WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

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February 2014

REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 19–20 February 2014

The OIE Biological Standards Commission (the Commission) met at the OIE Headquarters from 19 to 20 February 2014. Dr Elisabeth Erlacher-Vindel, Acting Head of the OIE Scientific and Technical Department, welcomed the Members of the Commission on behalf of Dr Bernard Vallat, Director General of the OIE: Prof. Vincenzo Caporale, President, Dr Rodolfo Rivero, Vice-President, Dr Beverly Schmitt and Dr Paul Townsend Dr Peter Daniels, Members of the Commission. Dr Hualan Chen, Vice-President, and Dr Peter Daniels, Member of the Commission, were invited but could not attend.

1. Adoption of Agenda

The proposed agenda was presented and adopted.

The Agenda and List of Participants are given at Annexes 1 and 2, respectively.

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

For this agenda item, the Commission was joined by the Consultant Editor of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*), Prof. Steven Edwards.

2.1. Decision on proposals of the Enlarged Bureau Group

The Commission reviewed the outcome of the Enlarged Bureau Group (EBG) meeting, which was held on 18 February 2014. The Commission approved the EBG Group's proposals (see Annex 3). Twenty chapters and the glossary were approved for circulation to Member Countries for second-round comment and eventual proposal for adoption by the Assembly in May 2014.

Three chapters and eight guidelines that had been sent for second-round comment would be proposed for adoption without further circulation. Of these, the chapter on biorisk management (Chapter 1.1.3 *Standard for managing biorisk in the veterinary laboratory and animal facilities*) would be numbered chapter 1.1.3a, its third appendix would be deleted (Appendix 1.1.3.3 *Examples of control measures for veterinary laboratories and animal facilities*), and it would be proposed for adoption and inclusion in the *Terrestrial Manual* alongside the current Chapter 1.1.3 *Biosafety and biosecurity in the veterinary microbiology laboratory and animal facilities* rather than replacing it. Chapter 1.1.3 was also identified for update by the *ad hoc* Group this year (eventual proposal for adoption in May 2015).

Chapter 2.7.10 Ovine pulmonary adenomatosis (adenocarcinoma) received no Member Country comments and so it would be proposed for adoption without further circulation.

Q fever was added to the list of chapters identified for proposal for adoption in May 2015.

The Commission noted that the amount of detail given to describe the diagnostic test methods varies largely among the chapters ranging from a few lines to a few pages. Following the successful development and use of a template for the vaccine section of the disease chapters, it was agreed that a similar template could usefully be developed for the diagnostic tests sections. The Consultant Editor agreed to carry out this task.

2.2. Reference standards– comment from Australia

Australia had commented that the recommendation that reference standards should be available from OIE Reference Laboratories for use by national reference laboratories to establish secondary or national standards against which working standards can be prepared and used in the diagnostic laboratory for daily routine use was included in some but not all disease chapter. Australia stated that this recommendation should either be consistently included in all disease chapters or should be included in Chapter 1.1.4 *Quality Management for Veterinary Testing Laboratories*.

The Commission fully agreed with Australia. OIE Reference Laboratories are mandated to produce or supply standard reference materials. Information on the availability and provision of such materials is requested through the annual reports of activities of the OIE Reference Laboratories, and the responses are analysed and quantified. The Commission is examining ways to assist laboratories to fulfil this Term of Reference (see agenda item 5.2: the mission of the new OIE Collaborating Centre for a Veterinary Biological Biobank). As stated in the previous meeting's report, this is a crucial activity and it has been added to the programme for the Third Global Conference of OIE Reference Centres (see agenda item 7.1).

2.3. Disease names in the *Terrestrial Code* and the *Terrestrial Manual*

A Member Country had commented that the disease names used in the *Terrestrial Animal Health Code* texts (*Terrestrial Code*) follow the format "Infection with [pathogen name]" while the *Terrestrial Manual* does not follow this format. The Biological Standards Commission stated that this discrepancy arises from the fact that the *Terrestrial Manual* covers diseases rather than infections. Later, the Secretariat from the OIE Headquarters asked the Director General for his opinion; he decided to ask the Council its view on this matter.

2.4. Sample banks for validating tests in wildlife

A Member Country had commented that it would be useful if OIE Reference Centres that work on diseases of wildlife could create sample banks as often there are not enough negative samples to fully validate the diagnostic test or positive controls. The Commission has identified a Collaborating Centre that could assist with this task (see agenda item 5.2).

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

At its last meeting and following a request from the Scientific Commission for Animal Diseases, the Commission had asked the OIE Reference Laboratory for epizootic haemorrhagic disease (EHD) to coordinate a study with the Reference Laboratories for Bluetongue to validate the competitive enzyme-linked immunosorbent assay (C-ELISA) for EHD.

The expert had responded that he had already worked on validating the assay and had provided the validation data. The Commission requested that these data be given to the OIE Reference Laboratories for Bluetongue for an opinion.

2.6. OIE validation guidelines

The Commission reiterated its proposal that once adopted by the Assembly the seven validation guidelines be put in Part 3 of the *Terrestrial Manual* in the on line version only with hyperlinks from the chapter to the appropriate guideline. Printed versions of these guidelines could be provided upon request only.

3. OIE Reference Centres

3.1. Applications for the status of OIE Reference Centre

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

OIE *Collaborating Centre for a Veterinary Biological Biobank*[1]
Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna "Bruno Ubertini" (IZSLER), Via Bianchi, 9, ITALY
Tel: (+39-30) 22.901; Fax: (+39-30) 24.25.251
E-mail: maura.ferrari@izsler.it /- Email2: info@izsler.it
Web: http://www.izsler.it
Contact Point: Dr Maura Ferrari.

OIE *Collaborating Centre for Viral Genomics, Bioinformatics and Transmission Dynamics*
Medical Research Council (MRC), University of Glasgow Centre for Virus Research (CVR), 464 Bearsden Road, Glasgow G61 1QH, UNITED KINGDOM
Tel.: (+44-[0]141) 330.25.41 (or 46.45); Fax: (+44-[0]141) 330.48.74;
E-mail: Massimo.Palmarini@glasgow.ac.uk
Contact Point: Prof. Massimo Palmarini.

OIE *Collaborating Centre for Laboratory Biorisk Management*
Sandia National Laboratories, International Biological Threat Reduction Program, 10600 Research Road SE, Albuquerque, NM 87123, UNITED STATES OF AMERICA
Tel.: (+1-505) 284.94.89; Fax: (+1-505) 284.06.09;
E-mail: jmgaudi@sandia.gov; web: http://www.biosecurity.sandia.gov/ibtr/home.html
Contact Point: Dr Jennifer Gaudioso.

OIE *Reference Laboratory for Peste des petits ruminants*
National Diagnostic Center for Exotic Animal Diseases, China Animal Health and Epidemiology Center, Ministry of Agriculture, No. 369 Nanjing Road, Qingdao 266032, CHINA (PEOPLE'S REP. OF)
Tel.: (+86-532) 87.83.91.88; Fax: (+86-532) 87.83.99.22
E-mail: zlwang111@163.com; web: www.cahec.cn
Designated Reference Expert: Dr Zhiliang Wang.

OIE *Reference Laboratory for Leishmaniosis*
Istituto Zooprofilattico Sperimentale della Sicilia (IZSSi), National Reference Centre for Leishmaniasis (C.Re.Na.L.), via Gino Marinuzzi 3, 90129, Palermo, ITALY
Tel.: (+39-091) 656.53.68; Fax: (+39-091) 656.35.68
E-mail: fabrizio.vitale@izssicilia.it; web: http://www.izssicilia.it
Designated Reference Expert: Dr Fabrizio Vitale.

OIE *Reference Laboratory for Babesiosis*
Istituto Zooprofilattico Sperimentale della Sicilia (IZSSi), Italian Reference Centre for *Anaplasma*, *Babesia*, *Rickettsia*, *Theileria* (C.R.A.Ba.R.T.), via Gino Marinuzzi 3, 90129, Palermo, ITALY
Tel.: (+39-091) 656.53.41 ext 219; Fax: (+39-091) 656.53.35
E-mail: santo.caracappa@izssicilia.it; web: http://www.izssicilia.it
Designated Reference Expert: Dr Santo Caracappa.

OIE *Reference Laboratory for Theileriosis*
Istituto Zooprofilattico Sperimentale della Sicilia (IZSSi), Italian Reference Centre for *Anaplasma*, *Babesia*, *Rickettsia*, *Theileria* (C.R.A.Ba.R.T.), via Gino Marinuzzi 3, 90129, Palermo, ITALY
Tel.: (+39-091) 656.53.41 ext 219; Fax: (+39-091) 656.53.35
E-mail: santo.caracappa@izssicilia.it; web: http://www.izssicilia.it
Designated Reference Expert: Dr Santo Caracappa.

[1] Currently the OIE Collaborating Centre for Cell Cultures: this is an application to change (enlarge) its title and remit.

OIE *Reference Laboratory for Rabies*
Centro Nacional de Servicios de Diagnóstico en Salud Animal Carretera Federal, Mexico-Pachuca Km. 37.5, 55740 Tecámac, Estado de Mexico, MEXICO
Tel.: (+52-55) 59.05.10.00 extension 53001;
E-mail: juan.montano@senasica.gob.mx; web: http://www.senasica.gob.mx
Designated Reference Expert: Dr Juan Antonio Montaño Hirose.

Although the OIE policy is to limit Collaborating Centres to one per topic per region, while, in an effort to increase the number of Member Countries hosting laboratories and to have a wide global distribution, Reference Laboratories are limited to one per country per disease, the Commission noted that Reference Laboratory applications continue to be from the same countries. For this reason, it does sometimes consider Reference Laboratories on a regional basis, while respecting the OIE *Basic Texts*.

