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REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 8–10 February 2012

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The OIE Biological Standards Commission (the Commission) met at the OIE Headquarters from 8 to 10 February 2012. Dr Kazuaki Miyagishima, Deputy Director General and 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 Beverly Schmitt, Vice-President, Dr Mehdi El Harrak, Vice-President, Dr Hualan Chen, Dr Alejandro Schudel and Dr Paul Townsend, members of the Commission.

Dr Miyagishima updated the Commission on developments at the Headquarters since the last meeting. The OIE has been attracting a new category of donor partners: Ministries of Foreign Affairs or of National Security, led by the growing interest in biological risks. In response, the OIE has developed a strategy document on biothreat reduction, building on the existing OIE activities.

1. Adoption of Agenda

The proposed agenda was presented and adopted.

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

2. OIE Reference Centres

2.1. Applications for the status of OIE Reference Centre

The Commission recommended acceptance of the following six applications for OIE Collaborating Centre and Reference Laboratory status:

OIE *Reference Laboratory for Contagious bovine pleuropneumonia*
Botswana National Veterinary Laboratory, Private Bag 0035, Gaborone, BOTSWANA
Tel: (+267) 392.8816; E-mail: cmarobela-raborokgwe@gov.bw
Designated Reference Expert: Dr Chandapiwa Marobela-Raborokgwe.

OIE *Reference Laboratory for Rabies*
Rabies Research Laboratory, Division of Viral Disease, Animal, Plant and Fisheries Quarantine and Inspection Agency (QIA), Ministry of Food, Agriculture, Forestry, and Fisheries (MIFAFF), 175 Anyang-ro, Manan-gu, Anyang, Gyeonggi 430-757, KOREA (REP. OF)
Tel: (+82) 31 467.1783, Fax: (+82) 31 467.1797; E-mail: yangdk@korea.kr; ydk40@hanmail.net
Designated Reference Expert: Dr Dong-Kun Yang.

OIE *Reference Laboratory for Equine babesiosis* (*piroplasmosis*)
Animal Disease Research Unit (ADRU), Agricultural Research Service, United States Department of Agriculture, Co-located at the College of Veterinary Medicine Washington State University Pullman, WA 99164-6630, UNITED STATES OF AMERICA
Tel: (+1-509) 335-6001; Fax: (+1-509) 335-8328; E-mail: dknowles@vetmed.wsu.edu
Designated Reference Expert: Dr Don Knowles.

OIE *Reference Laboratory for Myxomatosis*
Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna "Bruno Ubertini", Via Bianchi 9 – 25124 Brescia, ITALY
Tel: (+39[0]30) 2290.617; Fax: (+39[0]30) 2290.559; Email lorenzo.capucci@izsler.it
Designated Reference Expert: Dr Antonio Lavazza.

OIE *Reference Laboratory for Rabies*
Diagnostic Laboratory for Rabies and Wildlife Associated Zoonoses (DLR), Department of Virology, Changchun Veterinary Research Institute (CVRI), Chinese Academy of Agricultural Sciences (CAAS), Liuying Xi Road 666#, Jingyue Economic Development Zone, Changchun 130112, CHINA (PEOPLE'S REP. OF)
Tel: (+86) 431.8698.5921; Fax: (+86) 431.8698.5862; Email: changchun_tu@hotmail.com
Designated Reference Expert: Prof. Changchun Tu.

OIE *Reference Laboratory for Paratuberculosis*
Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (Anses), Laboratoire de Niort, 60, rue de Pied-de-Fond, BP 3081, 79012 Niort cedex, FRANCE
Tel: (+33 [0]5) 49.79.61.28; Fax: (+33 [0]5) 49.79.42.19; Email: pascale.mercier@anses.fr
Designated Reference Expert: Dr Pascale Mercier.

An application had been received from a European country for an OIE Collaborating Centre for Cell Cultures. The Commission requested more information on international activities, on meetings that the Centre had organised, and a more detailed curriculum vitae for the proposed contact point.

A country in the Middle East had submitted application for designation as an OIE Reference Laboratory for African horse sickness (AHS). The Commission noted that the laboratory and proposed expert had no scientific publications on this disease. 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.

An application had been received from a country in the Asia, the Far East and Oceania Region for an OIE Reference Laboratory for Rinderpest. The Commission noted that consultations were currently underway between the OIE and FAO[1] to finalise membership of a Joint FAO/OIE Advisory Committee on Rinderpest, the purpose of which would be to implement the sequestration guidelines that were adopted at the OIE's World Assembly in the light of global eradication of the disease, including agreeing on the number of biosecure facilities that would be permitted to hold rinderpest virus. The Commission put the application 'on hold' until this Committee is established and operational. Any laboratory permitted to hold the rinderpest virus would need to meet the standard of an OIE Reference Laboratory.

Two applications had been received from a country in the Asia, the Far East and Oceania Region, one for an OIE Reference Laboratory for Ovine theileriosis and the second for an OIE Reference Laboratory for Swine streptococcosis. Neither of these diseases was listed by the OIE and there were no chapters in the *Terrestrial Animal Health Code* or the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.* The Commission deferred its decision to its next meeting when it would discuss the necessity of commissioning *Terrestrial Manual* chapters for these two diseases.

2.2 Changes of experts in the List of Reference Laboratories

The OIE had been notified of the following changes of experts at OIE Reference Laboratories. The Commission recommended its acceptance:

New World Screwworm (Cochliomyia hominivorax)

Dr John Welch to replace Dr Augustin Sagel at COPEG (Panama–US Commission for the Eradication and Prevention of NWS), PANAMA.

[1] FAO: Food and Agriculture Organization of the United Nations

Porcine reproductive and respiratory syndrome

Prof. Zygmunt Pejsak to replace Prof. Tomasz Stadejek at the National Veterinary Research Institute in Pulawy, POLAND.

2.3. Annual reports of Reference Centre activities for 2011

Reports had been received from 161 out of 182 Reference Laboratories and from 36 out of 38 Collaborating Centres for terrestrial animal diseases or topics. The Commission expressed its on-going appreciation to the enthusiastic support and expert advice given to the OIE by the Reference Centres. It was noted that it had been decided to discontinue routine distribution of the CD-ROM and to keep the annual reports available on line. The international activities relevant to the work of the OIE are summarised in the following tables:

Reference Laboratories

	Activities	Percentage of Laboratories carrying out these activities
General activities		
1	Test(s) in use/or available for the specified disease	97%
2	Production, testing and distribution of diagnostic reagents	92%
Specific OIE activities		
3	International harmonisation/standardisation of methods	
	a. Networking with OIE laboratories	51%
	b. Proficiency testing with laboratories other than OIE ones	62%
4	Preparation and supply of international reference standards	71%
5	Research and development of new procedures	88%
6	Collection, analysis and dissemination of epizootiological data	73%
7	Maintenance of quality assurance, biosafety and biosecurity	88%
8	Provision of consultant expertise	86%
9	Provision of scientific and technical training	72%
10	Provision of diagnostic testing facilities	64%
11	Organisation of international scientific meetings	36%
12	Participation in international scientific collaborative studies	58%
13	Presentations and publications	84%

Collaborating Centres

	Activities	Percentage of Collaborating Centres carrying out these activities
1	Activities as a centre of research, expertise, standardisation and dissemination of techniques	94%
2	Proposal or development of any procedure that will facilitate harmonisation of international regulations applicable to the surveillance and control of animal diseases, food safety or animal welfare	72%
3	Networking: maintenance of a network with other OIE Collaborating Centres designated for the same specialty and/or of a network with Centres in other disciplines	90%
4	Placement of expert consultants at the disposal of the OIE	87%
5	Provision of scientific and technical training within to personnel from OIE Member Countries	90%
6	Organisation of scientific meetings on behalf of the OIE	46%
7	Coordination of scientific and technical studies in collaboration with other laboratories or organisations	65%
8	Publication and dissemination of information that may be useful to OIE Member Countries	90%

Dr Alejandro Schudel, who had read through the reports, identified a number of laboratories reporting little or no activities. These laboratories would be requested to clarify whether this is because of lack of requests from OIE Member Countries or an inability to fulfil the mandate. He also pointed out significant differences in the nature of the information provided under different headings, in the interpretation of the questions asked, and in the amount and style of content provided.

