Original: English January 2015

#### REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 28-30 January 2015

The OIE Biological Standards Commission (the Commission) met at the OIE Headquarters from 28 to 30 January 2015. Dr Bernard Vallat, Director General of the OIE, welcomed the Members of the Commission: Prof. Vincenzo Caporale, President, Dr Hualan Chen, Vice-President, Dr Rodolfo Rivero, Vice-President, Dr Paul Townsend and Dr Peter Daniels, Members of the Commission. Dr Beverly Schmitt, a Member of the Commission, was invited but could not attend.

Dr Vallat reminded the Commission that this was its last meeting before the elections that would be held during the General Session in May, and wished those members who were standing for re-election the best of luck. He reiterated the OIE's commitment to assisting the Commission to achieve its goals, including by convening *ad hoc* Groups on specific topics. Dr Vallat thanked the Commission and Prof. Steven Edwards for their achievements over the past 3 years.

Prof. Edwards also thanked the OIE and the Commission for the support it provides the team editing the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)*.

Dr Vallat informed the Commission that an informal request had been received for the OIE to undertake vaccine quality evaluation in production units and compliance with OIE standards. This very important issue needs to be carefully considered before a decision can be made.

Finally, on the topic of the legal status of OIE standards within the World Trade Organization, Dr Vallat explained that the Terrestrial Animal Health Code Commission had been asked to propose definitions to be adopted by the World Assembly and included in the OIE Organic Texts. One option would be to publish OIE standards, once adopted by the OIE Member Countries, in the *Terrestrial Animal Health Code* and *Terrestrial Manual*; guidelines and recommendations would be published only online.

The Commission and Prof. Edwards thanked Dr Vallat for his support over the past 3 years.

#### 1. Adoption of Agenda

The proposed agenda was presented and adopted.

The Agenda and List of Participants are given at <u>Annexes 1</u> and <u>2</u>, 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 29 January 2015. The Commission approved the EBG Group's proposals (see <u>Annex 3</u>). Eighteen 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 2015.

A Reference Laboratory had provided small technical amendments to the protocol for the agar gel immunodiffusion test in the chapter on avian influenza. The EBG and the Commission agreed to circulate these corrections to the Member Countries and propose them for adoption in May 2015.

The OIE Reference Laboratories for equine influenza had been asked by the President to update the chapter to include a section that would enable vaccine manufacturers to respond quickly to recommendations from the Equine Surveillance Panel on Equine Influenza Vaccine Composition. The EBG and the Commission approved the amended chapter for circulation to OIE Member Countries and proposal for adoption in May 2015.

A large volume of Member Country comments had been received on the draft *Terrestrial Manual* chapter on vaccine banks. The Commission recommended that the Director General convene an *ad hoc* Group, following the General Session, to review the comments and amend the chapter accordingly. The amended chapter could then be reviewed at the next meeting of the newly elected Biological Standards Commission in September 2015.

#### 2.2. Rinderpest chapter: vaccine standards

In Section C: Requirements for vaccines of the current chapter on rinderpest, manufacturers are required to challenge vaccinated animals with virulent virus as part of the safety and efficacy tests on the final batch of vaccine. In light of the global eradication of rinderpest, the Commission agreed to remove the text related to this challenge test. For vaccine efficacy testing, the level of immunological response in animals receiving a normal vaccine dose should be sufficient to protect them from infection with virulent rinderpest. The amended chapter will be circulated to OIE Member Countries and proposed for adoption in May 2015. The expected results of the current trial of PPR (peste des petits ruminants) vaccine for protection against rinderpest will be of great interest to the Commission.

#### 2.3. For information: draft chapters now available on Commission's web page

The Commission was informed that the draft chapters that are sent to Member Countries for comment are now also posted in the Commission's web page. The chapters can be found by clicking on "Draft Chapters" at the following link: <a href="http://www.oie.int/en/international-standard-setting/specialists-commissions-groups/laboratories-commission-reports/">http://www.oie.int/en/international-standard-setting/specialists-commissions-groups/laboratories-commission-reports/</a>.

#### 3. OIE Reference Centres

#### 3.1. Applications for the status of OIE Reference Centre

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

OIE Reference Laboratory for Equine rhinopneumonitis Irish Equine Centre, Johnstown, Naas, Co. Kildare, IRELAND

Tel.: (+353-45) 866.266; Fax: (+353-58) 866.273

E-mail: acullinane@equine-centre.ie

Designated Reference Expert: Prof. Ann Cullinane.

An application had been received from a country in the European region for an OIE Collaborating Centre for Laboratory Research, Preparedness and Response to Emerging and Re-Emerging Viral Zoonoses with Pandemic Potential. The Commission felt that the activities of this proposed Centre would overlap with a number of existing OIE Collaborating Centres in Europe, namely: the OIE Collaborating Centre for Diseases at the Animal/Human Interface, Padova, Italy; the OIE Collaborating

Centre for Food-Borne Zoonotic Parasites from the European Region, Maisons-Alfort, France; and the OIE Collaborating Centre for Zoonoses in Europe, Insel Riems, Germany. In light of the "one OIE Collaborating Centre per topic per region" rule, the Commission proposed that the applicant contact these Centres with a view to forming a consortium.

A country in the Americas region had submitted an application for an OIE Collaborating Centre for Management of Quality Systems in Testing Laboratories. The Commission found that the application did not fulfil the selection criteria for an OIE Collaborating Centre: the application lacked sufficient evidence of scientific leadership in the proposed field, particularly at the international level; the applicant had participated in but not organised meetings; and there were no recent peer-reviewed publications listed. Furthermore, no information was given on the infrastructure and manpower of the proposed Collaborating Centre. The Commission did not yet endorse the application, but awaits more information on the items mentioned above.

An application had been received from a country in the Americas region for an OIE Reference Laboratory for Rift Valley fever. Whereas the applicant showed strong evidence of scientific capability and competence, it did not provide sufficient evidence that it fulfilled all the requirements of a fully operational OIE Reference Laboratory: it lacked evidence of ongoing work such as supplying reagents, running proficiency tests, testing vaccines, etc. Neither was it clear that the institute could receive samples from abroad. The Commission did not yet endorse the application. The laboratory will be informed of the evaluation and encouraged to provide additional information to respond to the findings.

A country in the Asia, Far East and Oceania region had submitted an application for an OIE Reference Laboratory for Brucellosis (*Brucella abortus* and *B. melitensis*). Again the Commission found that the applicant did not provide sufficient evidence that it fulfilled all the requirements of a fully operational OIE Reference Laboratory, in particular the application lacked evidence that it was a reference point in the region, and there were few recent peer-reviewed publications listed. The Commission did not endorse the application. The Commission did not yet endorse the application, but awaits more information on the items mentioned above.

The Commission reviewed an application from a country in the European region for an OIE Reference Laboratory for avian infectious bronchitis. It felt that there was a lack of evidence of scientific leadership: all applicants should demonstrate that they are a reference point for the disease in the region in question, they should organise rather than just participate in proficiency tests, and they should be providing confirmatory diagnostic services, reference materials, etc., internationally, and they should have a number of recent relevant publications in peer-reviewed journals. Until the applicant could provide such evidence, and of course, evidence of their accredited quality management system, the Commission could not yet approve the application.

In September 2013, the Commission had reviewed an application from a country in the Americas region for an OIE Reference Laboratory for avian infectious bronchitis. At that time, the Commission requested more information on the laboratory's international activities and on its quality management system. Reviewing the supplementary information received, the Commission noted that the laboratory operated an in-house quality management system. As external accreditation is an integral part of a quality management system, and indeed OIE Reference Laboratories are requested to upload their accreditation certificates with their annual report, the Commission agreed to seek assurances that the laboratory undergoes external audits. Until then, the Commission could not endorse the application, awaiting demonstration of compliance with appropriate standards.

At its last meeting in September 2014, the Commission reviewed supplementary information requested to complete an application from a European country for a Reference Laboratory for Q fever. At that time, the Commission felt that there was a lack of evidence of scientific leadership. The applicant also needed to provide evidence of an accredited quality management system. The Commission was

encouraged by the reply, especially by the quality management accreditation certificates submitted. However, the Commission still did not feel that the laboratory was operating at the level of an OIE Reference Laboratory and did not endorse the application. The Commission urged the applicant to continue to build its strengths for a possible future designation.