At its previous meeting, the Commission had reviewed applications from a European country for the designation of two OIE Reference Laboratories: for bovine spongiform encephalopathy (BSE) and for scrapie. The Commission had requested more information on the institute's international activities. Reviewing the supplementary information that had been received, the Commission felt that there was a lack of evidence of leadership in the fields of training and dissemination of information on these two diseases compared with the existing OIE Reference Laboratories for these diseases, and therefore did not approve these applications.

In 2011, a laboratory in Europe that had completed a twinning project on avian influenza and Newcastle disease, had applied for OIE Reference Laboratory status. Following the advice received at that time on the technical aspects of the dossier, the Commission agreed that it was premature to accord the laboratory OIE Reference Laboratory status. Since then, a letter had been received from the Delegate of the country concerned explaining that the laboratory's diagnostic capacity had improved and increased, and that the institute planned to expand its international activities in the fields of diagnostics, surveillance, training and research. Before reaching a decision, however, the Commission felt that it would be useful to organise an expert mission to the laboratory to discuss ways to advance the application towards final designation as an OIE Reference Laboratory. Consulted after the meeting, the Director General endorsed this proposal.

An application that had been received from a country in the Asia, the Far East and Oceania Region for a Reference Laboratory for Equine piroplasmosis had been put on hold by the Commission at its previous meeting awaiting information on the laboratory's international activities, on its ability to receive samples from abroad and on its quality management system. The Commission reviewed the supplementary information received and agreed that it could not recommend the laboratory for designation as an OIE Reference Laboratory until an appropriate quality management system was in place.

Following completion of a twinning project, two applications had been received from an African country for Reference Laboratories for African horse sickness and Bluetongue. The Commission requested more information on the laboratory's international activities and on its quality management system.

Applications had been received from a country in the Asia, the Far East and Oceania Region for an OIE Collaborating Centre for Research on Emerging Avian Diseases and for OIE Reference Laboratories for bluetongue, for cysticercosis and for trichinellosis. The Commission requested more information on the laboratories' international activities, on their ability to receive samples from abroad, their quality management system, and on their legal and budgetary provisions specifically for the fulfilment of the OIE mandate.

Finally, applications had been received from a country in Europe for OIE Reference Laboratories for avian influenza and for equine influenza. The Commission noted that the applications did not include detailed information on international activities or on the institution's quality management system. The laboratory did not yet appear to have the level of expertise required of an OIE Reference Laboratory and it was suggested that it might be a good candidate for a twinning project.

3.2 Changes of experts in the List of Reference Centres

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

Equine infectious anaemia
Dr Wang Xiaojun to replace Dr Zhou Jianhua at the Harbin Veterinary Research Institute, CHINA (PEOPLE'S REP. OF).

Avian tuberculosis and paratuberculosis
Dr Iva Slaná to replace Dr Ivo Pavlik at the Veterinary Research Institute, Brno, CZECH REPUBLIC.

Dourine
Prof. K.P. Yurov to replace Prof. V.T. Zablotsky at the All-Russian Research Institute for Experimental Veterinary Medicine (VIEV), Moscow, RUSSIA.

Bovine spongiform encephalopathy and scrapie
Prof. Torsten Seuberlich to replace Prof Andreas Zurbriggen at the NeuroCentre, Department of Clinical Research and Veterinary Public Health, the University of Bern, SWITZERLAND.

Rabies
Dr Cathleen Hanlon to replace Dr Richard Franka at the Poxvirus and Rabies Branch, Centers for Disease Control and Prevention, UNITED STATES OF AMERICA.

Leptospirosis
Dr Matthew Erdman to replace Dr Mark Wilson at the National Veterinary Services Laboratories, USDA, APHIS, Veterinary Services, Ames, Iowa, UNITED STATES OF AMERICA.

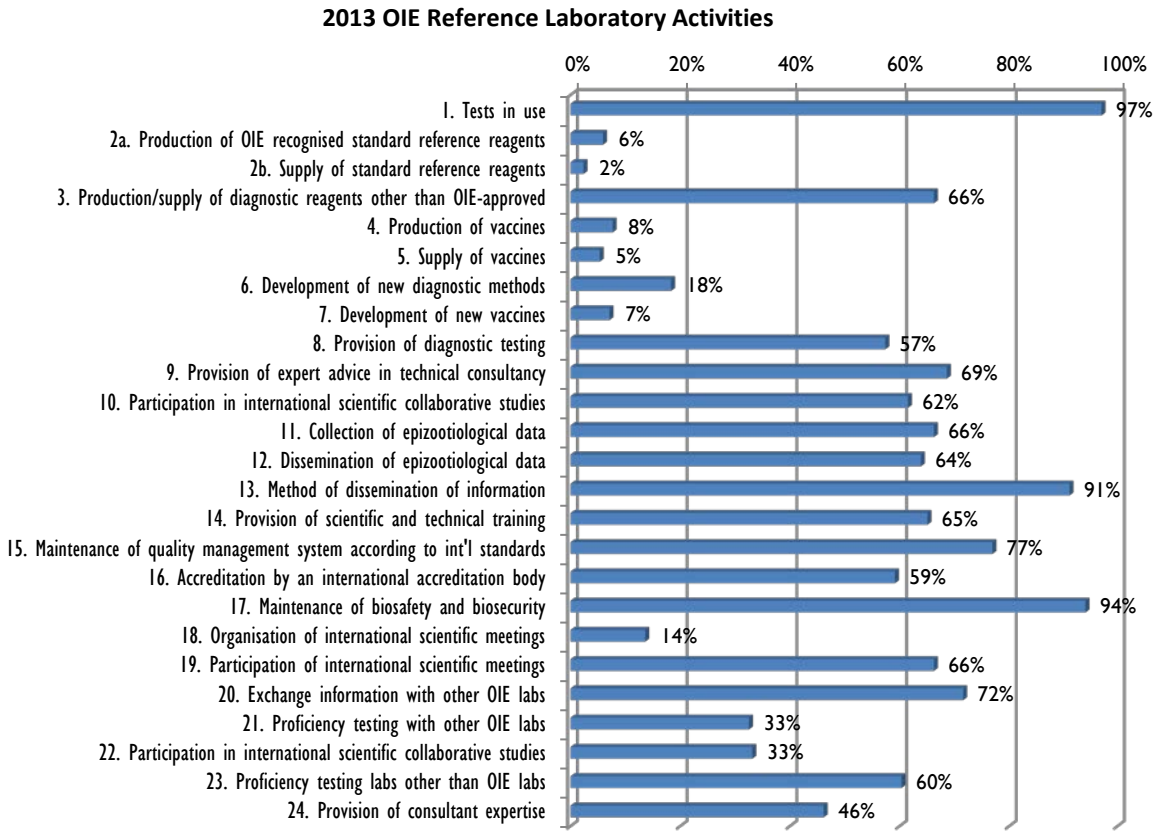
3.3. Specific issues related to Reference Centres

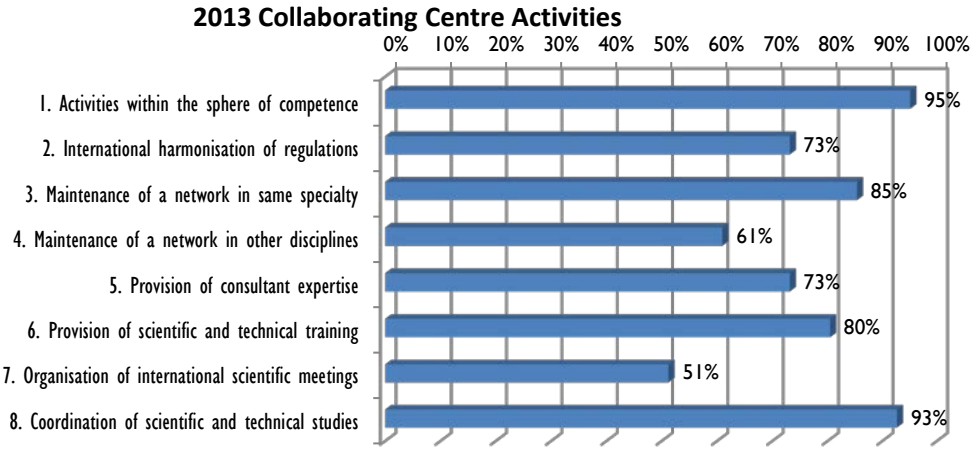
At its last meeting, the Commission agreed to develop a structured approach to monitoring Reference Centres so that under-performing or other problematic ones could be dealt with in a fair, timely, and coherent manner. The proposed procedure, which is based on the Terms of Reference, can be found at Annex 4. Consulted after the meeting, the Director General endorsed this proposal.

3.4. Annual reports of Reference Centre activities for 2013

Dr Min-Kyung Park, Scientific and Technical Department of the OIE, joined the meeting for this agenda item. The Commission was reminded that the new online web-based annual report template had been used by the Reference Laboratories for the first time. A number of comments and constructive criticisms on how to improve the tool had also been received and would be taken into account for next year's reports. Ms Park presented an analysis of the activities.

The Commission expressed its on-going appreciation for the enthusiastic support and expert advice given to the OIE by the Reference Centres. The international activities relevant to the work of the OIE are summarised in the following graphics:





For the 2013 reports of the Collaborating Centres, the template was an Office document rather than a web-based tool. An electronic version of the template should be available for the 2014 reports.

3.5. Feedback on Reference Laboratory quality management systems

As with the annual reports for 2012, the reports of OIE Reference Laboratory activities in 2013 were analysed and a number of laboratories that did not have an internationally recognised quality management system and were not in the process of achieving one were identified. The Commission drafted a letter for these laboratories confirm that they accept the concept of compliance with an appropriate laboratory Quality Management System. These laboratories would be reminded that it is difficult for the OIE to continue to maintain the designation of an OIE Reference Laboratory that is not quality assured to an appropriate standard.

