively when measured against any one of these criteria could be deemed to fail to fulfill the TORs and progress towards potential delisting.

Also includes timeline for achievement of quality management accreditation to ISO 17025 or equivalent; at end of 2017, BSC will review status for all labs; will suspend Ref. Lab. status for up to 2 years, if not attained, lab would need to reapply for Ref. Lab. designation.

If approved by Assembly, the document will be available on website.

BSC is working on Collaborating Centre criteria to evaluate performance.
Reference Laboratories and Collaborating Centres: update

Three OIE Reference Laboratories requested to be removed from list:
- Caprine arthritis/encephalitis and Maedi-Visna (France)
- Bee diseases (Germany)
- Leptospirosis (United Kingdom)

One OIE Reference Laboratory will be integrated into an OIE Collaborating Centre:
- Control of Veterinary Medicinal Products in Sub-Saharan Africa (Senegal)

Two OIE Reference Laboratories were delisted due to lack of activities and requests from Member Countries
- Caprine arthritis/encephalitis and Maedi-Visna (USA)
  - Willing to remain as subject matter expert
Reference Laboratories and Collaborating Centres: update

OIE Reference Laboratory for Bee diseases (France) confirmed its designation as OIE Reference Laboratories for the following diseases:

- Infestation of honey bees with *Acarapis woodi*
- Infection of honey bees with *Paenibacillus larvae* (American foulbrood)
- Infection of honey bees with *Melissococcus plutonius* (European foulbrood)
- Infestation with *Aethina tumida* (Small hive beetle)
- Infestation of honey bees with *Tropilaelaps* spp.
- Infestation of honey bees with *Varroa* spp. (Varroosis)
- Nosemosis of honey bees
New OIE Reference Laboratories recommended for adoption

<table>
<thead>
<tr>
<th>Disease</th>
<th>Institution</th>
<th>Expert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classical swine fever</td>
<td>China Institute of Veterinary Drug Control, People’s Republic of China</td>
<td>Dr Qin Wang</td>
</tr>
<tr>
<td>Classical swine fever</td>
<td>Animal Health Research Institute, Chinese Taipei</td>
<td>Dr Chia-yi Chang</td>
</tr>
<tr>
<td>American foulbrood of honey bees</td>
<td>Friedrich-Loeffler-Institut (FLI), Federal Research Institute for Animal Health, Institute of Infectology, Insel Riems, Germany</td>
<td>Dr Marc O. Schäfer</td>
</tr>
<tr>
<td>Small hive beetle infestation (Aethina tumida)</td>
<td>FLI, Insel Riems, Germany</td>
<td>Dr Marc O. Schäfer</td>
</tr>
<tr>
<td>Varroosis of honey bees</td>
<td>FLI, Insel Riems, Germany</td>
<td>Dr Marc O. Schäfer</td>
</tr>
</tbody>
</table>
New OIE Reference Laboratories recommended for adoption

<table>
<thead>
<tr>
<th>Disease</th>
<th>Institution</th>
<th>Expert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabies</td>
<td>Kimron Veterinary Institute, Israel</td>
<td>Dr Boris Yakobson</td>
</tr>
<tr>
<td>Contagious agalactia</td>
<td>Istituto Zooprofilattico Sperimentale della Sicilia, Italy</td>
<td>Dr Guido Ruggero Loria</td>
</tr>
<tr>
<td>Echinococcosis</td>
<td>Istituto Zooprofilattico Sperimentale della Sardegna, Italy</td>
<td>Dr Giovanna Masala</td>
</tr>
<tr>
<td>Classical swine fever</td>
<td>Institut de Recerca I Tecnologia Agroalimentaries (IRTA), Spain</td>
<td>Dr Lilianne Ganges</td>
</tr>
</tbody>
</table>
## Replacement experts at OIE Reference Labs