Reviewing the supplementary information and advice requested regarding an application previously received from a European country for an OIE Reference Laboratory for Brucellosis (*Brucella abortus* and *B. melitensis*), the Commission still felt that there was a lack of evidence of scientific leadership and the necessary level of scientific expertise. Regarding the supplementary information submitted from another European country for an application for an OIE Reference Laboratory for Infectious equine anaemia, the Commission drew the same conclusion: that the application lacked evidence of scientific expertise and leadership. The Commission did not endorse either application.

In January 2014, an application 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. At that time, the Commission requested more information on the Centre's international activities, on its ability to receive samples from abroad, its quality management system, and on its legal and budgetary provisions specifically for the fulfilment of the OIE mandate. Reviewing the supplementary information received, the Commission felt that the activities of this proposed Centre would overlap with two existing OIE Reference Laboratories in the same country (for highly pathogenic avian influenza and Newcastle disease) and two existing OIE Collaborating Centres in the region, namely: the OIE Collaborating Centre for Zoonoses of Asia-Pacific, Harbin, China (People's Rep. of) and the OIE Collaborating Centre for New and Emerging Diseases, Geelong, Australia. In light of the "one OIE Collaborating Centre per topic per region" rule, the Commission proposed that the applicant contact these Centres with a view to forming a consortium.

At its previous meeting, an application had been received from a European country for the designation of two OIE Reference Laboratories: for bovine spongiform encephalopathy (BSE) and for scrapie. At this meeting (January 2015), another application was received from a different country in the European region for a Reference Laboratory for foot and mouth disease. The Commission noted that within the European Union (EU), certain laboratories are identified and designated as EU Reference Laboratories for certain diseases, each laboratory being the only EU Reference Laboratory for the disease in question. All other laboratories in the EU region send samples to this EU Reference Laboratory for confirmatory diagnostic testing. Given this system, the Commission asked if the OIE wished to designate OIE Reference Laboratories in EU Member Countries that are not the EU designated one when the latter exists. A decision on the two applications was deferred until an opinion has been given by the OIE Council on this matter.

Finally, the Commission received an update from a laboratory in the Asia, the Far East and Oceania region concerning its implementation of an accredited quality management system. The applicant is seeking designation of a Reference Laboratory for Equine piroplasmosis. The Commission agreed that once it achieves accreditation, it could be designated as an OIE Reference Laboratory.

#### 3.2. Changes of experts at Reference Centres

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

Highly pathogenic avian influenza and Newcastle disease

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

Salmonellosis

Dr Istvan Szabo to replace Dr Matthias Hartung at the Federal Institute for Risk Assessment, Berlin, GERMANY.

Brucellosis

Dr Adrian Whatmore to replace Ms Judy Stack at the Animal and Plant Health Agency, Weybridge, UNITED KINGDOM.

Rabies

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

## 3.3. Specific issues related to Reference Centres: amended guidelines for applicants for OIE Reference Laboratory status

At its previous meeting, the Commission noted the growing number of OIE Reference Laboratory applications, many of which are unsuccessful, and identified the need to give clearer guidance to applicants on what is expected of an OIE Reference Laboratory and what should be emphasised in their applications.

The Commission reviewed and accepted the proposed amendments to the *Guidelines for applicants for OIE Reference Laboratory status*. The document will be submitted to the Council and, if approved, would be uploaded onto the OIE website. The document can be found at <u>Annex 4</u> for information.

#### 3.4. Annual reports of Reference Centre activities in 2014

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 Collaborating Centres for the first time.

The Commission expressed its on-going appreciation for the enthusiastic support and expert advice given to the OIE by the Reference Centres. The web-based reporting system made it easy to identify areas for the Commission's focus. For example, many OIE Reference Laboratories produce and supply reference materials but few produce and supply OIE approved reagents. The Commission could review its guidelines on the preparation, validation and distribution of approved materials and encourage participation in its standardisation programme. The international activities relevant to the work of the OIE are summarised in Graphs 1 and 2.

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

A twinning proposal between the United Kingdom and Ethiopia for strengthening the capacity for foot and mouth disease diagnosis and surveillance in Ethiopia and East Africa was presented for the Commission's technical input. The Commission approved the project.

#### 4. Ad hoc Groups

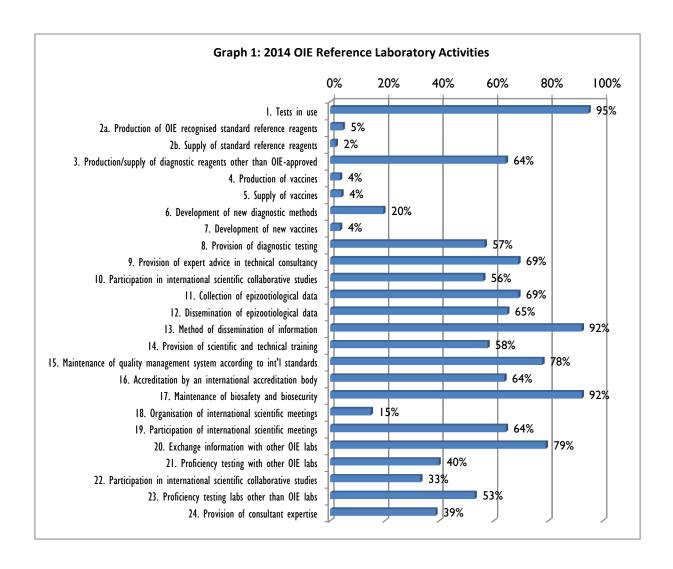
#### Past ad hoc Group meetings

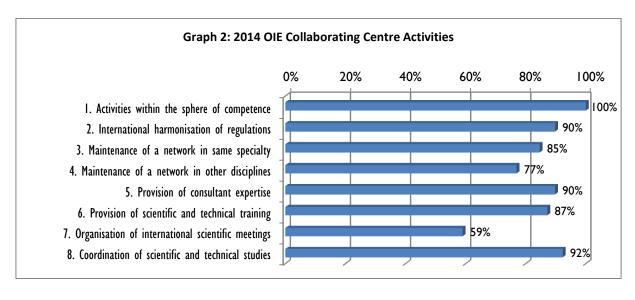
## 4.1. Report of the Meeting of the *ad hoc* Group on High Throughput Sequencing, Bioinformatics and Computational Genomics (HTS-BCG), 13–14 November 2014

Prof. Caporale briefed the Commission on this activity. The Commission adopted the report and encouraged the implementation of the work plan drafted by the *ad hoc* Group. The report can be found at <u>Annex 5</u> of this report.

## 4.2. Report of the Meeting of the *ad hoc* Group on Biosafety and Biosecurity in Veterinary Laboratories, 26–27 January 2015

Dr Daniels briefed the Commission on this activity. The Commission adopted the report, which can be found at Annex 6 of this report. The Group further amended Chapter 1.1.3. The chapter will now be entitled: *Biosafety and biosecurity: standard for managing biological risk in the veterinary laboratory and animal facilities.* The Commission approved the amended chapter for circulation to OIE Member Countries and proposal for adoption in May 2015.





#### 5. International Standardisation/Harmonisation

#### **Diagnostic tests**

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

Dr François Diaz, Scientific and Technical Department of the OIE, 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. Dr Diaz informed the Commission that one diagnostic kit (Check&Trace Salmonella), added to the OIE Register in 2011, was reaching the end of the 5-year term; the renewal would take place under the aegis of this Commission. In accordance with protocol, the kit manufacturer had been contacted to indicate whether it wished to maintain the same purposes for which its 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 propose to the vote of the Assembly in May 2016 to renew the registration of the Check&Trace Salmonella kit in the OIE register for the same purposes and for 5 additional years.

### 5.1.1. EU comment on the report of the September 2014 meeting of the OIE Biological Standards Commission

The Commission took note of the comment that had been received from the European Union (EU) on a kit mentioned in the report of the September 2014 meeting. The OIE Headquarters was requested to respond to the EU.