In the future, those Reference Laboratories that indicated that they have ISO 17025 accreditation would be requested, the through the annual report, to provide the date the certificate was issued and the date of its last renewal.

3.6. Review of new and pending applications for laboratory twinning

Dr Gounalan Pavade, Scientific and Technical Department of the OIE, updated the Commission on the OIE Laboratory Twinning programme. As of 19 February 2014, 19 projects have been completed, 28 are underway and 15 are approved.

One twinning proposal, namely between Italy and Turkey for contagious bovine pleuropneumonia (CBPP) was presented for the Commission's technical input. The Commission commented that the twinning project details have to be modified to indicate the specific objective of the project's outcomes and questioned how the final meeting/workshop could assess the candidate laboratory for reference laboratory status by the parent institute experts.

The Director General of the OIE had requested that another audit be conducted of the twinning projects; the last audit that had taken place 5 years ago. The completed twinning projects had been divided into three pools, each project was given a code name that was typed on a slip of paper and placed in one of three envelopes; members of the Commission selected one slip of paper from each pool sight unseen. The President of the Commission abstained from the selection process as he strongly believes that the Commission's role in the twinning programme is marginal.

4. *Ad hoc* Groups

- **Past *ad hoc* Group meetings**

4.1. Report of the Meeting of the *ad hoc* Group on High Throughput Sequencing, Bioinformatics and Computational Genomics (HTS, BCG), 25–27 November 2013

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

4.1.1. GMI (Global Microbial Identifier) project

Prof. Vincenzo Caporale, President of the Commission, presented the GMI project.

Its aim is to develop a global system to aggregate, share, mine and use microbiological genomic data to address global public health and clinical challenges. Such a system should be deployed in a manner that promotes equity in access and use of the current technology worldwide, enabling cost-effective improvements in plant, animal, environmental and human health. In 2011, several infectious disease control centres and other organisations took the initiative of a series of international scientific and policy meetings, to develop a common platform and to better understand the potentials of an interactive microbiological genomic database. In addition to experts from around the globe, intergovernmental organisations have been included in the action, notably the WHO[2] and the OIE.

Prof. Caporale stressed the importance of the OIE involvement in this initiative and of developing its own strategy, for example expanding the WAHIS database to include sequence data.

4.1.2. New technologies: the role of the OIE

One of the sessions included in the programme of the Global Conference (see agenda item 7.1) is entitled: *New diagnostic technologies and technology platforms.* Presentations will be given based on a questionnaire survey of the state-of-the-arts of these technologies within the OIE Reference Laboratory network that will be developed. The eventual aim would be a have a recommendation outlining the future OIE role and policy on HTS, BCG.

[2] WHO: World Health Organization

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

4.2. *Ad hoc* Group on Camelidae

The Commission noted the Terms of Reference for this Group, which would meet at the OIE Headquarters from 1 to 3 April 2014.

5. International Standardisation/Harmonisation

- **Diagnostic tests**

5.1. OIE Register of diagnostic kits: review of applications

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

According to the procedure, each kit included in the OIE Register must have its registration renewed every 5 years. In February 2013, Dr Diaz informed the Commission that one diagnostic kit (Bio-Rad TeSeE™ Western Blot), added to the OIE Register in 2009, was reaching the end of its 5-year term. In accordance with protocol, the kit manufacturer had been contacted to indicate whether they wished to maintain the same purposes for which their kit had been certified as validated or to add new purposes. The OIE experts for the diseases targeted by the kit had also been contacted and asked their opinion on the need for a new evaluation of the purposes for which the kit had been certified as validated. Based on this information, the Commission decided to ask the kit manufacturer for some additional data. The Commission, based on the data received, decided to propose to the vote of the Assembly in May 2014 to renew the registration of the kit in the OIE register for the same purposes and for 5 additional years.

5.2. Standardisation programme

The Commission reviewed a technical report for an OIE inter-laboratory trial to determine the titre of the new batch of anti-rabies positive reference serum of dog origin. The Commission agreed to adopt the serum as an OIE-approved standard.

In follow-up to the previous meeting, an expert at one of the OIE Collaborating Centre had agreed to draft guidelines on the preparation of international reference antigen standards to complement the existing Guide 3: *International Reference Antibody Standards for Antibody Assays*. It was hoped that the guidelines could be reviewed at the next Commission meeting.

5.2.1. Development of a database of available reagents

The current OIE Collaborating Centre for Cell Cultures, Brescia, Italy had applied to extend its remit and title to OIE Collaborating Centre for a Veterinary Biologicals Biobank. Its aim is to extend an existing national programme to the OIE Reference Centre network. The Centre would initially collect information from the OIE Reference Centres on what reference materials they produce and supply. The ultimate aim would be to create a "biobank" of correctly identified, quantified and stored materials.

This biobank would assist the Commission to expand its standardisation programme to evaluate and adopt more of the reference materials that OIE Reference Laboratories are mandated to develop.

- **Biosafety/Biosecurity**

5.3. Future of CWA[3] 15793 Laboratory Biorisk Management

Dr Keith Hamilton, OIE Scientific and Technical Dept, updated that Commission on the future of the CEN Workshop Agreement on biorisk management CWA 15793. At its previous meeting the Commission had been informed that CWA 15793 was due to expire in 2014, and it was likely that, once expired, it would be converted to a full International standard (ISO) status or other type of ISO deliverables. The Commission had expressed concerns that adoption as an ISO standard may result in an additional burden on laboratories because resources were required to achieve certification. Dr Vallat

[3] CWA: CEN Workshop Agreement (CEN: Comité Européen de Normalisation [European Committee for Standardization])

had written to ISO to convey these concerns and had proposed a meeting between ISO and the OIE to discuss the issue. The Commission would be interested in participating in this meeting to discuss this and veterinary laboratory accreditation.

6. Resolutions for the General Session

6.1. Resolutions that will be presented in May 2014

The Commission noted that the following resolutions would be proposed for adoption at the General Session in May 2014:

- A resolution proposing the adoption of the 24 draft chapters for the *Terrestrial Manual* and eight guidelines (see item 2.1);
- A resolution proposing the addition of one diagnostic kit to the OIE Register.

7. Conferences, Workshops, Meetings

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

The Commission reviewed the draft programme and potential speakers. Once finalised, the programme would be made available on the Conference website in the near future; this website will be accessible to invited experts.

8. Liaison with other Commissions

8.1. Scientific Commission for Animal Diseases (Scientific Commission)

Matters from the Scientific Commission to the Biological Standards Commission

8.1.1. Follow-up on African horse sickness

The Commission was reminded that the OIE Reference Laboratories for African horse sickness (AHS) all agreed to collaborate on an inter-laboratory comparison between different molecular diagnostic methods before recommending designation of a specific test as 'prescribed' for international trade. The Reference Laboratories were making progress with this project.

8.1.2. Follow-up on vaccination strategies for tuberculosis

The Commission noted the excerpt from the report of a meeting of the *ad hoc* Group on Tuberculosis entitled: *Advantages and disadvantages on vaccination strategies for tuberculosis*. Until vaccination was common practice, the Commission would not accept for evaluation and eventual inclusion on the OIE register a diagnostic test that had been developed to differentiate animals infected with bovine tuberculosis from vaccinated animals (DIVA test) (follow up from February 2012).

8.1.3. Revised glanders chapter for the *Terrestrial Code*

The Scientific Commission noted that the draft chapter on glanders for the *Terrestrial Code* included details of which diagnostic tests to use and how they should be interpreted to define a case of glanders. The Scientific Commission felt that the testing regimen should be described in the *Terrestrial Manual* rather than in the *Terrestrial Code*. The Biological Standards Commission fully agreed and would request the Code Commission remove such text from the *Terrestrial Code*.

The Commission agreed to seek the advice of the OIE Reference Laboratory experts on the technical questions regarding tests to define a case of glanders.

8.1.4. Revised foot and mouth disease chapter for the *Terrestrial Code*

The Biological Standards Commission agreed to seek the advice of the President of the OIE *ad hoc* Group on Vaccine Quality related to Foot and Mouth Disease (FMD) on the technical question regarding FMD vaccines.

The Commission noted that the chapter on FMD for the *Terrestrial Code* included a schematic representation of laboratory tests for determining evidence of FMDV infection through or following serological surveys. The Commission reiterated its view that details on diagnostic tests and their use and interpretation should be included in the *Terrestrial Manual* only and should not be included in the *Terrestrial Code*.

9. Matters of Interest for Information

9.1. Expert Surveillance Panel on Equine Influenza Vaccine Composition – Conclusions and Recommendations (4 March 2014)

The Report of the Meeting of Expert Surveillance Panel (ESP) on Equine Influenza Vaccine Composition, which had been held 4 March 2014 and which is appended to this report at Annex 6, was sent to the OIE Headquarters after the Commission meeting. The main conclusions of the ESP meeting were:

- Vaccines for the international market should contain both clade 1 and clade 2 viruses of the Florida sublineage.
- Clade 1 is represented by A/eq/South Africa/04/2003-like or A/eq/Ohio/2003-like viruses.
- Clade 2 is represented by A/eq/Richmond/1/2007-like viruses.

The Commission stressed the importance of the ESP report and the need for its widespread distribution. It would be published in the OIE *Bulletin* and clearly mentioned on the OIE Website.