<table>
<thead>
<tr>
<th>Disease</th>
<th>Country</th>
<th>Former expert</th>
<th>Replaced by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avian influenza and Newcastle disease</td>
<td>Italy</td>
<td>Dr Giovanni Cattoli</td>
<td>Dr Isabella Monne</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trichinellosis</td>
<td>Canada</td>
<td>Dr Alvin Gajahar</td>
<td>Dr Brad Scandrett</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Echinoccosis/hydatidosis</td>
<td>UK</td>
<td>Prof Philip Craig</td>
<td>Prof Michael Rogan</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paratuberculosis</td>
<td>France</td>
<td>Dr Pascale Mercier</td>
<td>Dr Virginie Thibault</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African horse sickness</td>
<td>South Africa</td>
<td>Dr Alison Lubisi</td>
<td>Dr Otto Koekemoer</td>
</tr>
<tr>
<td>Disease</td>
<td>Country</td>
<td>Former expert</td>
<td>Replaced by</td>
</tr>
<tr>
<td>---------------------------------------------</td>
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<td>-----------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>African swine fever</td>
<td>South Africa</td>
<td>Dr. Alison Lubisi</td>
<td>Dr Livio Heath</td>
</tr>
<tr>
<td>Brucellosis and ovine epididymitis</td>
<td>Italy</td>
<td>Dr Massimo Scacchia</td>
<td>Dr. Fabrizio De Massis</td>
</tr>
<tr>
<td>Contagious equine metritis</td>
<td>UK</td>
<td>Dr Paul Todd</td>
<td>Dr Ian Mawhinney</td>
</tr>
<tr>
<td>Equine rhinopneumonitis and equine influenza</td>
<td>Germany</td>
<td>Dr Armando Damiani</td>
<td>Dr Wlid Azab</td>
</tr>
<tr>
<td>Disease</td>
<td>Country</td>
<td>Former expert</td>
<td>Replaced by</td>
</tr>
<tr>
<td>------------------------------</td>
<td>-------------</td>
<td>------------------------------------</td>
<td>------------------------------</td>
</tr>
<tr>
<td>Foot and mouth disease</td>
<td>Thailand</td>
<td>Dr Somjai Kamolsiri-pichaiporn</td>
<td>Dr Wilai Linchongsubong-koch</td>
</tr>
<tr>
<td>Lumpy skin disease</td>
<td>South Africa</td>
<td>Dr Alison Lubisi</td>
<td>Dr David Wallace</td>
</tr>
<tr>
<td>Rabies</td>
<td>US</td>
<td>Dr Richard Franka</td>
<td>Dr Ryan Wallace</td>
</tr>
</tbody>
</table>
New OIE Collaborating Centres recommended for adoption

<table>
<thead>
<tr>
<th>Disease</th>
<th>Institution</th>
<th>POC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bee Health (Africa)</td>
<td>International Centre of Insect Physiology and Ecology, Kenya</td>
<td>Prof Suresh Raina</td>
</tr>
<tr>
<td>Diagnostic Test Validation Science (Asia-Pacific)</td>
<td>CSIRO Australian Animal Health Laboratory (Australia); University of Melbourne (Australia); and EpiCentre, Massey University (New Zealand)</td>
<td>Dr Axel Colling</td>
</tr>
<tr>
<td>Research and control of emerging and reemerging swine diseases in Europe</td>
<td>Institut de Recerca, Spain</td>
<td>Dr Joaquim Segales</td>
</tr>
</tbody>
</table>
Laboratory Twinning programme is functioning well

- Contributing to improving global disease control capacity

- Countries in all five OIE regions are benefiting

- Demand and interest remains high
Status May 2017

- 39 projects completed
- 31 projects underway
- 12 projects pending ("in the pipeline")

- Most popular topics
  - Avian influenza and Newcastle disease
  - Brucellosis
  - Rabies
  - Foot and mouth disease
Contribution of twinning to OIE Reference Centre network

**Adopted (May 2012)**
- RABIES – Changchun Veterinary Research Institute, China (People’s Rep. of)
- AVIAN MYCOPLASMOSIS – National Centre for Animal and Plant Health, Cuba
- CONTAGIOUS BOVINE PLEUROPNEUMONIA (CBPP) – National Veterinary Laboratory, Botswana