#### **5.2.** Standardisation programme

## 5.2.1. OIE-approved standard sera: review of datasheets for *Mycoplasma mycoides* subs. *mycoides* small colony antigen preparation for the complement fixation test for contagious bovine pleuropneumonia

The OIE Reference Laboratory in Portugal had submitted data sheets for antigens that it had prepared for the complement fixation test (CFT) for contagious bovine pleuropneumonia (CBPP). The Commission noted that there are already OIE-approved international standard sera for CBPP prepared by the OIE Reference Laboratory in Italy. The laboratory in Portugal would be asked to verify with the laboratory in Italy that the two sets of standard sera are identical.

#### 5.2.2. Update on progress developing guidelines for antigen standards

Dr Daniels reported that these guidelines are still in preparation.

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

The OIE Reference Laboratory experts had submitted a draft document entitled: *International Reference bovine purified protein derivative (PPD) Standards for tuberculin potency assay.* 

This first draft of the guidelines would be reviewed. It is hoped that they will be ready for endorsement by the Commission at its next meeting in September 2015 before being sent to Member Countries for comment and possible adoption in May 2016.

## 5.2.4. For information: project to develop a tool that laboratories can use to perform a self-assessment of their quality management system

The OIE had been informed of this project to develop a tool for laboratories to use to perform a self-assessment of their quality management system, obtain a gap analysis, provide real-time feedback as to the state of their compliance, and to have access to material to assist them in addressing the gaps. The Commission approved the principle of the project but had questions regarding the practical development and implementation of the tool, including related costs for users. The OIE Headquarters will request this additional information in support of further evaluation of the tool by the Commission.

#### **Biosafety/Biosecurity**

## 5.3. Mission report Biosafety Advisory Group (BAG) Meeting, 24–26 November 2014, World Health Organization (WHO), Geneva, Switzerland

The Commission noted the mission report and agreed that the OIE should be involved in such activities. The *ad hoc* Group (see item 4.2), which operated under the auspices of the Commission, had addressed Member Country concerns regarding the OIE approach to biosafety and biosecurity in veterinary laboratories.

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

This agenda item was postponed to the next meeting of the Biological Standards Commission.

#### 6. Resolutions for the General Session

#### 6.1. Resolutions that will be presented in May 2015

The Commission noted that the following resolutions would be proposed for adoption at the General Session in May 2015:

- A resolution proposing the adoption of the 18 draft chapters for the *Terrestrial Manual*;
- A resolution proposing the New Reference Laboratories;
- A resolution proposing the addition of one diagnostic kit to the OIE Register;
- A resolution on the whole genome sequencing project.

#### 7. Conferences, Workshops, Meetings

## 7.1. WAVLD, 15–18 June 2015, Saskatoon, Canada: 1-day OIE Symposium on New Diagnostic Technologies and International Standard Stetting: Wednesday 17 June 2015

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

## 7.2. Follow-up on Recommendations from the Third Global Conference of the OIE Reference Centres, Seoul, Korea (Rep. of), 14–16 October 2014

The Commission took note of the plan to implement the Final Recommendations from the Third Global Conference of the OIE Reference Centres. These recommendations will be presented to the World Assembly in May 2015.

#### 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. FMD serum provision to calibrate diagnostic tests

The Scientific Commission had forwarded a request from an *ad hoc* Group to amend the *Terrestrial Manual* chapter on FMD to include the requirement that vaccine manufactures provide, on request of the vaccine purchaser, post-vaccination sera produced during final product batch testing for potency. This could be used to calibrate the locally used tests for measuring population immunity. At its last meeting, the Biological Standards Commission had reviewed the expert opinion it received and decided to seek further input to find a way that the proposal could be practically implemented. At this meeting, the Biological Standards Commission decided to seek the advice of the OIE Reference Laboratories for FMD and those Collaborating Centres that deal with vaccine evaluation.

#### 8.1.2. Zoonoses transmissible from non-human primates

The Scientific Commission had referred to the Working Group on Wildlife a question from the Biological Standards Commission regarding Chapter 6.11 of the *Terrestrial Animal Health Code* and Chapter 2.9.12 of the *Terrestrial Manual*, both chapters being entitled: *Zoonoses transmissible from non-human primates*. The question was how to develop, categorise and divide information on the topic between the two publications. The Working Group noted the question and also recognised that the state of knowledge on several of the pathogens and tests has increased since the chapters were last updated. The Biological Standards Commission formally requested that the Working Group review the *Terrestrial Manual* chapter and propose an update that can be reviewed at its next meeting in September. The update should include the diseases of importance and for which there are diagnostic tests available.

#### 8.2. Terrestrial Animal Health Standards Commission

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

#### 8.2.1. Infection with avian influenza viruses

The Code Commission had referred to the Biological Standards Commission a Member Country comment regarding the number of haemagglutinin and neuraminidase subtypes listed in Chapter 10.4 Infection with avian influenza viruses of the *Terrestrial Code*. The advice of one of the OIE Reference Laboratories for this disease was that the standard tests for haemagglutinin and neuraminidase subtyping could not be applied in the case of newly proposed extra haemagglutinin and neuraminidase subtypes H17 and N11 and so the wording proposed by a Member Country regarding the proposed use of these tests for these newly proposed subtypes would not be correct at the present time. The Biological Standards Commission recommended therefore that the *Terrestrial Code* chapter remain unchanged.

Follow-up from last meeting for information

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

The *Terrestrial Code* currently has in a number of its disease-specific chapters schematic representations of the application of laboratory tests for determining evidence of the infection in question for various purposes. The Biological Standards Commission believes that such decision trees may be better suited to the *Terrestrial Manual* as the issue concerns the diagnostic performance of the test. This will be taken up by the newly elected Commission at its next meeting. It is important that the Biological Standards Commission, the Terrestrial Animal Health Standards Commission and the Scientific Commission for Animal Diseases achieve consensus on this issue.

#### 9. Matters of Interest for Information

## 9.1. Meeting of the Expert Surveillance Panel on Equine Influenza Vaccine Composition (6 March 2015)

The Commission noted that the Expert Surveillance Panel (ESP) would meet in March 2015. Its report, which would include recommendations on which strains should be included in equine influenza vaccines, would be published in the OIE *Bulletin* and clearly highlighted on the OIE Website.

The ESP would be asked to review and approve the *Terrestrial Manual* chapter on equine influenza that had been updated to include a section entitled: *Requirements for authorisation of strain updates to vaccines*, to enable vaccine manufacturers to respond quickly to recommendations from the ESP in accordance with the OIE recommendations (see also Item 2.1 and <u>Annex 3</u>). Should the ESP approve the amendments, the chapter will be circulated for Member Country comment and proposed for adoption in May this year.

#### 9.2. Update on OFFLU<sup>1</sup>

Dr Peter Daniels updated the Commission on OFFLU activities since the last meeting of the BSC.

An OFFLU strategy meeting was held 27–28 October 2014 by the combined OFFLU Steering and Executive Committees at the OIE Headquarters in Paris to discuss and recommend strategic directions for OFFLU. The meeting was chaired and facilitated by Dr Peter Daniels as Chair of the Steering Committee. In identifying broad strategic areas in which OFFLU should be delivering recognised outcomes, the group reaffirmed the importance of OFFLU being recognised as an authoritative source of information on influenza in animals globally and in being an effective laboratory network for diagnosis of influenza in animals.

In recognition of significant gaps in surveillance for influenza infections in animal populations, the meeting agreed that OFFLU should promote and, through its advocacy, see achieved more comprehensive surveillance. In line with developments in both OIE and FAO regarding the increasingly important role of sequence data in animal disease control, OFFLU should participate in existing and future international efforts for the development of more standardised processes for capturing, storing, quality assuring and analysing molecular data together with the corresponding epidemiological, clinical and other relevant data. Current work on the analysis of avian influenza (AI) isolates for antigenic matching for the purposes of vaccine antigen selection in both humans and poultry should be continued, broadened and improved, along with the similar work done for equine influenza.

In line with recommendations the OFFLU/STAR-IDAZ April 2014 workshop to develop a strategic agenda for animal influenza research, OFFLU will seek to be an active partner in international efforts to develop and promote effective methods of disease (influenza) control using an improved understanding of socioeconomic factors and value chains, and will also promote the science to identify *a priori* which emerging animal influenza viruses may pose a risk to animal health and public health. The full report of the meeting is in preparation.