9.2. Update on OFFLU[4]

Dr Pavade updated the Commission on OFFLU. A few changes had been made to the OFFLU Steering and Executive Committee since the beginning of 2014. After 8 years, Prof. Steven Edwards stepped down as the founding Chairman of the Steering Committee (SC). Dr Peter Daniels moved from the Chairman of the Executive Committee (EC) to take over the role of SC Chairman. Other new changes include: Dr Ian Brown is now an SC member, Dr David Swayne has taken on the role of EC Chairman and Dr Giovanni Cattoli is an EC member. At the 2013 WHO vaccine composition meeting, the OFFLU network contributed 140 H5N1 and 60 H9N2 virus sequences to help WHO in pandemic preparedness. The OFFLU swine influenza virus group paper entitled: Review of influenza A virus in swine worldwide, was published in the *Zoonoses and Public Health*. The LAMP (loop-mediated isothermal amplification) project funded by the OIE under OFFLU technical activities was completed and its final report was submitted. The report concluded that there is a clear need for robust and safe molecular assays that are affordable and applicable in low resource laboratories. OFFLU organised a 3-day technical meeting in December 2013 in Beijing, China (People's Rep. of) to update the recommendations and develop new guidance on vaccines and vaccination against highly pathogenic avian influenza (HPAI) from lessons learnt over the past 6 years. Government representatives from various countries including Bangladesh, China (People's Rep. of), Egypt, India, Indonesia, Mexico, Nepal, and Vietnam, and OIE, FAO, WHO and OFFLU experts participated in this meeting. OFFLU carried out its second ring trial in 2013. Twenty laboratories from 19 different countries, including nine OIE/FAO Reference Centres and 11 national/regional laboratories, participated in this exercise. The results of the ring trial showed that there is a substantial improvement in the accurate detection of influenza virus A by laboratories but some national/regional labs face challenges in the subtyping and sequence analysis. OFFLU in collaboration with STAR-IDAZ[5] will be organising a meeting at OIE Headquarters in April 2014 to develop a 10-year vision for global animal influenza research needs.

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

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

9.3. OIE PVS[6] Laboratory Mission Training

Dr Erlacher-Vindel updated the Commission on this topic. Members of the Commission had been invited to participate in the training session for experts that will be held in March 2014.

10. Any Other Business

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

The updated work plan was agreed and can be found at Annex 7.

10.2. Issues from various *ad hoc* Groups relating to the *Terrestrial Manual*

Throughout the year a large number of *ad hoc* Groups meet at the OIE and, occasionally, questions are raised by these Groups on issues relating to the *Terrestrial Manual* that could be addressed directly to the Biological Standards Commission without the need for the *ad hoc* Group's report to be first approved by the Specialist Commission to which it reports. It was agreed to add a permanent item to the agenda of the Biological Standards Commission's meetings: "upcoming issues"; under this item, technical questions could be put directly to the Commission.

10.3. Dates of the next Biological Standards Commission meeting

The Commission noted the dates for its next meetings: 10–12 September 2014 and 27–29 January 2015.

11. Adoption of the Report

The report was adopted by the Commission.

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[6] PVS: Performance of Veterinary Services

Annex 1

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 19–20 February 2014

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Agenda

1. Adoption of the Agenda

2. OIE Reference Centres

2.1. Decision on proposals of the Enlarged Bureau Group
2.2. Reference standards– comment from Australia
2.3. Disease names in the *Terrestrial Code* and the *Terrestrial Manual*
2.4. Sample banks for validating tests in wildlife
2.5. Follow-up request to validate C-ELISA for epizootic haemorrhagic disease
2.5. OIE validation guidelines

3. OIE Reference Centres

3.1. Applications for the status of OIE Reference Centre
3.2. Changes of experts at OIE Reference Centres
3.3. Specific issues related to Reference Centres
3.4. Annual reports of Reference Centre activities for 2013
3.5. Feedback on Reference Laboratory quality management systems
3.6. Review of new and pending applications for laboratory twinning

4. *Ad hoc* Groups

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

4.1. Report of the Meeting of the *ad hoc* Group on High Throughput Sequencing, Bioinformatics and Computational Genomics (HTS, BCG), 25–27 November 2013
  4.1.1. Technical Item II and Resolution for the General Session on this topic
  4.1.2. GMI (Global Microbial Identifier) project

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

4.2. *Ad hoc* Group on Camelidae

5. International Standardisation/Harmonisation

▪ Diagnostic tests

5.1. OIE Register of diagnostic tests: update and review of applications
5.2. Standardisation programme
  5.2.1. Development of a database of available reagents

▪ Biosafety/Biosecurity

5.3. Future of CWA 15793 Laboratory Biorisk Management

6. Resolutions for the General Session

6.1. Resolutions that will be presented in May 2014

7. Conferences, Workshops, Meetings

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

8. Liaison with other Commissions

8.1. Scientific Commission for Animal Diseases
- 8.1.1. Follow-up on African horse sickness
- 8.1.2. Follow-up on vaccination strategies for tuberculosis
- 8.1.3. Revised glanders chapter for the *Terrestrial Code*
- 8.1.4. Revised foot and mouth disease chapter for the *Terrestrial Code*

9. Matters of Interest for Information

9.1. Expert Surveillance Panel on Equine Influenza Vaccine Composition – Conclusions and Recommendations (4 March 2014)
9.2. Update on OFFLU
9.3. OIE PVS Laboratory Mission Training

10. Any Other Business

10.1. Workplan and activities (as of February 2014)
10.2. Issues from various *ad hoc* Groups relating to the *Terrestrial Manual*
10.3. Dates of the next Biological Standards Commission meeting: 10–12 September 2014; 27–29 January 2015

11. Adoption of the report

Annex 2

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 19–20 February 2014

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MEETING OF THE ENLARGED BUREAU GROUP OF THE OIE BIOLOGICAL STANDARDS COMMISSION
Paris, 18 February 2014

Status of the chapters identified for update and proposal for adoption in 2014

No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
1.1.3a.	Standard for managing biorisk in the veterinary laboratory and animal facilities; Guideline 3.5 Managing biorisk: examples of aligning risk management strategies with assessed biorisks	RECEIVED	Suggest proposing for adoption the chapter that was circulated (numbering it as chapter 1.1.3.a) in relation to biosafety (i.e. without Appendix 1.1.3.3). The Consultant Editor, in liaison with the *ad hoc* Group, will check that the wording does not conflict with the old chapter (current chapter 1.1.3). This old chapter on biocontainment will be retained in the *Terrestrial Manual* and should be put forward for revision next year (adoption 2015). Guideline can be proposed for adoption in May.	Agree.
1.1.6.	Principles of veterinary vaccine production (re-write as a standard)	Collaborating Centre for Veterinary Medicinal Products has undertaken to draft the texts in collaboration with other OIE Centres working on vaccines	Awaiting text	For 2015
1.1.8.	Minimum requirements for vaccine production facilities		Awaiting text	For 2015
1.1.9.	Quality control of vaccines		Awaiting text	For 2015
1.1.10.	International standards for vaccine banks	RECEIVED	Amended and approved to be sent to Member Countries (MCs) as final version	Agree
2.1.3.	Bluetongue	RECEIVED	Approved to be sent to MCs as final version subject to clarification of some points by the authors	Agree.
2.1.4x	Crimean–Congo haemorrhagic fever	RECEIVED	Approved to be sent to MCs as final version	Agree
2.1.6x.	Epizootic haemorrhagic disease	RECEIVED	Approved to be sent to MCs as final version	Agree.
2.1.4.	Echinococcosis/Hydatidosis	Not yet received	Awaiting text	
2.1.6.	Heartwater	Not yet received	Awaiting text	
2.1.8.	Leishmaniosis	RECEIVED	Amended and approved to be sent to MCs as final version	Agree
2.1.9.	Leptospirosis	RECEIVED	Approved to be sent to MCs as final version	Agree.
2.1.11.	Paratuberculosis (Johne's disease)	RECEIVED	Approved to be sent to MCs as final version subject to clarification of some points by the authors	Agree.
2.1.14.	Rift Valley fever	RECEIVED from AHG	Approved to be proposed for adoption in May	Agree.

No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
2.2.1	Acarapisosis of honey bees	AHG revising bee disease chaps (coor. Ritter). Not yet received	Awaiting text	
2.2.2.	American foulbrood of honey bees	RECEIVED	Approved to be sent to MCs as final version subject to clarification of some points by the authors	Agree
2.2.3.	European foulbrood of honey bees	Not yet received	Awaiting text	
2.2.6.	*Tropilaelaps* infestation of honey bees (*Tropilaelaps* spp.)	Not yet received	Awaiting text	
2.2.7.	Varroosis of honey bees	Not yet received	Awaiting text	
2.3.5.	Avian mycoplasmosis (*M. gallisepticum, M. synoviae*)	Not yet received	Awaiting text	
2.3.3.	Avian infectious laryngotracheitis	RECEIVED	Approved to be sent to MCs as final version subject to clarification of some points by the author	Agree.
2.3.4.	Avian influenza	RECEIVED	Approved to be sent to MCs as final version subject to clarification of some points by the authors	Agree.
2.3.6.	Avian tuberculosis	RECEIVED	Approved to be sent to MCs as final version	Agree.
2.3.9.	Fowl cholera	RECEIVED	Approved to be sent to MCs for first-round comments	Agree
2.3.10.	Fowl pox	Not yet received	Awaiting text	
2.3.12.	Infectious bursal disease (Gumboro disease)	Received diagnostic section. Awaiting vaccine section	Awaiting text	
2.4.1.	Bovine anaplasmosis	RECEIVED	Approved to be sent to MCs for first-round comments	Agree
2.4.2.	Bovine babesiosis	RECEIVED	Approved to be sent to MCs as final version	Agree
2.4.5.	Bovine genital campylobacteriosis	Asked to be moved to 2014	Awaiting text	
2.4.8.	Bovine viral diarrhoea	Not yet received	Awaiting text	
2.4.9.	Contagious bovine pleuropneumonia	RECEIVED	Approved to be sent to MCs as final version subject to clarification of some points by the authors	Agree.