At this point, the Commission was joined by Dr Rafaella Nisi of the OIE Scientific and Technical Department, who, as part of a USAID-funded project, had analysed the 2010 reports of 62 OIE Reference Laboratories covering 13 diseases. Dr Nisi gave a presentation of her findings, which, while highlighting the high level of activities, particularly capacity building activities, carried out by OIE Reference Laboratories to the benefit of Member Countries, also revealed a number of shortcomings with the current annual report template.

The Commission agreed that the template needed to be re-evaluated to better fit the mandate and to increase the usefulness of the information gathered. It proposed that the OIE consider using a web-based format with more close-ended questions for quantitative analyses. The Commission recommended that the OIE Scientific and Technical Department continue to work on developing the template and expanding the guidance notes for experts; a 'model' report could also be developed to give the experts an example of what the OIE and the Commission would like to receive from its experts in their annual reports. All proposals would be reviewed at the next Commission meeting in September 2012.

2.4. Review of new and pending applications for laboratory twinning

Dr Keith Hamilton provided an update on the OIE Laboratory Twinning programme. Currently over 30 OIE laboratory twinning projects were underway and four had been completed. Demand and interest in OIE Laboratory Twinning remained high, with at least 15 applications in the pipeline. As some projects came to an end, post-twinning activities became important and Dr Hamilton reported on three successful post-twinning workshops (Italy-Eritrea for brucellosis; United Kingdom-Turkey for brucellosis; Germany-Egypt for avian influenza and Newcastle disease), which aimed to set a direction for post-twinning activities in these Candidate Laboratories and to promote them as centres of expertise in their regions. Dr Hamilton also reported on some pre-twinning project meetings that aimed to coordinate applicant projects with existing projects and other capacity building initiatives. Dr Hamilton showed the Commission members the new OIE laboratory twinning webpage, which improved transparency and visibility of twinning. Two twinning proposals were presented to the Commission for technical input: United States of America/Italy-Kazakhstan for brucellosis and France-China (People's Rep. of) for infectious bursal disease. The Commission approved the technical content of both proposals.

3. *Ad hoc* Groups

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

3.1. Report of the Meeting of the *ad hoc* Group on Biosafety and Biosecurity in Veterinary Laboratories, 19–21 September 2011

The Commission adopted the report, which can be found at Appendix III of this report.

3.2. Report of the Meeting of the *ad hoc* Group on Rift Valley Fever, 6–8 December 2011

Prof. Caporale explained that the draft chapter on Rift Valley fever (RVF) proposed by the *ad hoc* Group was one of the chapters that had been discussed at the meeting of the Bureau of the OIE Biological Standards Commission and Selected Experts to update the *Terrestrial Manual* ('Enlarged Bureau Group' [EBG], see item 5.2).

Taking into account the outcome of both the EBG and the Commission's discussions, along with the newly adopted vaccine section template (see item 5.2), the Commission decided to ask the Director General to reconvene the *ad hoc* Group to finalise the revised chapter according to this template.

3.3. Report of the Meeting of the *ad hoc* Group on Vaccine Quality related to Rabies, 10–12 January 2012

Dr Susanne Münstermann presented the report of the meeting of the *ad hoc* Group. She explained that the Group had worked on 'injectable' (parenteral) vaccines, and would work on oral vaccines at a future meeting.

3.4. Report of the Meeting of the *ad hoc* Group on the Scientific Partnerships among OIE Reference Centres: Networking, 17–19 January 2012

Prof. Caporale presented the report of the meeting of the *ad hoc* Group. Since the adoption in May 2011 of the new OIE *Basic Texts*, OIE Reference Centres were mandated to form networks. The Commission reviewed the Group's proposed *Guidance for the Management of OIE Reference Centre Networks*, and concluded that any reports that the networks submitted to the OIE Director General should be made available to the Commission. The Commission amended the guidance document accordingly.

The Commission adopted the amended report, which can be found at Appendix IV of this report.

■ Planned *ad hoc* Groups

3.5. *Ad hoc* Group on Vaccine Quality related to Classical Swine Fever (to be held after February 2012)

The Commission noted that the Terms of Reference for this meeting would be the same as those for the *ad hoc* Group on Vaccine Quality related to FMD, using the definitive vaccine section template and guidelines (see item 3.2 above).

3.6. Second meeting of the *ad hoc* Group on Biosafety and Biosecurity in Veterinary Laboratories, 13–15 February 2012

The *ad hoc* Group would meet at the OIE Headquarters from 13 to 15 February 2012. It would finalise three *Terrestrial Manual* chapters: on standards for the management of biorisk in veterinary laboratories, on collection of samples and on shipment of samples.

3.7. Second meeting of the *ad hoc* Group on Validation of Diagnostic Tests for Wildlife

The Commission reiterated the importance of this issue and the urgent need to make progress in this field.

3.8. Fourth meeting of the OIE *ad hoc* Group on Validation of Diagnostic Assays

The updated chapter and seven explanatory appendices that had been developed by the *ad hoc* Group had generated a large volume of Member Country comments; though overwhelmingly positive the comments were also quite technical and it was agreed that the Group would need to be re-convened to address them. There was some disagreement within the Commission with regards to the perceived level of prescriptiveness in the *Terrestrial Manual* chapter: one member believed it to be a prescriptive document that aimed at an unachievably high standard while others did not find it prescriptive at all, but rather a guidance document, albeit a lengthy one. The approach endorsed by the Commission to progress the issue was for the Consultant Editor, Prof. Steven Edwards, to prepare an analysis of the comments; the analysis and the comments would be provided to the Group. A decision on whether to include the appendices in the *Terrestrial Manual* or elsewhere was deferred.

■ Proposed *ad hoc* Groups

3.9. Brainstorming on new approaches to diagnosis in animal health

New diagnostic technologies, such as direct diagnosis on samples by whole genomic sequencing, could have an important impact on the way laboratories function and diagnoses are made. As the cost of this technology had dropped and its use was increasing, a number of issues had arisen, such as the ownership of sequencing and surveillance data. Given its potential importance and impact, the Commission felt that the OIE should convene an *ad hoc* Group to draft an OIE White Paper on this topic. The Commission could subsequently discuss implementation of the Paper's recommendations.

4. International Standardisation/Harmonisation

- **Diagnostic tests**

4.1. 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.

He informed the Commission that the evaluation of the dossier on "IDEXX *M. bovis* Antibody Test Kit" had been completed. Based on the final report from the expert evaluation panel, the Commission provided a favourable opinion for the inclusion in the OIE register of this diagnostic kit with the following purposes:

> The IDEXX *M. bovis* Antibody Test Kit is fit for the detection of antibody to *Mycobacterium bovis* (*M. bovis*) in cattle serum and plasma samples and to be used as a supplemental test, in conjunction with other methods, for diagnosing and managing tuberculosis infection. The test also has utility when performing sero-surveys to understand prevalence and risk at a herd management level.

Further to the decision of the OIE Director General, this would be proposed for adoption by the World Assembly of Delegates at the General Session in May 2012.

4.2. Request for validation of bovine tuberculosis DIVA test

A diagnostic test had been developed in a European country to differentiate animals infected with bovine tuberculosis from vaccinated animals (DIVA test). The test developers had asked if this test could be submitted for evaluation and eventual inclusion on the OIE register. Given that vaccination of animals was not currently used in the field, there were no data from the field but rather the test performance had been evaluated in a limited number of experimentally vaccinated animals. To accept this validation with such small numbers of samples would require a new category to be included in the OIE Register: that of 'provisionally validated'. The Commission did not approve this precedent for the time being. The Commission also recommended that the Scientific Commission for Animal Diseases provide an opinion on the principle of using the DIVA strategy for this disease.

4.3. Prescribed and Alternative Tests – update on application from Canada

In follow-up to the last meeting, the Canadian developers of a monoclonal antibody-based antigen capture ELISA[2] for detection of *Campylobacter fetus* in preputial washings and other diagnostic samples had provided the further information that had been requested of them. The OIE expert and author of the *Terrestrial Manual* chapter on Bovine genital campylobacteriosis would be asked for a final review and decision on whether the test should be included in the *Terrestrial Manual.*

4.4. Prescribed and Alternative Tests – proposal to no longer list the mallein test as a prescribed test for glanders

The expert at the OIE Reference Laboratory for glanders in the Friedrich-Loeffer Institute, Jena, Germany had requested that the mallein test be removed from the list of prescribed tests for international trade. In support of this request he provided evidence that the mallein test had a low sensitivity (75.7%), which meant that one out of four glanderous animals might be misdiagnosed in a pre-transport investigation. The test depended largely on the experience of the operator applying the preparation. Equines produced antibodies against mallein that might interfere with serological tests such as the CFT[3]. This latter test was a sensitive and specific technique well established in most diagnostic laboratories worldwide.