In April 2015 OFFLU will hold its next General Meeting for all members in conjunction with the 9th International Symposium on Avian Influenza at the University of Georgia, Athens, Georgia, USA. The proposed strategic focus captured in the seven points outlined above will be presented to members and the implications for work programmes agreed.

OFFLU continues to contribute to the WHO vaccine composition meetings in October and February, presenting data on H5 and H9 AI sequences to help WHO with pandemic influenza preparedness.

<sup>1</sup> OFFLU: Joint OIE-FAO Network of Expertise on Animal Influenza

In its other routine work, OFFLU noted that twenty countries experienced highly pathogenic AI outbreaks during 2014 and 15 human deaths from H5N1 were reported. At the time of reporting H7N9 AI has been resurgent in China (People's Rep. of) in humans and the risk of international travel of human cases has increased. The year 2014 also saw the emergence and international transmission of new strains of AI subtypes H5N8, H5N6 and H5N3 in East and South-East Asia, H5N8 in Europe, and H5N8, H5N2 and H5N1 in North America. OFFLU has actively shared information regarding these outbreaks, appropriate diagnostics and other scientific and information among members and with the WHO.

#### 9.3. **OIE PVS<sup>2</sup> Laboratory Mission Manual**

The Commission felt that analysing a laboratory's performance on economic criteria alone might be erroneous and does not take into account the strategy of the Veterinary Services of the country in question. For example, should a country decide to eradicate a disease, the number of diagnostic samples will increase manifold and thus the costs of running a laboratory will increase. Carrying out an economic analysis of the performance of a laboratory in isolation of the strategy of the Veterinary Services may lead to incorrect conclusions and should be avoided.

#### 9.4. Proposed African horse sickness vaccine trial in Dubai

This Item was postponed to the next meeting.

#### 9.5. METAPANOMICS proposal

Metapanomics is defined in this proposal as the integration of data generated using metagenomics, metatranscriptomics and metaproteomics for the characterisation of microorganism communities in tick vectors of human and animal diseases. The Commission noted this proposal and would support the OIE's participation on the advisory board.

#### **9.6. Disease BioPortal**® (http://bioportal.ucdavis.edu/)

The Commission noted this initiative with interest.

#### 10. Any Other Business

#### 10.1. Work plan and activities

The Commission believed that the future newly elected members should determine the work plan at its meeting in September taking into account the outcomes of the 83rd General Session and the needs of the other Specialist Commissions.

#### 10.2. Other potential meetings of ad hoc Groups

The Commission agreed that the *ad hoc* Group on Diseases of Camelids could usefully meet again to progress the validation of diagnostic test methods and the development of international standard reagents and vaccines for priority camelid diseases.

As discussed by the EBG (see Item 2.1 and <u>Annex 3</u>) the Commission confirmed that the Member Country comments on the draft *Terrestrial Manual* chapter on vaccine banks would require careful consideration. The Commission would recommend that the Director General convene an *ad hoc* Group for this task.

<sup>2</sup> PVS: Performance of Veterinary Services

#### 10.3. The role of laboratories in national animal health strategies

Where Veterinary Services develop national animal health strategies, these strategies should include the requirements for veterinary laboratories in support of the strategy. Thus laboratories are integrally linked to animal health strategies, though this relationship is not always clearly delineated. Dr Daniels proposed to draft a text on this topic that would eventually be circulated to Member Countries.

#### 10.4. Dates of the next Biological Standards Commission meeting

The Commission noted the dates for its next meetings: the week beginning 31 August to 4 September 2015.

#### 11. Adoption of the Report

The report was adopted by the Commission.	

.../Annexes

#### MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

#### Paris, 28-30 January 2015

#### Agenda

#### 1. Adoption of Agenda

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

- 2.1. Decision on proposals of the Enlarged Bureau Group
- 2.2. Rinderpest chapter: vaccine standards
- 2.3. For information: draft chapters now available on Commission's web page

#### 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: amended guidelines for applicants for Reference Laboratory status
- 3.4. Annual reports of Reference Centre activities in 2014
- 3.5. Review of new and pending applications for laboratory twinning projects

#### 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), 13–14 November 2014
- 4.2. Report of the Meeting of the *ad hoc* Group on Biosafety and Biosecurity in Veterinary Laboratories, 26–27 January 2015

#### 5. International Standardisation/Harmonisation:

#### **Diagnostic tests**

- 5.1. OIE Register of diagnostic tests: update and review of applications
  - 5.1.1. EU comment on the report of the September 2014 meeting of the OIE Biological Standards Commission

#### 5.2. Standardisation programme

- 5.2.1. OIE-approved standard sera: review of datasheets for *Mycoplasma mycoides* subs. *mycoides* small colony antigen preparation for the complement fixation test for contagious bovine pleuropneumonia
- 5.2.2. Update on progress developing guidelines for antigen standards
- 5.2.3. Guidelines on the preparation and validation of an OIE-approved tuberculin standard
- 5.2.4. For information: project to develop a tool that laboratories can use to perform a self-assessment of their quality management system

#### Biosafety/Biosecurity

- 5.3. Mission report Biosafety Advisory Group (BAG) Meeting, 24–26 November 2014, World Health Organization (WHO), Geneva, Switzerland
- 5.4. Feedback from the Inaugural meeting of ISO/TC 212/JWG5, Laboratory biorisk management, London, UK, 13–14 January 2015

#### 6. Resolutions for the General Session

6.1. Resolutions that will be presented in May 2015

#### 7. Conferences, Workshops, Meetings

- 7.1. WAVLD, 15–18 June 2015, Saskatoon, Canada: 1-day OIE Symposium on *New Diagnostic Technologies and International Standard Stetting*: Wednesday 17 June 2015
- 7.2. Follow-up on Recommendations from the 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. FMD serum provision to calibrate diagnostic tests
  - 8.1.2. Zoonoses transmissible from non-human primates
- 8.2. Terrestrial Animal Health Standards Commission
  - 8.2.1. Infection with a vian influenza viruses
  - 8.2.2. The removal of details on diagnostic tests and their use from the *Terrestrial Code* and inclusion in the *Terrestrial Manual*

#### 9. Matters of Interest for Information

- 9.1. Meeting of the Expert Surveillance Panel on Equine Influenza Vaccine Composition (6 March 2015)
- 9.2. Update on OFFLU
- 9.3. OIE PVS Laboratory Mission Manual
- 9.4. Proposed African horse sickness vaccine trial in Dubai
- 9.5. METAPANOMICS proposal
- 9.6. Disease BioPortal®

#### 10. Any Other Business

- 10.1. Workplan and activities
- 10.2. Other potential meetings of ad hoc Groups
- 10.3. The role of laboratories in national animal health strategies
- 10.4. Dates of the next Biological Standards Commission meeting

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## MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION Paris, 28–30 January 2015

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## MEETING OF THE ENLARGED BUREAU GROUP OF THE OIE BIOLOGICAL STANDARDS COMMISSION Paris, 29 January 2015

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

No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
	Glossary	RECEIVED	Amended and approved to be sent to Member Countries (MCs) as the final version	Agreed
1.1.1.	Management of Veterinary Laboratories	RECEIVED	Approved to be sent to MCs as the final version	Agreed
1.1.3	Biosafety and biosecurity: standard for managing biological risk in the veterinary laboratory and animal facilities	RECEIVED		The ad hoc Group met from 26 to 27 January 2015 and further amended the chapter. Approved to be sent to MCs as the final version
1.1.7.	Tests for sterility and freedom from contamination of biological materials	Not yet received	Awaiting text	
1.1.6.	Principles of veterinary vaccine production (re-write as a standard)	Collaborating Centre for Veterinary Medicinal Products	Approved to be sent to MCs as the final version. The EBG and the BSC noted the comments of one of the expert reviewers.	Agreed
1.1.8.	Minimum requirements for vaccine production facilities: renamed as Recommendations for manufacturing sites for veterinary vaccines	has undertaken to draft the texts in collaboration with other OIE Centres working on vaccines: RECEIVED 1.1.6 and 1.1.8; the latter incorporates chapter	Approval deferred. Chapter authors to be requested to separate the information into requirements for manufacturing sites (chapter 1.1.8) and quality control of vaccines (chapter 1.1.9).	
1.1.9.	Quality control of vaccines	1.1.9	See above	
1.1.10.	Vaccine banks	RECEIVED	The chapter received a large volume of MC comments. Recommend that an ad hoc Group be convened to review the comments and amend the chapter accordingly	Agreed
1.1.11	Standards for high throughput sequencing, bioinformatics and computational genomics	RECEIVED	The ad hoc Group met 13–14 November and further amended draft chapter.	For 2016
2.1.4.	Echinococcosis/Hydatidosis	Not yet received	Awaiting text	