No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
2.4.16.	Theileriosis	RECEIVED	Approved to be sent to MCs as final version subject to clarification of some points by the reviewer	Agree.
2.5.8.	Equine piroplasmosis	RECEIVED	Approved to be sent to MCs as final version subject to clarification of some points by the authors	Agree.
2.5.9.	Equine rhinopneumonitis	Received diagnostic section. Awaiting vaccine section	Awaiting text	
2.6.1.	Myxomatosis	RECEIVED	Approved to be sent to MCs as final version	Agree.
2.7.6.	Contagious caprine pleuropneumonia	RECEIVED	Approved to be sent to MCs as final version subject to clarification of some points by the author	Agree.
2.7.10.	Ovine pulmonary adenomatosis (adenocarcinoma)	RECEIVED	Approved to be proposed for adoption	Agree.
2.8.3.	Classical swine fever (hog cholera)	RECEIVED chapter from AHG	Approved to be proposed for adoption	Agree.
2.9.1.	Bunyaviral diseases of animals (excluding Rift Valley fever)	RECEIVED	Approved to be sent to MCs as final version subject to clarification of some points by one author	Agree.
2.9.2.	Camelpox	RECEIVED	Approved to be sent to MCs as final version	Agree
2.9.4.	Cryptosporidiosis	RECEIVED	Under study	Agree.
2.9.5.	Cysticercosis	RECEIVED	Approved to be sent to MCs as final version subject to clarification of some points by the authors	Agree.
2.9.7.	*Listeria monocytogenes*	RECEIVED	Approved to be sent to MCs as final version	Agree.
2.9.11.	Verocytotoxogenic *Escherichia coli*	Not yet received	Awaiting text	

Status of the appendices identified for update and proposal for adoption in 2014

No.	Chapter title	EBG recommendation	BSC decision
Validation Guideline 3.6.1	Development and optimisation of antibody detection assays	Approved to be proposed for adoption in May	Agree.
Validation Guideline 3.6.2	Development and optimisation of antigen detection assays	Approved to be proposed for adoption in May	Agree.
Validation Guideline 3.6.3	Development and optimisation of nucleic acid detection assays	Approved to be proposed for adoption in May	Agree.
Validation Guideline 3.6.4	Measurement uncertainty	Approved to be proposed for adoption in May	Agree.
Validation Guideline 3.6.5	Statistical approaches to validation	Approved to be proposed for adoption in May	Agree.
Validation Guideline 3.6.6	Selection and use of reference samples and panels	Approved to be proposed for adoption in May	Agree.
Validation Guideline 3.6.7	Principles and methods for the validation of diagnostic tests for infectious diseases applicable to wildlife	Approved to be proposed for adoption in May	Agree.

New chapters and chapters proposed for update in 2014
(i.e. for proposal for adoption in May 2015)

No.	Title
New chapter	Management of Veterinary Laboratories (to include sections on quality and biorisk management)
2.1.19.	Vesicular stomatitis
2.4.3.	Bovine brucellosis*
2.4.5.	Bovine genital campylobacteriosis
2.4.10.	Dermatophilosis
2.5.4.	Epizootic lymphangitis
2.7.2.	Caprine and ovine brucellosis (excluding *Brucella ovis*)*
2.7 9.	Ovine epididymitis (*Brucella ovis*)*
2.8.5.	Porcine brucellosis*
2.8.10.	Teschovirus encephalomyelitis (previously enterovirus encephalomyelitis or Teschen/Talfan disease)
2.9.10.	Toxoplasmosis
1.1.7.	Tests for sterility and freedom from contamination of biological materials (2008)
2.4.7.	Bovine tuberculosis (2009)
2.8.7.	Porcine reproductive and respiratory syndrome (2010)
2.8.8.	Swine influenza (2010)
2.8.11.	Transmissible gastroenteritis (2008)
2.9.6.	Hendra and Nipah virus diseases (2010)

*Brucellosis chapters: the experts are working on amalgamating 2.4.3, 2.7.2 and 2.8.5 into one chapter – Brucellosis (*Brucella abortus, B. melitensis and B. suis*), and on updating the chapter on ovine epididymitis (*Brucella ovis*).
Struck through chapters have already been received.

The following two chapters were added to this list:

2.1.12.	Q fever
1.1.3.	Biosafety and biosecurity in the veterinary microbiology laboratory and animal facilities

Remaining chapters and guidelines and date last adopted.

No.	Title
2.1.7.	Japanese encephalitis (2010)
2.1.18.	Tularemia (2008)
2.3.8.	Duck virus hepatitis (2010)
2.3.13.	Marek's disease (2010)
2.3.15.	Turkey rhinotracheitis (avian metapneumovirus) (2009)
2.4.6.	Bovine spongiform encephalopathy (2010)
2.4.13.	Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (2010)
2.4.14.	Lumpy skin disease (2010)
2.6.2.	Rabbit haemorrhagic disease (2010)
2.7.1.	Border disease (2008)
2.7.3/4.	Caprine arthritis/encephalitis and Maedi-visna (2008)
2.7.13.	Scrapie (2009)
2.7.14.	Sheep pox and goat pox (2010)
2.9.3.	*Campylobacter jejuni* and *Campylobacter coli* (2008)
2.9.9.	Salmonellosis (2010)
Guideline 3.3.	The application of biotechnology to the development of veterinary vaccines (2010)
Guideline 3.4.	The role of official bodies in the international regulation of veterinary biologicals (2008)

For information: chapters adopted since 2012

No.	Title	Year adopted
1.1.1	Collection, submission and storage of diagnostic specimens	May 2013
1.1.2.	Transport of specimens of animal origin	May 2013
1.1.4.	Quality management in veterinary testing laboratories	May 2012
1.1.5.	Principles and methods of validation of diagnostic assays for infectious diseases	May 2013
2.1.1.	Anthrax	May 2012
2.1.2.	Aujeszky's disease	May 2012
2.1.5.	Foot and mouth disease	May 2012
2.1.10.	Screwworm (*Cochliomyia hominivorax* and *Chrysomya bezziana*)	May 2013
2.1.13.	Rabies (Vaccine section)	May 2013
2.1.15.	Rinderpest	May 2012
2.1.16.	Trichinellosis	May 2012
2.1.17.	*Trypanosoma evansi* infections (including surra)	May 2012
2.1.20.	West Nile fever	May 2013
2.2.4.	Nosemosis of honey bees	May 2013
2.2.5.	Small hive beetle infestation (*Aethina tumida*)	May 2013
2.3.1.	Avian chlamydiosis	May 2012
2.3.2.	Avian infectious bronchitis	May 2013
2.3.4.	Avian influenza	May 2012
2.3.7.	Duck virus enteritis	May 2012
2.3.11.	Fowl typhoid and Pullorum disease	May 2012
2.3.14.	Newcastle disease	May 2012
2.4.1.	Bovine anaplasmosis	May 2012
2.4.11.	Enzootic bovine leukosis	May 2012
2.4.12.	Haemorrhagic septicaemia	May 2012
2.4.15.	Malignant catarrhal fever	May 2013
2.4.17.	Trichomonosis	May 2012
2.4.18.	Trypanosomosis (Tsetse-transmitted)	May 2013
2.5.1.	African horse sickness	May 2012
2.5.2.	Contagious equine metritis	May 2012
2.5.3.	Dourine	May 2013
2.5.5.	Equine encephalomyelitis (Eastern & Western)	May 2013
2.5.6.	Equine infectious anaemia	May 2013
2.5.7.	Equine influenza	May 2012
2.5.10.	Equine viral arteritis	May 2013
2.5.11.	Glanders	May 2013
2.5.13.	Venezuelan equine encephalomyelitis	May 2013
2.7.5.	Contagious agalactia	May 2013
2.7.7.	Enzootic abortion of ewes (ovine chlamydiosis)	May 2012
2.7.11.	Peste des petits ruminants	May 2013
2.8.1.	African swine fever	May 2012
2.8.2.	Atrophic rhinitis of swine	May 2012
2.8.9.	Swine vesicular disease	May 2013
2.9.8.	Mange	May 2013

No.	Title	Year adopted
Guideline 3.1.	Laboratory methodologies for bacterial antimicrobial susceptibility testing	May 2012
Guideline 3.2.	Biotechnology in the diagnosis of infectious diseases	May 2012

MEETING OF THE ENLARGED BUREAU GROUP OF THE OIE

BIOLOGICAL STANDARDS COMMISSION

Paris, 18 February 2014

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

1.1. Update on progress since last meeting
1.2. Review of chapters proposed for first round of comments and eventual adoption in May 2014 [opinion and recommendations]