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2 ELISA: enzyme-linked immunosorbent assay

3 CFT: complement fixation text

The Commission examined the request in the context of the current *Terrestrial Manual* chapter. Three forms of the mallein test were described: the intradermo-palpebral test, the ophthalmic test, and the subcutaneous test. The Commission agreed to delete the ophthalmic test on animal welfare grounds, to delete the subcutaneous test on the grounds that it was not very reliable and interfered with subsequent serological diagnosis, and to keep the intradermo-palpebral test, but to delete the designation "a prescribed test for international trade". The proposed updated chapter would be circulated shortly for Member Country comment.

4.5. Robust novel assay for the rapid PCR-based molecular pathotyping of H5 and H7 avian influenza viruses

The Commission noted with interest a published article entitled Rapid PCR[4]-Based Molecular Pathotyping of H5 and H7 Avian Influenza Viruses that had been developed by the OIE Collaborating Centre for Biotechnology-based Diagnosis of Infectious Diseases in Veterinary Medicine in Uppsala, Sweden.

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

For this agenda item, the Commission was joined by the Consultant Editor of the *Terrestrial Manual*, Prof. Steven Edwards.

5.1. Follow-up from brainstorming meeting for modernising the *Terrestrial Manual*

At its last meeting in September 2011, the Commission endorsed the report of the brainstorming meeting[5], and agreed that it would be further discussed at the next meeting of the Commission. The brainstorming meeting report identified a number of problems associated with the *Terrestrial Manual* and proposed some ideas/comments for improvements. The Commission went through all the points and categorised them as those that had already been taken into account, those that required action by the editorial team, by the authors (OIE Reference Laboratory experts), by the OIE Headquarters, etc. All of the suggestions had been or would soon be implemented.

The Commission noted that the next printed edition of the *Terrestrial Manual* would be published in the third or fourth quarter of 2012. Some of the improvements would already be taken into account (for example the order of the introductory chapters and the suggestion to move those that are guidelines rather than standards to a separate section at the end of the *Terrestrial Manual*), but others would be implemented in stages over the forthcoming years. This would mean that the disease chapters in the 2012 edition would not be homogenous (some but not all would follow the modified vaccine section template); for the 2016 edition, this discrepancy would be solved. The *Terrestrial Manual* should be considered as a 'work in progress' requiring continual efforts to improve it.

The Commission agreed to add to the end of each disease chapter of the *Terrestrial Manual* an indication of when (which year) the chapter had last been updated.

5.2. Review of outcome of meeting of the Meeting of the Bureau of the OIE Biological Standards Commission and Selected Experts to update the *Terrestrial Manual* ('Enlarged Bureau Group' [EBG])

The List of Participants for this meeting can be found at Appendix V.

The main purpose of this meeting that took place on 7 and 8 February 2012 was to further adapt the procedure for updating the *Terrestrial Manual* such that it would be clear and transparent for Member Countries, workable, productive and would improve consistency across the chapters. A number of chapters that were currently under review and that required expert input were also discussed.

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4 PCR: polymerase chain reaction

5 Brainstorming Meeting for Modernising the OIE the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals,* which was held at the OIE Headquarters from 12 to 13 September 2011; the report can be found as Appendix V of the Report of the Meeting of the OIE Biological Standards Commission September, 14 to 16 September 2011.

The issue of vaccines and the vaccine section of the *Terrestrial Manual* chapters were recurrent in the work plan of the Biological Standards Commission. Prof. Caporale stated that the *Terrestrial Manual* should provide the OIE Delegates with the information they needed to have when procuring vaccines. It was clear from the output of the three *ad hoc* Groups that had been convened to date to address vaccine quality and the *Terrestrial Manual* chapter (for FMD, Rift Valley fever and Rabies) that a definitive agreed upon (by the Biological Standards Commission) template for this section of the *Terrestrial Manual* disease chapters along with detailed guidance on its use, including the amount of detail being requested under each subheading, were urgently needed and must be adopted by the Commission at its meeting. The Biological Standards Commission endorsed this approach, and Dr Michel Lombard and Dr François Diaz were given the task of elaborating (and proposing for adoption by the Commission) the definitive template and guidelines. A template was finalised and proposed for adoption by the Commission; guidance on its use would be presented in the near future (see Appendix VI).

The need to include experts on vaccine production and the registration procedure as well as disease experts in the future *ad hoc* Groups in charge of updating the vaccine section of the disease specific chapters of the *Terrestrial Manual* was also emphasised by the EBG.

Dr Michel Lombard, Chair of the OIE *ad hoc* Group on Vaccine Quality related to Foot and Mouth Disease, brought to the attention of the EBG comments that had been received from the OIE FMD network on the proposed amendments to the chapter's vaccine section and the Group's consensus responses. The EGB agreed with the *ad hoc* Group's rationale for accepting or rejecting a comment, and recommended that the Commission approve the amended chapter for circulation as the final version to be proposed for adoption.

Dr Mehdi El Harrak briefed the EGB on the outcome of the meeting of the *ad hoc* Group on Rift Valley Fever (see item 3.2).

The discussion on the vaccine section of the disease-specific chapters of the *Terrestrial Manual* led to a discussion on vaccines that were not produced according to GMP and on the possible need to provide guidance on the minimum requirements for safe vaccine production. Vaccines produced following GMP should always be preferred, but under certain circumstances 'conditional vaccines' for limited use at the regional, subregional or national level might be unavoidable.

Dr Concepción Gómez-Tejedor Ortiz from the OIE Reference Laboratory for African horse sickness (AHS) in Madrid, Spain, and a colleague, joined the meeting to discuss the diagnostic tests for AHS. She explained that some of the tests in widespread use (for example the PCR) were not in the *Terrestrial Manual* chapter because it was difficult to fully validate them for all serotypes, while some of the tests in the chapter were no longer in use, were not validated and the reagents to carry them out were no longer available. The EBG recommended that the Biological Standards Commission accept the draft chapter even though it included tests that are not fully validated according to OIE Standards and to review the validation chapter (see item 3.8).

Dr Gómez-Tejedor Ortiz requested that commercial brand names of reagents or equipment, etc., be omitted from the *Terrestrial Manual*. Prof. Edwards responded that the editorial team was actively reducing mention of commercial brands.

Finally, the OIE Scientific and Technical Department presented a proposed procedure for updating the *Terrestrial Manual* chapters. The proposal indicated the tasks and responsibilities of both the EBG and the Commission. After small amendments, the Commission adopted it; it can be found at Appendix VII. A table would be appended to the report of each meeting of the Commission listing the status of the chapters that had been identified for revision. Member Countries could therefore follow the progress of each chapter under revision. Prof. Caporale would present this at the General Session in May 2012 after which it would be made available on the OIE website.

5.3. Review of chapters proposed for adoption in May 2012 before final versions being sent to Member Countries

In October 2011, ten chapters and seven appendices had been sent for Member Country comment. One chapter and the seven appendices (on validation) were on hold pending a further meeting of the *ad hoc* Group (see item 3.8.). The Consultant Editor had amended the remaining chapters according to the comments received. Some of the comments concerned matters of policy and principle and for these the Editor requested the guidance of the Commission. Once all the comments have been addressed, the chapters, along with chapters that had been circulated previously, would be marked to show the new changes and would be sent again to Member Countries, this time as the final texts that would be proposed for adoption by the Assembly at the General Session in May 2012. The twenty-five chapters are:

1.1.3. Quality management in veterinary testing laboratories
1.1.6. Laboratory methodologies for bacterial antimicrobial susceptibility testing
1.1.7. Biotechnology in the diagnosis of infectious diseases
2.1.1. Anthrax
2.1.2. Aujeszky's disease
2.1.5. Foot and mouth disease
2.1.15. Rinderpest
2.1.16. Trichinellosis
2.1.17. *Trypanosoma evansi infection* (surra)
2.3.1. Avian chlamydiosis
2.3.4. Avian influenza
2.3.7. Duck virus enteritis
2.3.11. Fowl typhoid and Pullorum disease
2.3.14. Newcastle disease
2.4.1. Bovine anaplasmosis
2.4.11. Enzootic bovine leukosis
2.4.12. Haemorrhagic septicaemia
2.4.17. Trichomonosis
2.5.1. African horse sickness
2.5.2. Contagious equine metritis
2.5.7. Equine influenza
2.7.7. Enzootic abortion of ewes (ovine chlamydiosis)
2.7.11. Peste des petits ruminants (diagnostic section)
2.8.1. African swine fever
2.8.2. Atrophic rhinitis of swine