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No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
2.1.6.	Heartwater	Not yet received	Awaiting text	
2.1.12.	Q fever	RECEIVED	Amended and approved the diagnostic section to be sent to MCs as the final version. Vaccine section on hold	Agreed
2.1.15	Rinderpest	RECEIVED	Amended to remove requirement to challenge vaccinated animals for safety testing the vaccine. Approved to be sent to MCs as the final version.	Agreed
2.1.19	Vesicular stomatitis	RECEIVED	Amended and approved to be sent to MCs as the final version	Agreed
2.1.X	Infection with Brucella abortus, B. melitensis and B. suis	RECEIVED		For 2016
2.2.1	Acarapisosis of honey bees	AHG revising bee disease chaps (coor. Ritter). Not yet received	Awaiting text	
2.2.3.	European foulbrood of honey bees	Not yet received	Awaiting text	
2.2.6.	Tropilaelaps infestation of honey bees (Tropilaelaps spp.)	Not yet received	Awaiting text	
2.2.7.	Varroosis of honey bees	Not yet received	Awaiting text	
2.3.4.	Avian influenza	RECEIVED	A Reference Laboratory had provided small technical amendments to the protocol for the agar gel immunodiffusion test. Approved to be sent to MCs as the final version with corrections indicated	Agreed
2.3.5.	Avian mycoplasmosis ( <i>M. gallisepticum, M. synoviae</i> )	Not yet received	Awaiting text	
2.3.9.	Fowl cholera	RECEIVED	Amended and approved to be sent to MCs as the final version	Agreed
2.3.10.	Fowl pox	RECEIVED		For 2016

Enlarged Bureau of the Commission/January 2015

No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
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 as the final version	Agreed
2.4.5.	Bovine genital campylobacteriosis	Not yet received	Awaiting text	
2.4.7.	Bovine tuberculosis	Not yet received	Awaiting text	
2.4.8.	Bovine viral diarrhoea	Received diagnostic section. Awaiting vaccine section	Amended and approved to be sent to MCs as the final version	Agreed
2.4.10.	Dermatophilosis	Not yet received	Awaiting text	
2.4.16.	Theileriosis	Intermediary version adopted May 2014. Further review to come	Awaiting text	
2.5.4.	Epizootic lymphangitis	Not yet received	Awaiting text	
2.5.7.	Equine influenza	RECEIVED	The Equine Surveillance Panel on Equine Influenza Vaccine Composition updated the chapter to include a section entitled: Requirements for authorisation of strain updates to vaccines, to enable vaccine manufacturers to respond quickly to recommendations in accordance with the OIE recommendations. Approved to be sent to MCs as final version	Agreed
2.5.9.	Equine rhinopneumonitis	Received diagnostic section. Awaiting vaccine section	Approved the diagnostic section to be sent to MCs as final version subject to clarification of some points by the authors. Vaccine section on hold	Agreed
2.5.11.	Glanders	RECEIVED	Amended and approved to be sent to MCs as final version subject to clarification of some points by the authors	Agreed
2.7.9.	Ovine epididymitis (Brucella ovis)	RECEIVED	Approved to be sent to MCs as the final version	Agreed

Enlarged Bureau of the Commission/January 2015

No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
2.8.7.	Porcine reproductive and respiratory syndrome	RECEIVED	Approved to be sent to MCs as the final version	
2.8.8.	Influenza A virus of swine	RECEIVED	Amended and approved to be sent to MCs as final version subject to clarification of some points by the authors	
2.8.10.	Teschovirus encephalomyelitis	Not yet received	Awaiting text	
2.8.11.	Transmissible gastroenteritis	Not yet received Awaiting text		
2.9.4.	Cryptosporidiosis	RECEIVED	Under study	Agreed (February 2014)
2.9.6.	Nipah and Hendra virus diseases	RECEIVED	Amended and approved to be sent to MCs as final version subject to clarification of some points by the authors	
2.9.10.	Toxoplasmosis	Not yet received	Awaiting text	
2.9.11.	Verocytotoxogenic Escherichia coli	Not yet received	Awaiting text	
2.9.12.	Zoonoses transmissible from non-human primates	RECEIVED	Amended and approved to be sent to MCs as the final version.	Agreed

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

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

#### For information: chapters adopted since 2012

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

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

No.	Title	Year adopted
Guideline 3.6.4.	Measurement uncertainty	May 2014
Guideline 3.6.5.	Statistical approaches to validation	May 2014
Guideline 3.6.6.	Selection and use of reference samples and panels	May 2014
Guideline 3.6.7.	Principles and methods for the validation of diagnostic tests for infectious diseases applicable to wildlife	May 2014

## MEETING OF THE ENLARGED BUREAU GROUP OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 29 January 2015

1. Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

- 1.1. Update on progress since last meeting
- 1.2. Review of chapters proposed for first round of comments and eventual adoption in May 2015
- 1.3. Comments received from OIE Reference Laboratory expert on the agar gel immunodiffusion protocol in the avian influenza chapter
- 1.4. Question on the virus neutralisation test for Rift Valley fever
- 1.5. Updated chapter on equine influenza to include a section entitled: *Requirements for authorisation of strain updates to vaccines*
- 1.6. Review of the list of authors and reviewers

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

## MEETING OF THE ENLARGED BUREAU GROUP OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 29 January 2015

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#### Guidelines for applicants for OIE Reference Laboratory status

Please bear in mind that OIE Reference Laboratories must provide evidence of scientific leadership: all applicants should be the national reference laboratory and must demonstrate that they are a reference point for the disease in the region in question; they should organise rather than just participate in proficiency tests; they should be providing confirmatory diagnostic services, reference materials, etc., internationally; and the designated expert should have a number of recent relevant publications in peer-reviewed journals.

Applications shall be submitted in accordance with Article 1 of the <u>Internal Rules</u> and should include the following information:

- 1. Name of expert (an informal curriculum vitae and documented proof of international recognition for his/her expertise, e.g. publications in peer-reviewed journals, awards, membership in high-profile academic boards, should be included).
- 2. Name and address of laboratory (telephone and e-mail address [fax numbers or Web site, if available]).
- 3. Name of the Head of laboratory (Responsible Official).
- 4. Relevant legal and budgetary provisions in place that provide assurance on the sustainability and functioning of the laboratory.
- 5. Documented proof (certificates) of accreditation to the ISO 17025 or equivalent quality management system in diagnostic laboratories.
- 6. Experience in diagnostic testing for the disease according to the OIE Standards <u>nationally</u> and <u>internationally</u> (approximate number of tests performed annually for each technique).
- 7. Additional expertise in diagnostic techniques (agent characterisation techniques, molecular techniques, monoclonal antibody techniques, etc.), epidemiology and control of the disease.
- 8. Experience in standardisation and validation of diagnostic tests.
- 9. Reagent production capability (provide details of current stock of reagents for the disease).
- 10. Capability for timely international shipment and receipt of samples in accordance with the requirements for postage and packaging of biological materials described in the <u>OIE Manual of Diagnostic Tests and vaccines</u> for Terrestrial Animals, and the <u>OIE Terrestrial Animal Health Code</u> or the <u>OIE Aquatic Animal Health Code</u>.
- 11. Guarantees to ensure that staff respect the confidential nature of certain subjects, results or communications.
- 12. Current and completed research and methods development projects on the disease, including a list of relevant publications.
- 13 Organisation and participation in regular inter-laboratory proficiency testing.
- 14. Collaboration with other laboratories, centres or organisations.
- 15. Training and consultation experience for the disease in the last 2 years (courses provided, number of people trained, examples of international consultation).
- 16. Organisation and participation in scientific meetings.
- 17. Contribution to the preparation or reviewing of reference documents (chapters for the OIE <u>Manual of Diagnostic Tests and Vaccines for Terrestrial Animals</u>, <u>OIE Manual of Diagnostic Tests for Aquatic Animals</u>, disease cards, etc.).