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

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MEETING OF THE ENLARGED BUREAU GROUP OF THE OIE

BIOLOGICAL STANDARDS COMMISSION

Paris, 18 February 2014

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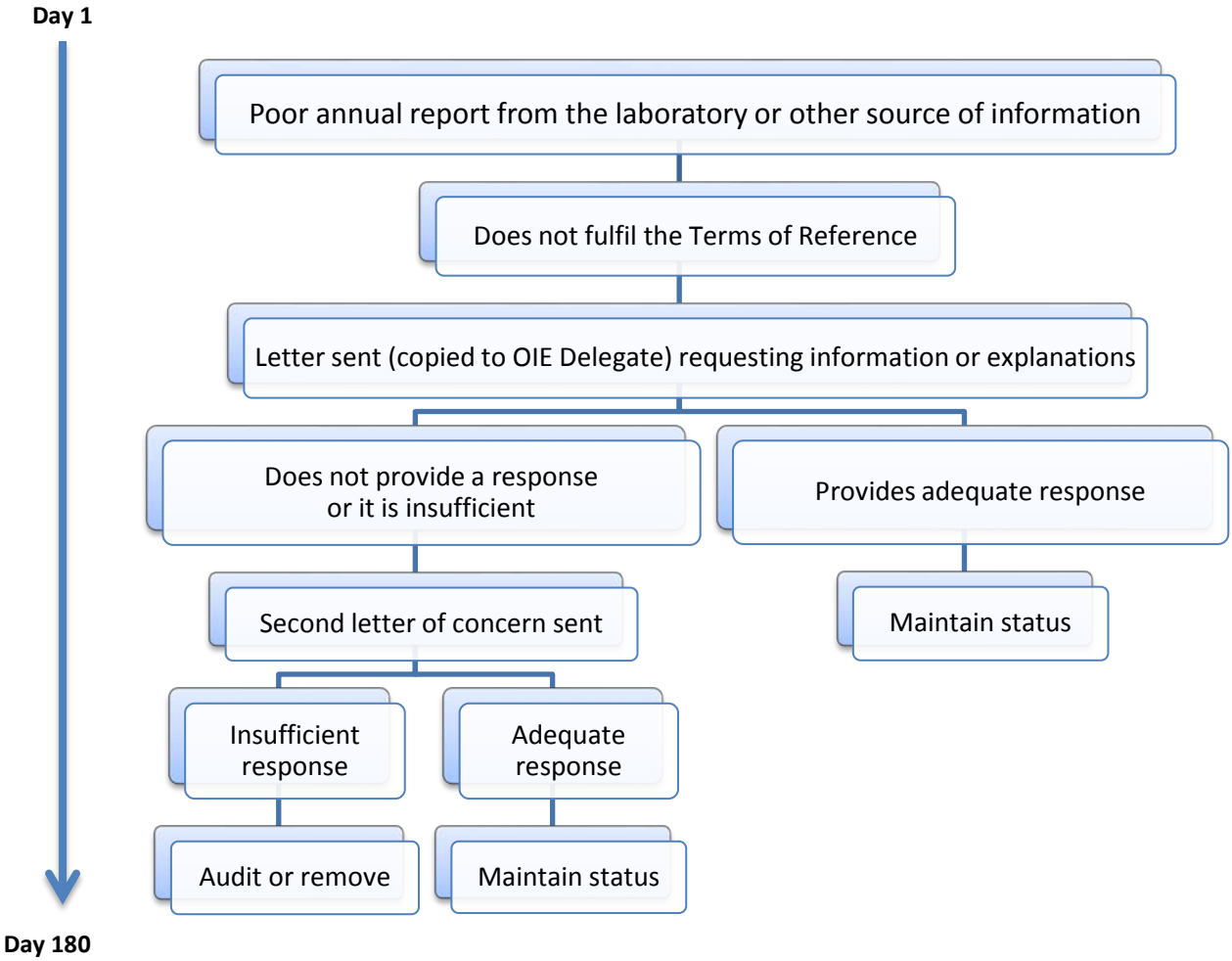
DECISION TREE ON HOW TO EVALUATE AND REACT TO UNDER-PERFORMING OR PROBLEMATIC OIE REFERENCE CENTRES



Annex 5

Original English
November 2013

AD HOC GROUP ON HIGH THROUGHPUT SEQUENCING, BIOINFORMATICS AND COMPUTATIONAL GENOMICS (HTS-BCG)

Paris, 25–27 November 2013

An *ad hoc* Group (AHG) on High Throughput Sequencing, Bioinformatics and Computational Genomics (HTS-BCG) was convened at the OIE Headquarters from 25 to 27 November 2013.

The Agenda and List of Participants are given at Appendices I and II, respectively.

1. Opening

Dr Elisabeth Erlacher-Vindel, Acting Head of the Scientific and Technical Department, welcomed the participants of the meeting on behalf of Dr Bernard Vallat, Director General of the OIE. She explained that the specific task of the Group was to develop an OIE strategy on the topic for use by the OIE, the OIE Reference Laboratory and Collaborating Centre (Reference Centre) network and the Member Countries (MCs).

2. Appointment of chairperson and rapporteur

The meeting was chaired by Prof. Massimo Palmarini, and Dr Peter Daniels was designated as rapporteur.

3. Terms of Reference for the *ad hoc* Group meeting

The Terms of Reference (ToRs) were adopted with minor modifications; they can be found at Appendix III.

4. Summary of key recommendations

4.1. The genome sequence of infectious agents and its subsequent analysis are integral components of disease investigation now and in the foreseeable future.

4.2. The strengths of the OIE include its animal disease information system and its network of 284 Reference Centres. Accordingly, the inclusion of the genomic sequence data of infectious agents should be an integral part of reports of animal disease and surveillance. Consequently, the OIE should adapt its animal disease information systems to include this information.

4.3 HTS-BCG will increasingly be a major tool in the generation of genomic sequence data, and the OIE should develop standards for the management of this technology in laboratories and the inclusion of HTS-BCG procedures in the laboratory methods for specific animal diseases. These matters should be urgently progressed through the development of pilot projects that will address the database issues, develop the standards for inclusion in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*), initiate networking among suitably qualified Reference Centres and produce standard data sets for use in quality assurance programme.

5. Addressing the Terms of Reference

5.1. ToR 1: Globalisation of Microbial Diagnostics in Animal Health

The AHG noted the increasing role that sequence information is playing in the diagnosis and management of microbial infections, including in the characterisation of infectious agents, their possible phenotypic characteristics and the likely distribution of their spread from place to place and through time. The AHG recommended that the OIE should develop a strategy, and adopt policies and practices on analysing and managing genomic sequence data of microorganisms as they are becoming essential to the understanding and control of infectious diseases.

The AHG considers that in the current and future scientific environment a microorganism is not identified satisfactorily unless essential features of its genome are described. For viruses this may be the whole genome while for bacteria and parasites, it may be just partial sequences. However, the technology is growing so rapidly that within a short time whole genome sequences for these larger microorganisms may also be routinely generated.

The OIE has the responsibility to be the leading agency internationally on matters relating to animal health. Consequently, for the OIE to discharge this mandate, it will be necessary to play a leading and central role in the management, interpretation and use of sequence information in matters related to animal health. This will include but not be limited to the development of standards for the generation of such data during investigations of infections of single animals, animal populations and their immediate environment and at any point along the "value chain" linking animal production with the ultimate beneficiaries.

The AHG noted that the clear trend to increasing reliance on generating and using sequence information for the study of infectious agents has implications not only for the generation, management and use of such data, and the need for accompanying standards and services, but also ultimately for the design and management of veterinary laboratories. This might ultimately include devices and systems for the generation of sequence data away from the laboratory and closer to the point of sampling on the farm or at other points along the "value chain" including animal health and food safety. Such developments will require standards to ensure supervision by the veterinary services and adequate quality assurance.

5.2. ToR 2: A Global Network of OIE Reference Centres for a Coordinated International Approach to Implementation of HTS-BCG

The OIE through its designated Reference Centres and access to other national expertise through the offices of the official Delegates from MCs has at its disposal much of the expertise that would underpin the scientific understanding of the use of sequence information of microorganisms in relation to animal health. The AHG recommends that this expertise be harnessed to assist the OIE in further developing its policies and practices relating to managing and using sequence information in the discharge of its mandate.

In the first instance this should be progressed by involving suitable qualified scientists from the existing global network of Reference Centres to address specific matters on which advice will be needed from time to time. A more detailed approach to assessing the depth and location of such expertise is suggested in the AHGs report in Section 5.5 below.

5.3. ToR 3. Coordination of Data Management, and a Role for the OIE in Managing a Dedicated Database

The AHG further recommends that the OIE develops a more comprehensive approach to the collection and storage of sequence information relating to animal disease, and to the making of such information open access.

The AHG considers that sequence data of microorganisms such as generated by HTS, metagenomics approaches is only a tool, although a powerful one, to investigate issues regarding animal health and food safety. Consequently, the whole process of interpretation of sequence data in relation to the disease investigation should be led by suitably qualified veterinarians, consistent with the usual requirements for diagnosis of animal disease. To further emphasise that considerations of the sequence analysis will be an integral aspect of animal health decision making in the future, the AHG further recommends that the sequence and sequence analysis of infections associated with cases, outbreaks and investigations of animal disease should be recorded together with all other information relating to the reporting and recording of such cases and outbreaks, and be considered a necessary part of such reports and records.

Consequently, the AHG further recommends that the OIE require reporting of genomic information in formal reports to the OIE, and that it develops systems for the receipt, storage, accessing and sharing of such information.

The meeting was joined by Dr Paola Caceres and Dr Lina Awada from the OIE Animal Health Information Department, to assist the AHG to further explore practicalities and strategies for the implementation of this concept.

It is the understanding of the AHG that the storage of sequence information of microorganisms relevant to animal health is currently somewhat fragmented. Although GenBank is thought to be the primary repository of such information, the AHG is aware of other activities such as agent-specific databases maintained by some Reference Centres and a mixture of public and private databases for other agents such as influenza viruses. Importantly, it is common practice for public funding agencies to have a mandatory requirement for timely depositing of sequences generated by their funding on open access databases. The AHG is also aware of international discussions initiated with the purpose of consolidating information relating to microorganisms and accompanying metadata including epidemiological information.

Against this background, and recognising its complexity, the AHG discussed the role of the OIE and the stability it offers. The OIE is an organisation of voluntary membership of most of the countries engaged in animal health and production on the planet. OIE membership is formal, on the basis of being an official government membership. Furthermore it has been formally ratified internationally that the OIE shall be the official arbiter on matters and standards relating to animal health in international processes such as the WTO. Hence, the AHG suggests that it is appropriate, even necessary, for the OIE to take a leading role in the management of sequence information relating to infections of animals internationally. The OIE offers a stable and enduring base for such involvement.

The OIE already maintains a database of reports of animal disease situations from MCs. Consistent with above recommendations and considerations, the AHG recommends that the inclusion of sequence information be required in such reports, and that the OIE considers the technical requirements to expand its reporting and recording role in this manner.

In support of this recommendation, the AHG notes that the OIE has an established reporting framework supported by the legal authority and obligation, it is further supported by a laboratory network through which it might be expected that much of the relevant sequence information will be generated.