5.4. Selection of chapters for proposal in May 2013

The following chapters were identified for revision with a view to possible adoption in May 2013. Updates would be commissioned in accordance with the updated Guidelines for authors:

1.1a. Collection of diagnostic specimens
1.1b. Shipment of diagnostic specimens
1.8. Principles of veterinary vaccine production
1.10. Guidelines for international standards for vaccine banks
Crimean–Congo haemorrhagic fever
Epizootic haemorrhagic disease
2.1.3. Bluetongue
2.1.4. Echinococcosis/Hydatidosis
2.1.6. Heartwater
2.1.8. Leishmaniosis
2.1.10. Screwworm (*Cochliomyia hominivorax* and *Chrysomya bezziana*)
2.1.11. Paratuberculosis (Johne's disease)
2.1.13. Rabies (vaccine section)
2.1.14. Rift Valley fever
2.1.20. West Nile fever
2.2.1. Acarapisosis of honey bees
2.2.2. American foulbrood of honey bees
2.2.3. European foulbrood of honey bees

2.2.4. Nosemosis of honey bees
2.2.5. Small hive beetle infestation (*Aethina tumida*)
2.2.6. Tropilaelaps infestation of honey bees (*Tropilaelaps* spp.)
2.2.7. Varroosis of honey bees
2.3.2. Avian infectious bronchitis
2.3.5. Avian mycoplasmosis (*M. gallisepticum, M. synoviae*)
2.3.9. Fowl cholera
2.3.10. Fowl pox
2.3.12. Infectious bursal disease (Gumboro disease)
2.4.5. Bovine genital campylobacteriosis
2.4.8. Bovine viral diarrhoea
2.4.9. Contagious bovine pleuropneumonia
2.4.15. Malignant catarrhal fever
2.4.16. Theileriosis
2.4.18. Trypanosomosis (Tsetse-transmitted)
2.5.3. Dourine
2.5.5. Equine encephalomyelitis (Eastern & Western)
2.5.6. Equine infectious anaemia
2.5.8. Equine piroplasmosis
2.5.9. Equine rhinopneumonitis
2.5.10. Equine viral arteritis
2.5.11. Glanders
2.5.14. Venezuelan equine encephalomyelitis
2.6.1. Myxomatosis
2.7.5. Contagious agalactia
2.7.10. Ovine pulmonary adenomatosis (adenocarcinoma)
2.7.11. Peste des petits ruminants (vaccine section)
2.8.3. Classical swine fever (hog cholera)
2.8.9. Swine vesicular disease
2.9.1. Bunyaviral diseases of animals (excluding Rift Valley fever)
2.9.2. Camelpox
2.9.4. Cryptosporidiosis
2.9.5. Cysticercosis
2.9.7. Listeria monocytogenes
2.9.8. Mange
2.9.11. Verocytotoxogenic *Escherichia coli*

5.5. Rinderpest – discussion on updated *Terrestrial Manual* chapter

For this agenda item, the Commission was joined by Dr Bill Taylor, author of the *Terrestrial Manual* chapter on rinderpest.

At the September 2011 meeting, the Commission noted that a number of changes had been made to the *Terrestrial Manual* chapter on rinderpest in the light the declaration of global rinderpest freedom by the two authors of the chapter. The President of the Commission expressed the view that it should be mentioned somewhere, though the *Terrestrial Manual* was not necessarily the right place, that no one should be manipulating the virus or working on rinderpest genetic material. This opinion would be transferred to the Joint FAO/OIE Advisory Committee on Rinderpest, to be established soon. All references to international trade were removed from the chapter, which was subsequently approved by the Commission for circulation as the final text that would be proposed for adoption in May 2012.

6. Resolutions

6.1. Resolutions that will be presented in May 2012 (*Manual*, Register, new OIE Reference Centres)

The Commission noted that in accordance with new OIE policy, starting from May 2012, all OIE Reference Centres would be adopted through a formal Resolution.

The Commission noted that the following resolutions would be proposed for adoption at the General Session in May 2012:

- A resolution proposing the adoption of the 25 draft chapters for the *Terrestrial Manual* (see item 5.3);
- A resolution proposing the addition of one diagnostic kit to the OIE Register.
- A resolution proposing the adoption of new OIE Reference Centres.

7. Conferences, Workshops, Meetings

7.1. Report of the 4th meeting of the Group of High Containment Laboratory Directors (GOHLD)

The Commission noted the report of this meeting.

7.2. OIE Laboratory Network on Diseases of Camelids, Teramo, Italy, 21–22 October 2011

Dr El Harrak updated the Commission on this meeting. The main discussion point among the network was the problems encountered validating diagnostic tests in camels. In conclusion, the participants agreed on a proposal to carry out a survey based on the collection of 5000 sera (1000 per country involved: Morocco, Mauritania, Tunisia, Sudan, Syria). Such effort would allow a preliminary validation of the available diagnostic tests. The next meeting was planned in November or December 2012.

7.3. OIE Expert Meeting on FMD Vaccine Matching in Ecuador

The Commission noted the report of this expert meeting and in particular the recommendations.

7.4. WAVLD[6], 5–8 June 2013, Berlin, Germany (theme, programme and speakers)

The Commission was informed that the next WAVLD conference would be held in Berlin, Germany from 5 to 8 June 2013. As usual, there would be a 1-day OIE Symposium in the middle of the Conference. The Commission determined that the theme of this Symposium could be either new approaches in molecular diagnostics (including whole genomic sequencing), or diagnostic test validation (which might also address wildlife diagnostics). The OIE Headquarters was invited to contact the organisers to identify what would be the best option with regards to their programme.

A detailed programme and speakers for the 1-day OIE Symposium would be determined at the next Commission meeting.

8. Liaison with other Commissions

8.1. Scientific Commission for Animal Diseases (Scientific Commission)

The Commission recommended that the Scientific Commission provide an opinion on the principle of using the DIVA strategy for bovine tuberculosis (see item 4.2)*:*

8.2. Terrestrial Animal Health Standards Commission (Code Commission)

The Commission noted that *Terrestrial Code* Chapter 14.5 on *Chlamydophila abortus* infection (Enzootic abortion of ewes, ovine chlamydiosis) required testing of semen (Article 14.5.4), and that the *Terrestrial Manual* did not give a method for this. Upon consulting the OIE Reference Laboratory experts, the Commission was informed that there was no validated protocol for testing of semen, but that as the disease was not sexually transmitted, there was no scientific justification for requiring such a test. This information was transmitted to the Code Commission for consideration.

6 WAVLD: World Association of Veterinary Laboratory Diagnosticians

9. Matters of Interest for Information

9.1. Expert Surveillance Panel (ESP) on Equine Influenza Vaccine Composition – Conclusions and Recommendations (27 February 2012)

Dr Ann Cullinane, Chair of the Expert Surveillance Panel (ESP), sent to the OIE Headquarters a summary Report of the Meeting of ESP for equine influenza and the International Federation for Animal Health (IFAH), which had been held 9 December 2011. The purpose of the meeting was to discuss the basis for the recommendations made by the ESP, the methods employed to assess vaccine efficacy and ways to expedite the updating of the virus strains in the vaccines.

The IFAH had written to the OIE to raise its concern at the rate at which the ESP was updating its recommendations for the strain composition of equine influenza vaccines. The ESP stated that they had only recommended the addition of two strains during the past 8 years and the omission of one strain. The industry representatives explained that from a regulatory perspective the omission of a strain had the same impact as the addition or replacement of a strain. There was a discussion on the legislative framework and the difficulties in adding or removing a strain from a vaccine. The ESP was informed that it takes at least 2 years to develop and to obtain a marketing authorisation for a vaccine with updated influenza strain composition. In response the ESP expressed its willingness to work with industry and the regulatory authorities when the legislation is being revised, in order to remove unnecessary hurdles to the update of vaccines.