**Adopted (May 2014)**
- Infectious salmon anaemia – Aquaculture Pathology Laboratory, Chile
- OIE Collaborating Centre for Veterinary Epidemiology and Public Health – China Animal Health and Epidemiology Centre (CAHEC), China (People’s Rep. of)

**Adopted (May 2016)**
- BRUCELLOSIS – National Institute of Animal Health, Thailand
- AVIAN INFLUENZA – Laboratório Nacional Agropecuário em Campinas – Lanagro-SP, Brazil
- NEWCASTLE DISEASE – Laboratório Nacional Agropecuário em Campinas – Lanagro-SP, Brazil
Activities

3. *Ad hoc* Groups (AHG)
Veterinary Biobanking

OIE Reference Laboratories have a mandate to develop reference reagents for surveillance and diagnosis of animal diseases

- The OIE Virtual Biobank is a centralised web-based portal to inform on the location of biobank materials, including reagents and reference materials supplied by OIE Reference Laboratories

- Outcomes of the ad hoc Group:
  - Definition of quality requirements for biobank materials
  - Definition of the associated metadata
  - Items to be included in a common Material Transfer Agreement
  - Key business requirements and functions of the OIE virtual biobank
Proposed ad hoc Groups

- Transport of biological materials (June 2017)
- Development of Quality Management System Implementation Tools (5–7 September 2017)
- High Throughput Sequencing, Bioinformatics and Computational Genomics (27–29 June 2017)
Activities

4. International standardisation/harmonisation
International Standardisation/Harmonisation

- Guidelines for the preparation of antigen standards, entitled *International Reference Standards for Antigen Detection Assays*, were reviewed and endorsed by the BSC and are available online.

- OIE Reference Laboratories were contacted as potential providers of OIE-approved reference sera for certain diseases. The BSC invited labs to work together to evaluate serum before endorsement.
OIE Register of diagnostic kits:

Renewal for an additional 5 years

<table>
<thead>
<tr>
<th>Name of the diagnostic kit</th>
<th>Mycobacterium bovis Antibody Test Kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>IDEXX Laboratories</td>
</tr>
</tbody>
</table>
Fitness for purpose of the Kit

- Fit for the detection of antibody to *Mycobacterium bovis* (*M. bovis*) in cattle serum and plasma samples and to be used as a supplemental test, in conjunction with other methods, for diagnosing and managing tuberculosis infection.

- The test can also be of use when performing sero-surveys to understand prevalence and risk at a herd management level.
Summary: Draft Resolutions

- No. 17: Amendments to the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
- No. 18: Designation of OIE Reference Laboratories for terrestrial animal diseases
- No. 19: Register of diagnostic kits validated and certified by the OIE
- No. 20: Procedures for the designation of OIE Reference Laboratories
Update to Resolution No 18 (2011)

Proposed changes:

1. Removal of reference to biosafety lever (BSL3) with regards Rinderpest Holding Facilities.
2. Inclusion of references to FAO-OIE Standard Operating Procedures (SOP) pertaining to rinderpest virus.
3. Removal of references to actions that have already been concluded.

Reasoning/Recommendation/Endorsement

- Considering practical vaccine manufacturing, BSL lower than 3 is acceptable
  [FAO/OIE rinderpest Joint Advisory Committee and OIE Biological Standard Commission (both September 2013)].

- OIE Terrestrial Manual introduces Biological Risk Analysis and Biological Risk Management System instead of risk groups (BSL)
  [Chapter 1.1.4. of OIE Terrestrial Manual (revised on May 2015)].

- Proposed that Guidelines for rinderpest virus sequestration are revised according to the above-mentioned
  [OIE Biological Standard Commission (February 2017)].
Acknowledgements

- Dr Monique Eloït
- Dr Elisabeth Erlacher-Vindel
- Ms Sara Linnane
- Dr François Diaz
- Dr Min Kyung Park
- Dr Gounalan Pavade
- Ms Jennifer Lasley
- Dr Glen Gifford
- Dr Mária Szabó
- Dr Antonino Caminiti
- Dr Steve Edwards
Thank you for your attention!