A possible negative consideration, to be further addressed by the OIE as it develops a business plan for uptake of this recommendation, is that of duplication among databases and their roles. A strategy to manage perceptions and real overlaps in this area would be necessary. The costs and resourcing implications of establishing a sequence database and managing it would also have to be addressed. For an OIE sequence database to be considered useful by the international scientific community it would have to be easy to use, operate effectively and managed efficiently.

It is the preference of the AHG to leave more detailed technical considerations to others with specific expertise, but note there was discussion within this Group on the strategies around linking the current OIE database, WAHIS, to other databases rather than being the primary repository of data. The AHG tended to consider that a strategy of just being a gateway linking to data elsewhere may not be consistent with the recommendation that the OIE develops its operations to continue to be the primary reliable source of animal health information globally.

5.4. ToR 4: Aspects of HTS Test Systems for which Standards should be Developed

5.4.1. The Range of Purposes for HTS-BCG

HTS-BCG is a powerful and versatile technology that can be deployed for a range of purposes in the detection of infectious agents and their characterisation, either in biological material such as diagnostic or surveillance specimens or propagated in cultures or as isolates. As such the users of the technology should consider the purposes of their testing in relation to the normal purposes of testing as defined in Chapter 1.1.5 *Principles and methods of validation of diagnostic assays for infectious diseases* of the OIE *Terrestrial Manual*.

Further to these general purposes of testing, HTS-BCG offers specific opportunities in:

- Detection, identification and characterisation of previously unidentified microorganisms;
- Improved diagnosis of known diseases;
- Improved diagnosis of emerging or re-emerging diseases with known or unknown aetiology;
- Single “universal” diagnostic assays, able to identify any potential pathogen, that can be developed in concert with established diagnostic approaches;
- Multiple agents that can be simultaneously and quickly detected in diseases with multifactorial aetiologies;
- Increased capability to study the evolutionary dynamics of pathogens at the farm, local, national and global level;
- Deeper understanding of the epidemiology of infectious diseases and the phylogeography of infectious agents;
- Enhanced traceability of infectious diseases and modes of pathogen transmission including applications in forensic epidemiology;
- More extensive characterisation of “populations” of known pathogens (e.g. relevant minority strains, escape mutants) that in turn facilitates the design of better vaccines, antivirals, etc.;
- Better links between pathogen genotype and phenotypes enabled through full genome sequence of multiple strains (including reference strains) of a single agent.

5.4.2. Sampling, Specimens, and Sample Preparation

HTS-BCG is a new technological tool in the management of diseases of animals and its use should be adopted within the context of tried and accepted processes for the management of animal health. In laboratories where it is utilised, it should be managed within the context of the habitual veterinary investigation process and within the context of the laboratory’s quality assurance system. The use of any capability of the technology should be appropriate to the purpose of the investigation, and the sampling strategy and the specimens taken should be appropriate for that investigation, based on an understanding of the pathogenesis and epidemiology of the infection under study or the likely pathogenesis and epidemiology of any novel infectious agent suspected. Such investigations should be under the supervision of appropriately qualified veterinarians.

Similarly the results of HTS-BCG must be interpreted in the context of the pathogenesis and epidemiology of the infection in the animal species under study. Results should be reported by appropriately qualified veterinary investigators with the authority to make diagnoses of animal diseases under the laboratory's quality assurance system and in the jurisdiction where the investigation is conducted.

Specimens will be collected and submitted to the testing laboratory in accordance with the standards communicated in Chapter 1.1.1 *Collection, submission and storage of diagnostic specimens* of the OIE *Terrestrial Manual* and the normal comprehensive information regarding the individual animal, the case or reason for sampling and the relevant epidemiological information recorded in the laboratory's accessions process as for any submission to the laboratory.

As with other laboratory processes, and molecular techniques in particular, ensuring the integrity of the specimen and the samples to be tested is critical. HTS-BCG can be subject to contamination of samples during the processes of sample preparation and initial workup. Separation of work areas from the possibility of cross contamination with nucleic acid from other molecular investigations is an essential requirement.

5.4.3. Commercially Available Sequencing Platforms

There are a number of commercially available sequencing platforms or services for the purpose of generating sequence information from test samples. The choice of platform should be based on a consideration of the intended purpose or combination of purposes as outlined in Section 5.4.1 above.

Of primary concern is that the technology to be selected is fit for the intended purpose, that it is appropriate to produce sequence information from the types of genome intended for study. Other considerations may include the time required to conduct a sequencing run, including sample preparation; ancillary equipment needed in addition to the actual sequencing device; the capital cost of the purchase and set up of all necessary equipment and the cost of annual licences or service agreements; the availability of supporting expertise from the supplier; the cost of reagents for a sequencing run and the likely availability of reagents in the country concerned; the staff requirements to operate the equipment and to conduct the associated bioinformatic analyses and the data management requirements. Currently available systems have been reviewed (Belák *et al.*, 2013, OIE *Sci. Tech. Rev*.) but new models and technologies can be expected to frequently become available.

5.4.4. Bioinformatics

An absolute requirement for any laboratory intending to establish an HTS-BCG capability is the employment of specialised bioinformatics skills. In the future, academic or commercial suppliers may market platforms with supporting software for specific analyses in defined clinical situations, but the use of such packages does not remove the responsibility of the laboratory to be able to competently analyse its own data, and reliance on any such inbuilt analytic capability would seriously limit the potential of the technology for broader applications.

The bioinformatics that assemble the genomic sequence from the raw data and the subsequent analysis are the critical elements in HTS-BCG. Hence the approaches used must be transparent and a declaration of the software packages used should be a component of every report of sequence analysis. Software programs used for these analyses must be available (commercially or open access) in order to be evaluated by the international community.

As with any laboratory procedure, attention must be given to quality assurance. It is required that every sequencing run will include positive and negative controls appropriate to the investigation and that have been incorporated through the sample preparation processes of the sequencing run as well as the actual run on the technology platform. The test method should include criteria for acceptance or rejection of each run based on the satisfactory analyses of the controls.

The appropriateness of chosen bioinformatics software for particular analyses can be evaluated through testing its performance against standard data sets containing data relating to agents expected to be present in the specimens to be tested (see Section 5.5. below).

5.4.5. Data Management

The data generated from HTS-BCG operations are essential to reach the diagnosis or other scientific purpose of the investigation, and so are an integral component of the process. As such it is an essential requirement of laboratories to have policies, processes and supporting systems to curate, manage and store the data generated.

Different HTS technology platforms produce raw data in different formats and stages of pre-analysis so it is necessary for laboratories to have policies and processes specific for the technology platform in use. Data management systems will include aspects of which data to keep, and the length of time for which it will be kept, and the back-up strategies to protect against accidental loss or deliberate erasure.

Where a sequence analysis leads to an output of animal health significance, especially one of trade or international significance, it is an absolute requirement that the data on which the analysis was performed be kept available for audit or confirmatory analysis for a period of time commensurate with the significance of the animal health finding. This is particularly important where the finding may be disputed. Failure to be able to produce the required data for independent analysis could be taken to invalidate the finding.

Sequence data should be stored in a manner in which there is a clear link to the metadata associated with the specimen that was the subject of the analysis. As for other laboratory investigations, such metadata include information regarding the animal sampled, its ownership and location, and accompanying clinical and epidemiological information in the animal population.

5.4.6. Validation of Test Systems for Designated Purposes

The concepts of test validation as stated in Chapter 1.1.5 of the OIE *Terrestrial Manual* are broadly applicable to HTS-BCG. Stage 1 validation data must be developed to confirm the analytic sensitivity and specificity of the technique, and its repeatability. It is recognised that it may not be practical to produce large data sets on test performance such as would normally allow calculation of test diagnostic sensitivity and specificity, but other aspects of validation such as demonstration of test reproducibility among laboratories conducting similar investigations should be undertaken. Where proficiency testing strategies have been developed laboratories using HTS-BCG should participate.

5.5. ToR 5: Training, quality management and dissemination of knowledge

The AHG considered that a useful starting point would be a stock take of the level of use and expertise currently existing in the OIE Network of Reference Laboratories and Collaborating Centres (the Reference Centres). Hence it was recommended that the OIE, through the OIE Biological Standards Commission (BSC), should solicit information from Reference Centres by means of a questionnaire. Information to be sought should include:

- Whether laboratories currently utilise HTS-BCG
- Whether laboratories maintain their own sequencing capability, or outsource the sequencing
- Whether laboratories maintain in-house bioinformatics capability, or outsource the bioinformatics analyses
- For what disease investigations or other purposes do they utilise HTS-BCG
- A list publications arising from their work or collaborations with others

Such a survey of the Reference Centres would indicate the base of capability in the OIE network, facilitate identification of centres of expertise for involvement in network activities and help to spread awareness of the level of OIE interest in this technology.

Regarding training, it was noted that this would most usefully be conducted within the context of accepted OIE standards for HTS-BCG, the foundations for which have been outlined in Section 4.4 above.

Regarding quality assurance it was noted that standard data sets against which the usefulness of bioinformatics software packages could be verified would be useful. The AHG recommended that selected Reference Centres with relevant expertise and data resources should be brought together to develop this concept and use their combined resources to construct standard data sets. It was further recommended that these data sets be recognised as OIE Standards and be maintained by the OIE for MC access.

Once a user network has been identified and HTS-BCG standards agreed there will be a role for proficiency testing (PT). An appropriately qualified Reference Centre could be approached to coordinate network Reference Centres with relevant expertise and access to resources of appropriate biological materials to develop a PT strategy relevant to one or more purposes of HTS-BCG testing and construct PT panels accordingly.

Regarding dissemination of knowledge the opportunity of the scheduled meeting of OIE Reference Centres in October 2014 was noted. The AHG recommended that the programme include information sessions on HTS-BCG and the status of the draft OIE Standards relating to that technology, the recommendations for inclusion of test methods in the OIE *Terrestrial Manual*, where appropriate, and the activities of the OIE HTS-BCG network of Reference Centres.