The application will be processed by OIE in accordance with Articles 2, 3 and 4 of the Internal Rules.

<u>A short summary of activities of relevance to the status of OIE Reference Laboratory (no more than one page) should be included.</u>

Applications must be no longer than 15–20 pages in A4 format, single-spaced using Times New Roman font size 10 pt. Relevant appendices (curriculum vitae of the proposed reference expert, accreditation certificates) may be attached to the core document. The core document must be prepared in one of the official languages of the OIE (English, French or Spanish).

Original: English November 2014

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

Paris, 13-14 November 2014

An *ad hoc* Group (AHG) on High Throughput Sequencing, Bioinformatics and Computational Genomics (HTS-BCG) was convened at the OIE Headquarters from 13 to 14 November 2014.

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

#### 1. Opening

Dr Elisabeth Erlacher-Vindel, Deputy 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 to be used ultimately by the OIE, the OIE Reference Laboratory and Collaborating Centre (Reference Centre) network and the OIE Member Countries.

#### 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.

The AHG discussed the challenges presented by the increasing utilisation of HTS-BCG in pathogen discovery and characterisation, and the subsequent interpretation of results in respect of clinical disease manifestation, and validity of diagnostic tools and vaccines. The Group acknowledged that HTS-BCG was a rapidly developing technology mostly driven by available platforms and software packages for sequence generation, with few standards for quality assurance of the results. Different to other diagnostic technologies, the Group recognised both the need for and the opportunity to develop standards regarding the generation of sequence information.

Leadership was necessary in assessing the implications of the technology for animal health, international trade and disease status and control, and the OIE was considered the appropriate organisation to provide this leadership. The recent discovery, characterisation and assessment of the animal health implications of the Schmallenberg virus were considered a good example of the opportunities and challenges related to the use of HTS-BCG. The Group considered it likely that the number of such discoveries would become more frequent with time. It identified the need for a regular permanent monitoring mechanism and the establishment of a regular permanent process for the assessment of the implications of the findings for animal health, trade and disease status and control.

Due to the sensitivity of the technology for detecting genetic material, maintenance of the genetic integrity of specimen and samples is of paramount importance. Whilst there was guidance for the different commercially available sequencing platforms and kits, the Group noted the need for general guidance and standards on critical aspects of HTS-BCG. In a future step, the OIE would need to consider disease-specific implications of the technology.

In consideration of the Terms of Reference for this meeting, the Group agreed that both charges would need to be advanced in parallel.

## 3.1. To further elaborate the concept for the Pilot Project: Creation of an OIE platform for the collection and management of genomic sequences in animal health

The Group discussed the state of affairs subsequent to the Third Global Conference of OIE Reference Centres (14–16 October 2014, Incheon, Korea [Rep. of]).

It was noted that the OIE continually adapts to animal health challenges, such as changing emphasis from focusing on diseases to developing standards for dealing with infections. Responding to the challenge of managing sequence information is part of this continuum. Genetic sequences for infectious agents, including for animal pathogens relevant to the work of the OIE, would likely be generated in even greater numbers in the future. This could potentially have implications for international trade and disease management. It was therefore considered necessary for the OIE to prepare a recording system that would allow capture and access to genetic sequence information stemming from relevant animal health alerts.

Such a system should (a) consider the need for reference genetic sequences and pathogens (biological references), (b) accommodate the fact that pathogens are likely to evolve and change over time, so that new or modified references would need to be added over time, (c) address the phenotypic implication of genetic sequence information, such as differences in clinical signs or the need to adapt vaccines and diagnostics, and (d) enable the OIE to address trade implications and disease control implications for diseases of concern to the OIE.

Importantly, the OIE system should be capable of and routinely decide on the significance of descriptions of new infectious agents, including those based solely on the reporting of novel sequences or new variations of previously recognised genetic profiles. This will involve a monitoring capacity to flag new pathogens or strains, a rapid and regular mechanism for evaluation of the new information and a process of consultation to advise on implications for trade, disease status and disease control.

The Group extensively discussed the idea of the pilot project. It agreed that the OIE platform should hold sequence data combined with relevant epidemiological information. The Group considered the project as needing full time personnel guided by Professor Caporale as the project coordinator representing the OIE to advance in a reasonable time frame that is matched to advances in the technology and international efforts to drive standardisation. The Group recognised the expertise already available amongst the OIE Reference Centres and the need for acceptance of the project.

## 3.2. To develop standards for high throughput sequencing, bioinformatics and computational genomics for inclusion in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*

The Group agreed that it would be worth developing specific standards for HTS-BCG for inclusion in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* to give guidance to potential users of the technology for purposes relevant to animal health. Due to the nature of the methodology, there is potential for it to be used outside the context of quality assured laboratories, and there are potentially far-reaching implications, which set this methodology apart from other diagnostic methodologies.

A first draft of a potential chapter based on the report of the first meeting of the AHG was reviewed. The Group agreed that the methodology would always be used as a primary diagnostic tool, whether the specific purpose was pathogen discovery or confirmation of the genetic sequence of a suspected or known pathogen. Additional guidance was developed to address procedural differences in approach for these two use scenarios.

Maintaining the integrity of the genetic information contained in the original sample was a key challenge of the methodology and further recommendations to ensure genetic integrity were developed.

A generic guide to the key steps involved in HTS-BCG was developed for a public interested in taking up the technology in an animal health related context.

The Group further developed a new section on interpretation of results, stressing the importance of the relevant context of the interpretation of results, including appropriate preparation of genetic reference libraries, the epidemiological context, and the use of reference sequences, where available.

The draft chapter can be found at <u>Appendix IV</u> of this report. The draft Chapter will be submitted to the Biological Standards Commission for review and forwarding to Member Countries for comment.

#### 3.3. Draft Work Plan

The Group agreed that two work plans would be required that needed to progress in parallel. One needed to advance the OIE pilot project, the other should consider the development of OIE standards.

Regarding the concept for the Pilot Project: Creation of an OIE platform for the collection and management of genomic sequences in animal health, the need to have staff fully dedicated to this project was recognised and the following steps for the Pilot Project were proposed:

- 1. Conduct a process of consultation with selected OIE Reference Centres to more fully develop the functional specifications to implement a pilot project based on the proposed platform framework and on country/laboratory visits.
- 2. Understanding of current systems used in the scientific community would be sought through a questionnaire.
- 3. Based on consideration of experience and solutions available from the OIE Reference Centres, develop the draft functional specifications for an OIE platform solution for managing sequence data and accompanying epidemiological information, ensuring interoperability with WAHIS<sup>1</sup>.
- 4. Develop acceptance of the functional specifications through a process of iteration with the OIE Reference Centres leading to a pilot entry of data to the platform. Bluetongue is recommended for this pilot data entry.
- 5. In a second phase, progress to other diseases is envisaged (foot and mouth disease [FMD], avian influenza, Newcastle disease, etc.).
- 6. Upon successful completion of these two phases and presentation to the Member Countries, the system could be launched.

Regarding the development of OIE standards, the Group recommended the following steps:

- 1. The adoption of a draft chapter on general aspects of HTS-BCG for inclusion in the *Terrestrial Manual* as the first step.
- 2. Reconvene the ad hoc Group with additional expertise to consider:
  - a. horizontal issues of the technology, such as appropriate validation of the technology;
  - b. specific requirements for quality assurance;
  - c. bioinformatics;
  - d. disease-specific implications of the technology.

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WAHIS: World Animal Health Information System (of the OIE)

All work will be progressed taking into account the responses to the OIE questionnaire on the use of the technology that was sent out to the Reference Centres in preparation of the Third Global Conference of OIE Reference Centres.