It was accepted by industry that many of the vaccines had not been updated in line with the 2004 recommendations and that their most recent strains were from the early 1990s. It was agreed that vaccines should be updated in a more timely manner and that the ESP and industry would continue to communicate on how best to facilitate the process.

The next meeting of the ESP would be at the end of February 2012. The Commission stressed the importance of the ESP report and the need for its widespread distribution. It would be published in the OIE *Bulletin*. Although it arrived too late to be appended to this report, the main conclusions of the ESP meeting are:

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.

9.2. Visit from the International Federation of Biosafety Associations (IFBA)

Dr Maureen Ellis, Co-Chair IFBA, joined the Commission for this particular agenda item and briefed the Commission on the work of the IFBA and on possible areas of collaboration with the OIE.

9.3. Update on OFFLU

Dr Hamilton informed the Commission that OFFLU – the joint OIE-FAO network of expertise on animal influenza – was a success story, boasting significant concrete outputs and strengthened links between animal influenza laboratories and with the public health sector.

In 2011, OFFLU provided support to the World Health Organization (WHO) vaccine strain selection process by presenting antigenic, genetic and epidemiological data at the two WHO annual meetings and by participating in a meeting aimed at improving the overall WHO vaccine strain selection process. OFFLU also collaborated with WHO over proficiency testing, the WHO PCR working group, H5N1 evolution working group, and influenza naming task force.

OFFLU had launched a swine influenza group that serves as a platform for sharing global swine influenza data and for coordinating and harmonising approaches to swine influenza surveillance worldwide. The first meeting was held in April 2011 and the second meeting was planned for March 2012.

Dr David Swayne had completed his secondment to OFFLU to review global avian influenza control measures, focussing on vaccination. Outputs were being published in several peer-reviewed journals including the OIE *Scientific and Technical Review*.

OFFLU would hold its annual technical meeting in April 2012 in conjunction with the 8th International Symposium on Avian Influenza.

9.4. Trypanosidal drugs

Dr Munstermann informed the Commission that the OIE would publish monographs on the main trypanosidal drugs (in the OIE *Scientific and Technical Review*) as the diseases had a bigger economic impact in Africa than any other disease group, and the monographs were so far not available elsewhere.

9.5. Joint Advisory Committee on Rinderpest

Dr Hamilton updated the Commission on rinderpest post-eradication activities. As a first step to implementing the OIE and FAO Resolutions on post-rinderpest activities, FAO and OIE should appoint an independent Joint Advisory Committee. FAO and OIE were close to agreement on the membership of this committee. It was important to maintain the momentum that had been achieved by the declaration of global rinderpest freedom to facilitate the destruction and sequestration of remaining rinderpest virus stocks.

The Commission recommended that the designation of institutes as additional OIE Reference Laboratories for rinderpest, accompanied by a recommendation to OIE Member Countries that rinderpest virus should only be stored in these facilities, would be a means of ensuring that remaining stock of the virus were sequestered safely. The OIE should develop a system for approving such Reference Laboratories in collaboration with the yet to be appointed Joint Advisory Committee.

10. Any Other Business

10.1. Work plan and activities (as of February 2012)

The updated work plan was agreed and can be found at Appendix VIII.

10.2. Need for an official OIE statement on the use of Thiomersal in animal vaccines

Those OIE Collaborating Centres dealing with vaccines had been asked if they had and could provide information on whether thiomersal was used in animal vaccines and if there were any toxicity data. The responses indicated that small quantities were indeed being used in animal vaccines but that no adverse effects had been observed. Thiomersal use might be a cause for concern for human health but it was not for animal health.

10.3. Question on emergency subunit veterinary vaccine

The Commission acknowledged that emergency subunit veterinary vaccines were composed of semi-pure or purified proteins that were produced *in vitro* using recombinant DNA technology. According to VICH[7] regulations (VICH GL40: specifications: test procedures and acceptance criteria for new biotechnological/biological veterinary medicinal products [section 2.1.4]) "impurities should be minimized by the use of appropriate well-controlled manufacturing processes." A question had been received from a pharmacist regarding regulations covering semi-pure recombinant protein vaccines for use in DIVA strategies where host cell protein was also included. The Commission agreed with the principle of using cellular proteins in vaccines to be used in DIVA strategies, but believed that the regulatory question should be forwarded to VICH.

[7] VICH: The International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products

10.4. OIE in the certification of vaccine producers in developing countries

The OIE Collaborating Centre for Veterinary Medicinal Products in Fougères, France, acknowledged that there was lack of a mechanism to assess the compliance of manufacturing processes and quality control of vaccines produced in developing countries/transition countries with the OIE Standards. The Centre had proposed that the Pharmaceutical Inspection Co-operation Scheme (PIC/S) be adapted to the needs of veterinary vaccine manufacture. The Commission approved this proposal and encouraged the Collaborating Centre and the OIE Headquarters to take it forward.

10.5. Dates of the next Biological Standards Commission meeting

The Commission noted the dates for its next meeting: 10–14 September 2012.

11. Adoption of the Report

The report was adopted by the Commission.

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.../Appendices

Appendix I

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 8–10 February 2012

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Agenda

1. Adoption of Agenda

2. OIE Reference Centres

2.1. Applications for the status of OIE Reference Centre
2.2. Changes of experts in the List of Reference Laboratories
2.3. Annual reports of Reference Centre activities for 2011
2.4. Review of new and pending applications for laboratory twinning

3. *Ad hoc* Groups

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

3.1 Report of the Meeting of the *ad hoc* Group on Biosafety and Biosecurity in Veterinary Laboratories, 19–21 September 2011
3.2. Report of the Meeting of the *ad hoc* Group on Rift Valley Fever, 6–8 December 2011
3.3. Report of the Meeting of the *ad hoc* Group on Vaccine Quality related to Rabies, 10–12 January 2012
3.4. Report of the Meeting of the *ad hoc* Group on the Scientific Partnerships among OIE Reference Centres: Networking, 17–19 January 2012

Planned *ad hoc* Groups: approve/draft ToRs and designate Commission representatives

3.5. *Ad hoc* Group on Vaccine Quality related to Classical Swine Fever (to be held after February 2012)
3.6. Second meeting of the *Ad hoc* Group on Biosafety and Biosecurity in Veterinary Laboratories, 13–15 February 2012
3.7. Second meeting of the *ad hoc* Group on Validation of Diagnostic Tests for Wildlife
3.8. Fourth meeting of the OIE *ad hoc* Group on Validation of Diagnostic Assays

Proposed *ad hoc* Groups: scheduling and drafting ToRs

3.9. Brainstorming on new approaches to diagnosis in animal health

4. International Standardisation/Harmonisation:

- **Diagnostic tests**

4.1. OIE Register of diagnostic tests: review of applications
4.2. Request for validation of bovine tuberculosis DIVA test
4.3. Prescribed and Alternative Tests – update on application from Canada
4.4. Prescribed and Alternative Tests – proposal to no longer list the mallein test as a prescribed test for glanders
4.5. Robust novel assay for the rapid PCR-based molecular pathotyping of H5 and H7 avian influenza viruses

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

5.1. Follow-up from brainstorming meeting for modernising the *Terrestrial Manual*
5.2. Review of outcome of meeting of the Meeting of the Bureau of the OIE Biological Standards Commission and Selected Experts to update the *Terrestrial Manual*
5.3. Review of chapters proposed for adoption in May 2012 before final versions being sent to Member Countries
5.4. Selection of chapters for proposal in May 2013
5.5. Rinderpest – discussion on updated *Terrestrial Manual* chapter

6. Resolutions

6.1. Resolutions that will be presented in May 2012

7. Conferences, Workshops, Meetings

7.1. Report of the 4th meeting of the Group of High Containment Laboratory Directors (GOHLD)
7.2. OIE laboratory network on diseases of camelids, Teramo, Italy, 21–22 October 2011
7.3. OIE Expert Meeting on FMD Vaccine Matching in Ecuador
7.4. WAVLD, 5–8 June 2013, Berlin, Germany (theme, programme and speakers)

8. Liaison with other Commissions

8.1. Scientific Commission for Animal Diseases
8.2. Terrestrial Animal Health Standards Commission

9. Matters of Interest for Information

9.1. Expert Surveillance Panel on Equine Influenza Vaccine Composition – Conclusions and Recommendations (27 February 2012)
9.2. Visit from the International Federation of Biosafety Associations (IFBA)
9.3. Update on OFFLU
9.4. Trypanosidal drugs
9.5. Joint Advisory Committee on Rinderpest

10. Any Other Business

10.1. Workplan [action]
10.2. Need for an official OIE statement on the use of Thiomersal in animal vaccines
10.3. Question on emergency subunit veterinary vaccine
10.4. OIE in the certification of vaccine producers in developing countries
10.5. Dates of the next Biological Standards Commission meeting: 10–14 September 2011

11. Adoption of Report

Appendix II

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION
Paris, 8–10 February 2012

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Appendix III

Original: English
September 2011

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON BIOSAFETY AND BIOSECURITY IN VETERINARY LABORATORIES

Paris, 19–21 September 2011

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1. Opening and purpose of the meeting

The OIE *ad hoc* Group on Biosafety and Biosecurity in Veterinary Laboratories met from 19 to 21 September 2011 at the OIE Headquarters in Paris, France. Dr Kazuaki Miyagishima, Deputy Director General of the OIE and Head of the Scientific Department, welcomed the participants on behalf of the OIE Director General, Dr Bernard Vallat, and provided information on the OIE's strategic approach to bio-threat reduction, which included biosafety and biosecurity in veterinary laboratories.