6. Conclusions

The AHG recommends that rapid progress be made on matters covered in this report. This could be addressed by pilot projects regarding the database requirements, the development of standard data sets, and the questionnaire to Reference Centres. The BSC should consider development of the standards recommended in this report as a draft chapter for the OIE *Terrestrial Manual*.

7. Finalisation and adoption of the draft report

The AHG finalised and adopted the draft report.

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…/Appendices

Appendix I

AD HOC BRAINSTORMING GROUP ON HIGH THROUGHPUT SEQUENCING, BIOINFORMATICS AND COMPUTATIONAL GENOMICS (HTS-BCG)

Paris (OIE Headquarters), 25–27 November 2013

Agenda

1. Opening
2. Appointment of chairperson and rapporteur
3. Terms of Reference for the *ad hoc* Group meeting
4. Summary of key recommendations
5. Addressing the Terms of Reference
6. Conclusions
7. Finalisation and adoption of the draft report

Appendix II

AD HOC BRAINSTORMING GROUP ON HIGH THROUGHPUT SEQUENCING, BIOINFORMATICS AND COMPUTATIONAL GENOMICS (HTS-BCG)

Paris (OIE Headquarters), 25–27 November 2013

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Appendix III

AD HOC GROUP ON HIGH THROUGHPUT SEQUENCING, BIOINFORMATICS AND COMPUTATIONAL GENOMICS (HTS-BCG)

Paris (OIE Headquarters), 25–27 November 2013

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Terms of Reference

Develop an OIE strategy in the context of:

1. The globalisation of microbial diagnostics in animal health.

2. The possibility of establishing a global network of OIE Reference Centres for a Coordinated International Approach to implementation of HTS-BCG.

3. The coordination of data management, in particular the possible role for the OIE in managing a dedicated database.

4. The need to develop standards for inclusion in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*) on the following aspects of HTS test systems:

   4.1. The range and purposes for HTS-BCG

   4.2. Sampling, specimens and sample preparation

   4.3. Commercially Available Sequencing Platforms

   4.4. Bioinformatics

   4.5. Data management

   4.6. Validation of test systems for designated purposes.

5. Training, quality management and dissemination of knowledge on the use of these new tool bags.

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Annex 6

OIE EXPERT SURVEILLANCE PANEL ON EQUINE INFLUENZA VACCINE COMPOSITION

OIE Headquarters, 4 March 2014

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Conclusions and Recommendations

Influenza activity in 2013

During 2012, individual animal cases and outbreaks of equine influenza were reported by Belgium, China (People's Rep. of), Germany, Turkey, Sweden, United Kingdom (UK), and United States of America (USA).

Sources of viruses characterised in 2013

Equine influenza A (H3N8) viruses were isolated and/or characterised from outbreaks in China (People's Rep. of), Germany, Turkey, Sweden, UK and USA.

Field data

Equine influenza virus infections were confirmed in both vaccinated and unvaccinated horses. Several outbreaks in Germany, Sweden, UK and USA were associated with recent transport of horses and/or the introduction of horses from sales or other countries. Equine influenza was diagnosed in 24 states in the USA, but in the majority of cases the vaccination history of the horses was unknown. Seventy-six horses in a population of 1143 housed at a racetrack in Turkey were clinically ill. The majority of the clinically affected horses were unvaccinated as they had not yet raced.

Characterisation of viruses isolated in 2013

Viruses isolated/identified from outbreaks in China (People's Rep. of), Germany, Turkey, Sweden, UK and USA were characterised genetically by sequencing of the haemagglutinin (HA) gene, in many cases the HA1 encoding region. Whole genome sequences for three Swedish isolates and the sequences of the neuraminidase (NA) genes for several virus isolates from the UK and the USA were determined. Viruses isolated in Turkey, UK and USA were also characterised antigenically by the haemagglutination inhibition (HI) assay using post-infection ferret antisera and chicken red blood cells.

Genetic characterisation

All HA sequences obtained from viruses were of the American lineage (Florida sublineage). The viruses detected in the USA, were characterised as clade 1 viruses. Viruses detected in China (People's Rep. of), Germany, Turkey, Sweden and UK were characterised as clade 2 viruses.

Two subpopulations of clade 2 viruses were identified with amino acid substitutions in HA1 at either position 144 or position 179. Viruses in this clade continue to diverge and a strain from China (People's Rep. of) was readily distinguishable from those circulating in Europe. The NA gene sequences of viruses from clade 1 and clade 2 were clearly distinguishable.

Representative sequences for HA and NA are available on GenBank and GISAID.

Antigenic characteristics

HI data available for viruses isolated in 2013, and antigenic cartography analyses thereof, show that the two clades of the Florida sublineage continue to co-circulate and evolve but currently remain antigenically closely related to the recommended vaccine viruses of that lineage.

Conclusions

No Eurasian viruses were detected in 2013. Viruses isolated and characterised were from clades 1 and 2 of the Florida sublineage.

Level of surveillance and updating of vaccines

The Panel continues to emphasise the importance of increased surveillance and investigation of vaccination breakdown in different countries. Increased surveillance in Asia has been facilitated by the OIE twinning programme. Rapid submission of viruses to reference laboratories is essential if antigenic and genetic drift is to be monitored effectively on a global basis.

Although one vaccine available within the American market has been updated to include a virus from clade 2, in accordance with the recommendations of 2010 to 2013, the majority of current vaccines contain out-dated strains.

The updating of vaccines with epidemiologically relevant viruses is necessary for optimum protection. The Panel welcomes the Revision of the EU Guideline on Data Requirements for Strain Updates to Equine Influenza Vaccines and any amendments to regulatory procedures that allow equine influenza vaccines to be updated as speedily as possible without compromising safety and efficacy.

Recommendations (March 2014)

These are unchanged from those made in March 2013.

It is not necessary to include an H7N7 virus or an H3N8 virus of the Eurasian lineage in vaccines as these viruses have not been detected in the course of the most recent surveillance and are therefore presumed not to be circulating.

Vaccines for the international market should contain both clade 1 and clade 2 viruses of the Florida sublineage.
Clade 1 is represented by A/eq/South Africa/04/2003-like or A/eq/Ohio/2003-like viruses.
Clade 2 is represented by A/eq/Richmond/1/2007-like viruses.

A panel of viruses covering both clades is available from the OIE Reference Laboratories.

Manufacturers producing vaccines for a strictly national market are encouraged to liaise with Reference Laboratories. The selected viruses should induce responses which are immunogenically relevant to the equine influenza viruses circulating nationally. Sequence determination of both HA and NAs should be completed before use.

Reference reagents

Freeze-dried post-infection equine antisera to A/eq/Newmarket/1/93 (American lineage H3N8) and A/eq/South Africa/4/2003 (Florida clade 1, sublineage of the American lineage) are available from the European Directorate for the Quality of Medicines (EDQM). These sera have been assigned single radial haemolysis (SRH) values through an international collaborative study and can be used as primary reference sera for the assay. There is no SRH reference serum available currently for A/eq/Richmond/1/2007, representative of Florida clade 2.

There is currently a shortage of single radial diffusion (SRD) reagents and they will no longer be produced by the National Institute for Biological Standards and Control (NIBSC). There is a need for updated SRD regents for both Florida clade 1 and clade 2.

Recent virus strains, including suitable vaccine candidates for clades 1 and 2, are available from the OIE Reference Laboratories. In the event that an OIE Reference Laboratory cannot supply suitable vaccine candidates for both clades, it will assist the vaccine company to source the viruses from an alternative OIE Reference Laboratory.

Small quantities of ferret antisera for antigenic characterisation are available from the OIE Reference Laboratory in the UK.

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OIE EXPERT SURVEILLANCE PANEL ON EQUINE INFLUENZA VACCINE COMPOSITION

OIE Headquarters, 4 March 2014

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List of Participants

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Annex 7

BSC Work Plan: to February to September 2014

Topic/Issue	Responsible(s)	Deadline
Manual of Diagnostic Tests and Vaccines for Terrestrial Animals		
Circulate the chapters approved by the EBG and the BSC as final versions for adoption in May 2014	SL	By mid- to end-March 2014
Remind authors of the chapters identified by the EBG and the BSC for adoption in 2014 and 2015 but not yet received	SL	On going
Commission the chapters identified by the EBG and the BSC for proposal for adoption in 2014	SL	On going
Update all the disease-specific chapters of the *Manual* according to the new template	BSC/SST	Continuing implementation with the aim of finalising all these modifications for the publication of the paper version of the *Manual* in 2016
Ad hoc Groups		
High throughput sequencing and bioinformatics and computational genomics (HTS-BCG)	SST: EEV, SL, Member of the BSC who attended: VC, PD	Dates: 26–28 November 2013 Meet again before next BSC meeting in September 2014
Camelidae	SST: EEV, FD, KH, Member of the BSC who will attend: VC	Dates: 1–3 April 2014
Vaccines to update chapter 1.1.6 *Principles of veterinary vaccine production*, and to draft two chapters: 1.1.8 *Minimum requirements for vaccine production facilities*, 1.1.9 *Quality control of vaccines*	SST: BF, FD	On-going: Collaborating Centre for Veterinary Medicinal Products offered to do. Commission asked they collaborate with other OIE Centres working on vaccines, to produce consensus documents. First drafts have been circulated to the other Centres. Once received, it will be determined whether they could be sent directly to Member Countries for comment or whether they could be used by an *ad hoc* Group as base documents for further elaboration.
Meetings		
Third Global Conference of the OIE Reference Centres, Seoul, Korea (Rep. of) 14–16 October 2014	SST & BSC	Announcement made (18.09.2013). Concept note and detailed programme in progress