## 4. Provide input on the programme for the 1-day OIE Seminar on *New Diagnostic Technologies* and *International Standard Stetting* to be held on Wednesday 17 June 2015 in Saskatoon, Canada during the WAVLD<sup>2</sup> Symposium

The Group considered the title of the meeting in the light of the discussions around the draft *Terrestrial Manual* chapter and the proposed OIE Pilot Project *Creation of an OIE platform for the collection and management of genomic sequences in animal health.* It suggested that the seminar would use whole genome sequencing as an example diagnostic method and the discussions be structured around the sections of the draft *Terrestrial Manual* chapter on HTS-BCG.

The following topics were suggested:

- · OIE introduction
- HTS-BCG: Evolution or revolution?
- The increasing importance of sequence information in managing animal health information globally; actions by the OIE in response to the increasing detection of new agents and new variants described by sequence information
- Approaches to validation of HTS in the diagnostic laboratory
- Bioinformatics (how to standardise) / assembling raw data into sequences. What does it mean for a lab to use such technologies (example?)
- New types of bluetongue –animal health issues arising from reports of different sequences of known viruses
- Quality assurance of HTS in the diagnostic laboratory
- Genetic evolution of avian influenza in Asia and related challenges
- · Data interpretation
- Opportunity given by this technology to study the spread of diseases in time and space (animated maps)

#### 5. Any other matters

The Chair reported on his consultations with FAO<sup>3</sup> regarding the sharing of FMD sequences among the scientific community linked to geographical information. He had informed the FAO of the OIE pilot project and noted the potential for overlap between the two projects.

#### 6. Finalisation and adoption of the draft report

The AHG finalised and adopted the draft report.

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.../Appendices

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WAVLD: World Association of Veterinary Laboratory Diagnosticians

FAO: Food and Agriculture Organization of the United Nations

Appendix I

# AD HOC BRAINSTORMING GROUP ON HIGH THROUGHPUT SEQUENCING, BIOINFORMATICS AND COMPUTATIONAL GENOMICS (HTS-BCG) Paris, 13–14 November 2014

#### Agenda

- 1. Opening
- 2. Appointment of chairperson and rapporteur
- 3. Terms of Reference for the *ad hoc* Group meeting
  - 3.1. To further elaborate the concept for the Pilot Project: Creation of an OIE platform for the collection and management of genomic sequences in animal health
  - 3.2. To develop standards for high throughput sequencing, bioinformatics and computational genomics for inclusion in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
  - 3.3. Draft Work Plan
- 4. Provide input on the programme for the 1-day OIE Seminar on *New Diagnostic Technologies and International Standard Stetting* to be held on Wednesday 17 June 2015 in Saskatoon, Canada during the WAVLD<sup>4</sup> Symposium
- 5. Any other matters
- 6. Finalisation and adoption of the draft report

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WAVLD: World Association of Veterinary Laboratory Diagnosticians

#### Appendix II

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

Paris, 13-14 November 2014

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Appendix III

# AD HOC BRAINSTORMING GROUP ON HIGH THROUGHPUT SEQUENCING, BIOINFORMATICS AND COMPUTATIONAL GENOMICS (HTS-BCG) Paris, 13–14 November 2014

#### **Terms of Reference**

- 1. To further elaborate the concept for the Pilot Project: Creation of an OIE platform for the collection and management of genomic sequences in animal health
- 2. To develop standards for high throughput sequencing, bioinformatics and computational genomics for inclusion in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
- 3. Draft Work Plan

Original: English January 2015

# REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON BIOSAFETY AND BIOSECURITY IN VETERINARY LABORATORIES Paris, 26–27 January 2015

#### 1. Opening of the meeting

The OIE *ad hoc* Group on Biosafety and Biosecurity in Veterinary Laboratories met from 26 to 27 January 2015 at the OIE Headquarters in Paris, France.

Dr François Diaz, Scientific and Technical Department, welcomed the participants on behalf of the Director General of the OIE, Dr Bernard Vallat. He informed the Group that the chapter 1.1.3.a. of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)*, "Standard for managing biorisk in the veterinary laboratory and animal facilities", was adopted by the World Assembly of OIE Delegates in May 2014 and published in addition to the chapter 1.1.3., "Biosafety and biosecurity in the veterinary diagnostic microbiology laboratory and animal facilities". He mentioned that although the 180 Member Countries adopted the Chapter 1.1.3.a. at the General Session in May 2014, some Member Countries expressed concerns on an approach for biosafety and biosecurity in veterinary laboratories based only on a biological risk analysis. He mentioned that the main objective of the meeting was to combine these two chapters to propose a balanced approach to the Biological Standards Commission.

The OIE Director General, Dr Bernard Vallat, came to welcome the participants the second day of the meeting. He thanked the participants for their support to the OIE activities related to Biosafety and Biosecurity in the veterinary laboratories and emphasised the importance of this topic for OIE Member Countries. He informed the participants about the OIE Global Conference on Biological Threat Reduction that will be held in Paris, France from 30 June to 2 July 2015. He pointed out the importance of the development of standards at the international level for harmonisation of the national regulations worldwide. In reply to a question of a participant asking if the quality management in laboratories was addressed by FAO<sup>1</sup>, OIE and WHO<sup>2</sup> in the framework of the tripartite agreement, he stated that this will be put in the agenda of the next tripartite steering committee meeting that would be held at the OIE Headquarters in February.

#### 2. Appointment of chairperson and rapporteur and adoption of the agenda

The meeting was chaired by Dr Peter Daniels, and Prof Sharon Hietala and Dr Kathrin Summermatter acted as rapporteurs. The adopted Agenda and the List of Participants are presented at <u>Appendices I and II</u> of this report, respectively.

#### 3. Presentations related to Biorisk management

The Group had not met since September 2013 and so it was considered advisable for the Group to receive inputs from partner international organisations to update Group members on developments in this rapidly developing area of expertise internationally.

In particular it was noted that the Member Countries of the OIE are also Member States of the WHO and so each country would have obligations to both of these organizations that could be considered binding. Hence harmonisation between OIE and WHO standards and guidance would be an important requirement for Member Countries.

FAO: Food and Agriculture Organization of the United Nation

<sup>2</sup> WHO: World Health Organization

The following presentations were given by participants of the Group:

- WHO: "WHO activities and position on Biosafety/Biosecurity", presented by Dr Kazunobu Kojima.
  - The presentation detailed the current WHO activities related to Biosafety/Biosecurity. Dr Kojima mentioned in particular that the Laboratory Biosafety Manual (Third edition) would be revised and updated.
- "Minimum Biorisk Management Standard for Foot and Mouth Disease Virus Laboratories A
  journey towards risk based controls", presented by Dr Uwe Mueller-Doblies
  - Dr Uwe Mueller-Doblies outlined the successful application of a biological risk management approach to the management of laboratories handling FMD virus in the EU, developed over time and delivering both the flexibility to respond to changing circumstances and the certainty to EU member countries that the risks of an FMD infection from a laboratory source were adequately managed.
- IFBA<sup>3</sup> / Sandia: "Overview of the Laboratory Biosafety and Biosecurity Risk Assessment Guidance Document", presented by Dr Jennifer Gaudioso
  - The presentation informed the participants on the development of a 50 page technical manual to assist laboratories with the intricacies of conducting biological risk assessments as a key part of the management process.
- FAO: "The FAO South/South East Asia Regional Biosafety Program 2012-2014", presented by Dr Stuart Blacksell
  - Dr Blacksell informed the participants on the FAO activities relevant for Biosafety and Biosecurity in the veterinary laboratories and described in particular the FAO Laboratory management tool.

From the presentations and further discussions, the Group drew the conclusion that managing biological risks through a process of risk analysis was a well-established international practice and that it was growing in the scope of its applications.

Of possible concern is that there has not been a standard approach and that the decisions of numerous countries in responding to the balance between managing laboratory biological risks and animal health operational requirements has not been clearly recorded or performed in consistent and reproducible ways. The Group considered there was a clear need for the OIE to be setting the standards by which such considerations could be conducted in Member Countries in a comprehensive, evidence based, repeatable and transparent manner.