The overall objective of the Group was to review and update Chapter 1.1.2. of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*), on biosafety and biosecurity in the veterinary microbiology laboratory and animal facilities, and to identify possible measures to improve the current situation regarding the shipment of infectious substances, including to review and update, if necessary Chapter 1.1.1. of the *Terrestrial Manual* on the collection and shipment of diagnostic specimens.

2. Designation of chairperson and rapporteur

The meeting was chaired by Dr Peter Daniels and Prof. Sharon Hietala acted as rapporteur.

3. Adoption of the Agenda and Terms of Reference

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

4. Review and update of Chapter 1.1.2. Biosafety and biosecurity in veterinary laboratories of the *Terrestrial Manual*

The Group reviewed Chapter 1.1.2. of the *Terrestrial Manual* in the light of existing standards/guidelines in this area. It recognised that important developments in biosafety and biosecurity had occurred since the chapter was written, and agreed that an update should reflect the current developments in biorisk management. The Group noted that, to facilitate harmonisation and communication between public health and animal health laboratories and authorities, the terminology and approach used in Chapter 1.1.2 should be consistent and aligned with the CEN[1]Workshop Agreement CWA 15793 on "Laboratory biorisk management standard" developed recently and endorsed by the World Health Organization (WHO).

The Group was informed by the representatives of the Biological Standards Commission that the chapter should be considered as an international standard. As such it should be comprehensive, practical and provide sufficient guidance to OIE Member Countries. The Group therefore suggested a new title for the Chapter: "Standard for managing biorisk in veterinary laboratories and animal facilities", with the understanding that biorisk management encompassed biosafety and biosecurity. It recommended defining the basic terms that

1 CEN: European Committee for Standardization.

would be used in this chapter either in a separate appendix or by inclusion in the current glossary of the *Terrestrial Manual*. The basic terms that would need to be defined were: biosafety, biosecurity, biocontainment, biorisk and biorisk management.

Considering its content, the Group agreed that Chapter 1.1.2 should emphasise that the use of engineering controls and technologies does not substitute for competent personnel using good laboratory practices to effectively contain pathogens. The proposed biorisk management approach would help define appropriate mitigation measures to be described in the revised chapter.

The Group discussed the confusion arising from the current chapter's terminology assigning pathogens to risk groups without consideration of the national endemic disease situation. The Group therefore decided that the approach proposed in the updated chapter should help identify mitigation measures based on assessed risk taking account of endemic animal disease status, animal industry priorities and, where relevant, public health considerations.

The Group agreed that Chapter 1.1.2. would introduce risk management as a means to assess, implement, monitor and continuously improve laboratory biosafety and biosecurity measures.

The Group developed a detailed structure of the proposed contents of the revised chapter. However, due to time constraints and the need to interact with other experts, the Group could not finalise it. As the proposed new chapter would constitute a departure from the existing chapter, a process of iteration is anticipated. The Group has agreed to develop concepts and text under the following section headings:

Introduction
A. Biorisk Management System
B. Assessment of Biorisk from Pathogens
C. Risk Mitigation Strategies
D. Conformity and Compliance
E. Continuous Improvement and Maintenance

In developing the content under these sections, the Group proposed to share the work among its members and to complete a redrafting of the chapter through email exchanges by the end of December 2011. It also suggested that a second meeting of the Group be held at the OIE Headquarters in January 2012 to further refine this draft and to finalise a version of the chapter for the consideration of the Biological Standards Commission.

5. Consideration of existing barriers to rapid and secure transfer of infectious substances and identification of possible measures to improve the current situation

The Group reviewed Chapter 1.1.1. of the *Terrestrial Manual* on the collection and shipment of diagnostic specimens, and considered that an update would be useful. It noted that the current version addresses two separate activities: those aspects of veterinary science covering the sampling of animals for various purposes and the appropriate biological specimens resulting from this process, and also the standards for packing these biological specimens for transport from the field location to the laboratory facility and then between laboratories. The Group therefore supported the decision of the Biological Standards Commission to divide the chapter into two separate chapters: one on the collection and storage of diagnostic specimens, and the other on transport of infectious substances.

Regarding the future chapter on the collection and storage of diagnostic specimens, the Group proposed a structure based on the following headings:

A. Epidemiological approaches to sampling
B. Information to be sent with specimens
C. Collection of specimens (including biosafety in field collection)
D. Storage and archiving of specimens and materials derived from these (isolates of pathogens, genetic materials, etc.)

The chapter would include epidemiological criteria for sampling, as well as general information on specimen collection pertaining to diagnostic procedures on both the live animal and at post-mortem examination. Specimens appropriate for testing by the current laboratory technologies will be addressed.

For parts A and B, the Group suggested that the OIE identifies epidemiologists to develop these sections giving consideration more to the approach to sampling than to specific sample and sample size calculations. The Group would prepare Terms of Reference to brief these epidemiologists. It is envisaged that these sections together should be no more than 2 to 3 pages long. Parts C and D would initially be drafted by designated members of the Group and further developed by email correspondence among all Group members with the intention of having agreed text by the end of December 2011.

Regarding the future chapter on transport of infectious substances, the WHO representative informed the Group that guidance on regulations for the transport of infectious substances had been developed by WHO and was updated every two years. The Group would evaluate the inclusion of this guidance in the chapter with or without modifications to address conditions that apply from the field to the laboratory and also between laboratories. A proposal would be developed by members of the Group and discussed at its next meeting.

The Group suggested that the OIE and WHO engage in dialogue with the World Customs Organization to address issues related to the international transfer of infectious substances.

The Group also mentioned the importance of educating veterinary students and animal technicians on the preparation and transport of infectious substances. It suggested the OIE encourage its Member Countries to include this topic in their veterinary education curricula.

6. Other matters

The Group suggested that the OIE continue to work in close collaboration with WHO regarding training programmes and general harmonisation of guidance on laboratory biorisk management. It also supported the OIE Twinning Programme as a tool to assist in the implementation and competency building of new biosafety, biosecurity and associated biorisk management programmes in Member Countries.

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…/Appendices

Appendix I

OIE *AD HOC* GROUP ON BIOSAFETY AND BIOSECURITY IN VETERINARY LABORATORIES

Paris, 19–21 September 2011

Agenda

1. Opening and purpose of the meeting
2. Adoption of the agenda and Terms of Reference
3. Appointment of chairman and rapporteur
4. Review and update of Chapter 1.1.2. on Biosafety and biosecurity in veterinary laboratories of the *Terrestrial Manual*
5. Consideration of existing barriers to rapid and secure transfer of infectious substances and identification of possible measures to improve the current situation
6. Other matters
7. Finalisation and adoption of the draft report

Appendix II

OIE *AD HOC* GROUP ON BIOSAFETY AND BIOSECURITY IN VETERINARY LABORATORIES

Paris, 19 – 21 September 2011

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Appendix III

OIE *AD HOC* GROUP ON BIOSAFETY AND BIOSECURITY IN VETERINARY LABORATORIES

Paris, 19–21 September 2011

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Terms of Reference

1. OIE Standard on Biosafety and Biosecurity in veterinary laboratories

- Consider the existing standards/guidelines (including the terminology), within and outside the OIE (in particular Chapter 1.1.2., Biosafety and biosecurity in the veterinary microbiology laboratory and animal facilities), dealing with biosafety and biosecurity and consider the need to update Chapter 1.1.2. Biosafety and biosecurity in the veterinary microbiology laboratory, of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*) taking into account these standards/guidelines;

- Consider potential collaboration with WHO including the possibility of developing a joint basis for OIE/WHO guidelines for laboratory biosafety and biosecurity.