4. Fusion of the current existing chapters 1.1.3. "Biosafety and biosecurity in the veterinary diagnostic microbiology laboratory and animal facilities" and 1.1.3.a. "Standard for managing biorisk in the veterinary laboratory and animal facilities" of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* 

#### General comments

The Group took note of the comments further the adoption of the Chapter 1.1.3.a. and determined to reassess the information and approaches in the chapters 1.1.3. and 1.1.3.a. for the purposes of developing an approach that would meet the requirements of Member Countries and also realistically deliver the standards for management of biological risks associated with laboratories and animal facilities, as needed by the international community.

The Group reaffirmed that the purpose of Chapter 1.1.3.a. was to be a high level document stating the principles for managing biological risks based on risk analysis. It was not intended to be a technical manual but should help to structure and standardise the risk analysis process to make it more consistent, transparent and communicable.

<sup>3</sup> IFBA: International Federation of Biosafety Associations

The Group discussed that, in the Chapter 1.1.3.a. as published, perhaps the context for the development of the standard could have been introduced more clearly to emphasize that the laboratory risk analysis process was not intended to be implemented separately from the national regulations or relevant authorities. Countries with veterinary laboratories are likely managing these within the context of a formally stated animal health policy that indicates clearly the purposes for which laboratory services are required. This animal health policy will usually include specific mention of the pathogens for which a diagnostic or research capability is required and will allow the subsequent design and development of a laboratory capability that is fit for purpose. This will include decisions regarding the use of particular direct and indirect tests and of tests that may require either the holding and use of particular infectious agents in the laboratory and/or their culture and propagation.

It follows that countries maintaining veterinary laboratories have responsibility to manage associated biological risks within the framework of the national animal health policy, based on international standards. The Group felt that additional language in the introduction should be included to reaffirm the need for national regulations to identify the country's animal health requirements and the role of the laboratories and animal facilities as well as the responsibilities for assessing and controlling biological risks.

The Group noted that in the Chapter 1.1.3.a. the essential basic standards to be followed for all laboratory work were clearly stated, carried forward from the previous chapter 1.1.3.

The Group noted numerous existing tools for laboratory and biological risk management and assessment such as the FAO "Laboratory management tool" and the WHO "Laboratory Biosafety Manual". The Group pointed out the need for harmonisation between WHO/OIE/FAO in the framework of one health. When relevant documents are developed or revised, the Group also emphasised the need for collaboration and participation of representatives of the three international organisations.

#### Terminology of "biorisk management"

The Group received some advice that the term "biorisk management" is considered by some to be associated with a particular set of technical guidelines and the Group considered that for the purposes of clarity in the OIE *Terrestrial Manual* the term "biological risk management" should be used, to emphasize that the requirements of the Chapter are of a general nature based on clearly communicated principles, a framework that sets minimum requirements. The selection of management strategies may be supported by technical inputs from other published reference sources.

#### Removal of reference to established risk groups

The Group considered whether the merged chapter would benefit from including the table of risk groups for pathogens as adapted from the WHO (Laboratory Biosafety Manual, third edition) in the Chapter 1.1.3. of the *Terrestrial Manual*. With respect to risk grouping of pathogens for the purposes of animal health, it was considered that this would defeat some of the purposes of drafting the Chapter from a biological risk assessment approach. The Chapter 1.1.3.a., adopted by Member Countries in May 2014, encourages countries to manage risks in a manner appropriate to their epidemiological, economic and social situations. It also encourages, indeed requires, an active process of understanding the hazards associated with the actual biological materials used in the laboratories in each country and the risks they pose, and the best strategies for their management. This will lead to better management of risks rather than a simple compliance approach that may not be accompanied by a comprehensive understanding of all aspects relevant to comprehensive laboratory biosafety and biosecurity. Development of such an informed understanding was not seen as aspirational, but rather an obligation on countries working with biological materials in laboratories.

Moreover, the Group agreed that the widely used 4 tiered classification of risk groups for pathogens refers primarily to the potential for human disease and the corresponding prophylactics and therapeutics available for human use. However in the application of these clear definitions to numerous newly emerged zoonotic agents such as Bovine Spongiform Encephalopathy, Nipah virus and H5N1 avian influenza there has been little consistency among countries in the use of the risk groups in aligning laboratory strategies with corresponding numbered levels of physical containment to manage the new situation. Rather countries have used an informal and not necessarily well documented approach to developing their procedures based on assessments of perceived risks and how these might be managed. Therefore the Group did not consider it useful to keep the

current pathogen risk grouping table in the OIE *Terrestrial Manual*, but rather it would be more useful to give a framework, a standard, for the analysis of risks, thereby building on the approaches that have occurred historically. The current chapter states the requirement and gives the framework for Member Countries to actively assess public and animal health risks and to manage these risks.

#### Technical guidelines

The guideline 3.5 "Managing Biorisks: Examples of aligning risk management strategies with assessed biorisks" was considered by some Member Countries as a particular useful template to help implement the Chapter 1.1.3.a.

In further considering the concern of Member Countries that the biological risk management chapter moved too far from existing practices in some countries of assigning pathogens to numerically ranked risk groups and requiring that these be worked with at corresponding levels of physical containment, the Group considered whether the material relating to this numerical ranking in the old chapter could be usefully included as an example in a guideline completing the Chapter 1.1.3.a. However the Group was concerned that inclusion of a table with numerically ranked groupings in an example would be at variance to the approach in the new chapter, and hence confusing rather than helpful.

Instead the Group substantially enhanced the Table 1 in the body of the Chapter 1.1.3.a. to give more details in each of the risks under consideration in reaching decisions as to the relative severity of the risk to be managed. The reworked chapter and its Table A clearly link the assessment of the severity of the risk, and the nature of the risk, to the need to adopt matching strategies to manage both the risk pathway and the severity of the negative impact. In this way the mitigation measure not only matches the potential magnitude of the risk but requires that the appropriate balance of risk management strategies be decided and implemented. The Group considered that within this approach it may be acceptable in the national context for responsible authorities to continue to use numerical ranking of risks and mitigation measures appropriate to their circumstances but realising that these national decisions could not automatically be applied universally.

#### Specific information on diseases

One concern of some Member Countries was whether all countries would have access to the relevant information to support the process of the risk analysis. The Group noted that it would be mostly published data that would be used by any country performing a risk analysis. The objective of the OIE Terrestrial Manual is to provide internationally agreed diagnostic laboratory methods and requirements for the production and control of vaccines and other biological products. Some specific diseases chapters still refer to risk groups and containment levels and should be updated in the future. The Group considered that it would be important, for facilitating risk assessment, to expand the disease specific chapter or the technical disease cards with each biological agent's specific information such as transmission route, infectious dose, host range, environmental stability, disinfection methods, etc.

#### Assessment and sustainability

The Group reaffirmed that, similar to quality management systems, biological risk management systems must be regularly assessed to ensure that the system is working as intended. As part of this, an implemented system for a given laboratory must be sustainable over the long term and include documentation, documented audit findings and responses, and hence continuous improvement.

#### 5. Finalisation of the report

The report was finalised and adopted by the Group at the end of the meeting.	
	/Appendice

Appendix I

## OIE *AD HOC* GROUP ON BIOSAFETY AND BIOSECURITY IN VETERINARY LABORATORIES Paris, 26-27 January 2015

#### Agenda

- 1. Opening of the meeting
- 2. Appointment of chair and rapporteur and adoption of the agenda
- 3. Presentations related to Biorisk management:
  - WHO activities and position on Biosafety, Biosecurity and Biorisk management
  - EUFMD approach on Biorisk management
  - Laboratory Biosafety and Biosecurity Risk Assessment Technical Guidance (IFBA/Sandia)
  - Current situation regarding the OIE approach for Biorisk management/Biosafety/Biosecurity
- 4. Fusion of the current existing chapters 1.1.3. "Biosafety and biosecurity in the veterinary diagnostic microbiology laboratory and animal facilities" and 1.1.3.a. "Standard for managing biorisk in the veterinary laboratory and animal facilities" of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)
- 5. Finalisation of the report

#### Appendix II

#### OIE AD HOC GROUP ON BIOSAFETY AND BIOSECURITY IN VETERINARY LABORATORIES Paris, 26-27 January 2015

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