2. OIE Standard for the shipment of infectious substances to veterinary laboratories

- Consider existing barriers to rapid and secure transfer of infectious substances and identify possible measures to improve the current situation, including:

    - If necessary, review and update Chapter 1.1.1. Collection and shipment of diagnostic specimens, of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*;

    - Consider developing a standard shipment form for veterinary diagnostic samples to facilitate their shipment to veterinary diagnostic laboratories (follow-up to the Recommendation No. 11 of the Second Global Conference of OIE Reference Laboratories and Collaborating Centres and building on chapter 1.1.1. item C. of the *Terrestrial Manual*);

- Identify common actions for WHO and OIE directed to specific relevant organisations (UNCTAD, IATA, etc.) for facilitating shipment of infectious substances to veterinary laboratories.

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Appendix IV

Original: English
January 2012

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON SCIENTIFIC PARTNERSHIPS AMONG OIE REFERENCE LABORATORIES AND COLLABORATING CENTRES: NETWORKING

Paris, 17–19 January 2012

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1. Opening, designation of the Chair and Rapporteur, and adoption of the Agenda

The third meeting of the OIE *ad hoc* Group on Scientific Partnerships among OIE Reference Laboratories and Collaborating Centres was held from 17 to 19 January 2012, at the OIE Headquarters in Paris. The participants were welcomed on behalf of the Director General by Dr Kazuaki Miyagishima, Deputy Director General of the OIE and Head of the OIE Scientific and Technical Department.

Dr Miyagishima updated the Group on the outcomes of the previous two meetings: the amendments to the Terms of Reference (ToR) for OIE Reference Laboratories and Collaborating Centres proposed by the Group had been reviewed by the OIE Council and many of the proposals had been incorporated into the revised OIE *Basic Texts* that had been adopted by the World Assembly in May 2011.

The new ToR included a clause on networking with other OIE Reference Laboratories or non-OIE laboratories. The purpose of this meeting was to provide guidance for OIE Reference Laboratory good network governance.

The meeting was chaired by Dr Francisco Javier Reviriego Gordejo; Dr Craig Carter was appointed Rapporteur.

The agenda for the meeting, adopted without amendment, and list of members of the *ad hoc* Group and other participants are given in Appendices I and II.

2. Terms of reference for the *ad hoc* Group meeting

The Terms of Reference had already been adopted at the first meeting of the *ad hoc* Group; they are given at Appendix III. The first two points having been addressed by the previous meetings of the *ad hoc* Group, the present meeting focused on the last point in the ToR.

3. Discussion on networking

The Group had an in-depth discussion on the topic of networks and networking. The Group noted that networks may also be part of or involve other international or regional organisations, but focused its discussions on OIE networks.

Key discussion and comments

In its discussions around the topic, the Group noted the following:

- The problem exists where OIE Reference Laboratories are not in agreement on testing results, causing considerable problems for movement of animals in international markets.

- Some OIE Reference Laboratories have assembled informal networks that do not communicate with the OIE.

- The *ad hoc* Group needs to provide a solution, without being overly prescriptive, that allows for adequate governance of laboratory networks that work for the OIE. This first step towards forming an OIE Reference Centre network might be difficult in some cases and may require action by the OIE Headquarters.
- The bluetongue network of testing laboratories appears to be a working model for other networks to follow (http://oiebtnet.izs.it/btlabnet/). A coordinator has been appointed and proficiency testing is being accomplished across the members of the network.
- It is not the intent of the OIE to control Reference Laboratories or networks, only to assure that they are functioning in the best way to fulfil their ToR.
- Some Reference Laboratories have lost their status as OIE Reference Laboratories over the last few years due primarily to lack of activity in accordance with their ToR.
- New ToR and Internal Rules were adopted for OIE Reference Centres (Reference Laboratories and Collaborating Centres) in May 2011. These provide a strong basis for fulfilling the mandate of the OIE. The importance of quality assurance and quality control in the successful operation of Reference Laboratories and their networks is self-evident. In addition, transparency of operation and sharing of diagnostic materials and information is essential to build trust across the network and with the clients (end users) of the network. OIE Reference Laboratories need to understand the importance of investing in these tools to be sure that all these things are accomplished and embraced.
- A template for annual reports of OIE Reference Centre activities in 2011 had been amended to take account of the new ToR. The reports should provide an indication of the extent of networking among OIE Reference Centres.
- The OIE twinning programme contributes to readdressing the imbalance in the regional distribution of OIE Reference Laboratories. Once a twinning project has been completed, the former candidate laboratory should take on the role of a regional centre assisting other laboratories to strengthen their capacities. Such twinning 'graduate' laboratories need to have a means, such as networking, to communicate with other laboratories in the region.
- Epidemiology programmes should be integrated into laboratory networks to ensure smooth and effective surveillance activities, because needed surveillance does not occur without good laboratories.
- The secretariat of a laboratory network should write an annual report that is not duplicative of the individual member laboratory reports but captures the essence of the network's output and added value as a whole while also listing obstacles to optimal operation and suggestions to improve on future operations.
- If there arises an important problem within a network (e.g. disagreement about methods and consistency of results), the OIE must be notified immediately so that action can be taken toward resolution.

Approach chosen for the guidance document

The Group focused on Reference Laboratories as it was considered that guidance was primarily needed for laboratories. The Group elected to merge the existing document on *OIE criteria for inclusion of Network website links on the Website of the OIE* within the draft guidance document produced. The Group understood that the guidance document would be made available on the OIE website. The scope of the guidance document would be easily expandable to Collaborating Centres.

The Guidance document can be found at Appendix IV.

4. Adoption of report

The Group adopted the report.

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…/Appendices

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON SCIENTIFIC PARTNERSHIPS AMONG OIE REFERENCE LABORATORIES AND COLLABORATING CENTRES

Paris, 17–19 January 2012

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Agenda

1. Opening, Designation of Chair and Rapporteur, Adoption of Agenda
2. Terms of Reference of the *ad hoc* Group Meeting
3. Discussion on networking
4. Adoption of report

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Appendix II

MEETING OF THE OIE *AD HOC* GROUP ON SCIENTIFIC PARTNERSHIPS AMONG OIE REFERENCE LABORATORIES AND COLLABORATING CENTRES

Paris, 17–19 January 2012

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Appendix III

MEETING OF THE OIE *AD HOC* GROUP ON SCIENTIFIC PARTNERSHIPS AMONG OIE REFERENCE LABORATORIES AND COLLABORATING CENTRES

Paris, 17–19 January 2012

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TERMS OF REFERENCE

– To consider and review, if necessary, the mandates, rules and procedures for OIE Reference Laboratories and Collaborating Centres;

– To assess the need for and approaches to scientific partnerships of laboratories (objectives, expected outcomes, incentives);

– To provide guidance for the management of such scientific partnerships (leadership, reporting rules and procedures, membership, good practices).

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Appendix IV

GUIDANCE FOR THE MANAGEMENT OF OIE REFERENCE CENTRE NETWORKS

Introduction

The global network of OIE Reference Centres is the central core of the OIE's scientific excellence. The First International Conference of OIE Reference Laboratories and Collaborating Centres (held in Florianopolis, Brazil, in 2006) recommended that a network of OIE Reference Laboratories and Collaborating Centres be developed with the objective of harmonising and exchanging data, information and reference material to improve disease surveillance and control worldwide.

The Second Global Conference of OIE Reference Laboratories and Collaborating Centres (held in Paris in June 2010) encouraged the networks of OIE Reference Laboratories and Collaborating Centres to continue working together to strengthen multilateral cooperation, in particular with the aim of producing and increasing availability of validated biological reference materials. In order to strengthen this collaboration, the OIE Reference Laboratories and Collaborating Centres should continue to exchange knowledge, reference materials and expertise to the benefit of OIE Member Countries.

The Terms of Reference (ToR) adopted in May 2011 explicitly require OIE Reference Centres to establish and maintain a network among all the OIE Reference Centres designated for the same pathogen or specialty. More details on the ToR of OIE Reference Centres are available at the following links:

http://www.oie.int/en/our-scientific-expertise/reference-laboratories/introduction/

and

http://www.oie.int/en/our-scientific-expertise/collaborating-centres/introduction/

The OIE has identified the need for further guidance on the coordination of the OIE Reference Centre networks. The objective is to assure unified expert opinions and advice to OIE Member Countries through the enhanced exchange of information.

The network of OIE Reference Laboratories shall assure congruent results across laboratories through the adherence to OIE Standards, the sharing of reference materials within the network and the participation in appropriate proficiency testing. Networking will improve the credibility and increase the visibility of OIE Reference Laboratories worldwide, and will attract the participation of other national reference laboratories from OIE Member Countries.

On a case-by-case basis, the OIE Headquarters could invite the existing Reference Laboratories to meet (physically or by telephone conference) to help to create a network, to appoint the secretariat, and to follow this guidance.

Recommendations:

- Networking among OIE Reference Laboratories is part of their ToR. When two or more OIE Reference Laboratories are designated for the same pathogen, a network must be established. Participation in the network is compulsory for OIE Reference Laboratories. Only OIE Reference Laboratories are accountable to the OIE. However other reference laboratories might participate in some of the activities of the network, as appropriate.

- The network should have a secretariat (officially notified to the OIE) in one of the participating OIE Reference Laboratories to serve as a liaison with the OIE Headquarters. Furthermore, the secretariat is responsible for coordination, leadership and accountability of the network. The secretariat may rotate among participating laboratories (e.g. every 3 years).

- Each network secretariat should provide the OIE Director General with an annual report of its activities[1]: achievements, obstacles, future initiatives (individual laboratories can make reference to the network report in its annual OIE Reference Laboratory report).

- When meetings are organised by the network, participation of OIE staff as observers should be allowed, and the secretariat should produce a meeting report that should be shared with the OIE Headquarters[2].

- If a discrepancy or disagreement arises that cannot be resolved within the network, the secretariat should inform the OIE Headquarters without delay. The OIE Headquarters will inform the Biological Standards Commission thereof accordingly.

- Conditions for inclusion of a network website link on the Website of the OIE:

  - The network may establish a website to disseminate information on its activities. The network should formally request the Director General of the OIE that a link to its website be added to the OIE website.
  - The website of the network must comply with OIE rules for graphic layout and other applicable OIE policies.
  - Any major changes to the website of the network should be notified to the OIE in advance.
  - The OIE Headquarters reserves the right to recommend any changes to the content of the web site of the network, as deemed appropriate, and to remove the link of the web site of the network at any time while providing the reasons to the secretariat of the network.

OIE contact point for networks:

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[1] These reports should be made available to the Biological Standards Commission
[2] These reports should be made available to the Biological Standards Commission

Meeting of the Bureau of the OIE Biological Standards Commission and Selected Experts to update the *Terrestrial Manual* ('Enlarged Bureau Group' [EBG])

OIE Headquarters, Paris, 7–8 February 2012

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C. REQUIREMENTS FOR VACCINES (AND DIAGNOSTIC BIOLOGICALS, IF ANY)

1. Background

- Brief description of availability, rationale and intended use of the vaccines available (e.g. for animal production, for control and eradication, etc. + the targeted species)
- *Elements of a target product profile*
- Compliance with OIE *Terrestrial Manual* Chapter 1.1.8. Principles of Veterinary Vaccine Production + biosafety/biocontainment considerations

2. Outline of production and minimum requirements for vaccines

a) Characteristics of the seed

i) Biological characteristics of the master seed

ii) Quality criteria (sterility, purity, freedom from extraneous agents)

iii) *Validation as vaccine strain* (*for the pathogen agents that have different serotypes: FMD, VS, AHS, etc.*)

iv) Emergency procedure for provisional acceptance of new master seed virus (MSV) in case of epizootic (with pathogens with many serotypes, e.g. bluetongue virus, highly pathogenic avian influenza, foot and mouth disease, etc.)

b) Method of manufacture

i) Procedure

ii) Requirements *for ingredients*

iii) In process controls

iv) Final product batch tests

Sterility
Identity
Safety
Batch potency

c) Requirements for authorisation/registration/licensing

i) Manufacturing process

ii) Safety requirements

Target and non-target animal safety
Reversion-to-virulence for attenuated/live vaccines and environmental considerations
Precautions (hazards)

iii) Efficacy requirements

iv) Vaccines permitting a DIVA strategy (detection of infection in vaccinated animals)

v) Duration of immunity

vi) Stability

3. Third point to allow topics specific to the disease in question to be addressed (oral vaccines, toxoids, specific requirements for biotechnology-based vaccines, etc.)

Enlarged Bureau Group (EBG): BSC Bureau + Consultant Editor + three members of the brainstorming meeting + on a case-by-case basis, invited experts selected

Proposed procedure for Updating the *Terrestrial Manual*

Responsibility for producing the *Terrestrial Manual* rests with the Biological Standards Commission (BSC), which is the decision-making body. Given the size of the task and the need to put in place a transparent procedure for updating the *Terrestrial Manual*, a group, the "enlarged bureau group (EBG)" would be convened for one or more meeting(s), as necessary, usually before the meeting of the BSC. The EBG will prepare the work and propose actions to be taken for selected *Terrestrial Manual* chapters to be endorsed by the Commission.

A. The BSC identifies annually the chapters for update in a given year (at its February meeting).

B. As a general rule, the OIE Reference Laboratory experts are requested to provide a consensus document. There are three possibilities:

1. The experts reach a consensus, the draft is up-to-date and up to standard: the EBG reviews the revised chapter and either proposes to send back the draft to the experts with specific guidance or recommends that the BSC approve it for **circulation to Member Countries** (for comment).

2. The experts do not reach a consensus: the EBG reviews the draft and agrees that a solution can be found through consultation with one or two experts invited to the **following EGB meeting.** The resulting draft is forwarded to the BSC with the recommendation that the BSC approve it for circulation.

3. The experts do not reach a consensus and the EBG agrees that the differences are too important to be resolved during its meeting and merit an ***ad hoc* Group**.

Two specific situations can be accommodated:

1. For the small number of chapters for which there are no OIE Reference Laboratory experts, the BSC recommends suitable experts.

2. For specific diseases with known controversial expert opinions, the Commission could directly recommend to convene an *ad hoc* Group.

The present procedure, which can be followed easily and allows for documentation of the steps taken, will help to enhance transparency of the revision process of the *Terrestrial Manual*:

The list of chapters identified by the BSC for revision is appended to the BSC meeting reports in table format that shows the progress of each chapter under revision: awaiting the update from the experts, being circulated for Member Country comments/ready for adoption or subject to discussion by the EBG, or requiring the organisation of an *ad hoc* Group.

The EBG will also review the comments received from Member Countries and propose any amendments necessary. All propositions are ultimately approved by the BSC.

BSC Work Plan: February to September 2012

Topic/Issue	Responsible(s)	Deadline
Manual of Diagnostic Tests and Vaccines for Terrestrial Animals		
Summarise and analyse the Member Country comments on the validation chapter and appendices so that the BSC can decide how to progress with the *ad hoc* Group	SE	By the General Session (May 2012)
Process for updating and developing chapters for the *Manual* in accordance with point 12 of the ideas/comments of the brainstorming meeting – *Disease chapters* One page to be presented by Prof. Caporale during the General Session and to be put on the OIE Website	SST	Done On going
Updated template for the disease-specific chapters and updated guidelines for authors of these chapters taking into account: - ideas/comments of the brainstorming meeting (points 1, 2, 4, 6, 8, 9, 10, 16, 17, and 18 – *Disease chapters*). - work done by the *ad hoc* Groups on vaccine quality (agreed upon template and appended to the BSC report)	SE and SST	By the General Session (May 2012)
Conversion of the guidelines in the OIE Quality Standard booklet into stand-alone chapters for the introductory part of the *Manual* (Point 5 of the ideas/comments of the brainstorming meeting – *Introductory chapters*).	SST	For the next meeting of the BSC (September 2012)
Update the structure of the *Manual* taking into account the ideas/comments of the brainstorming meeting (point 6 and 19 – *Disease chapters*)	SST	For the paper version of the *Manual* (2012)
Update all the disease-specific chapters of the *Manual* according to the new template	BSC/SST	Continuing implementation with the aim to finalise all these modifications for the publication of the paper version of the *Manual* in 2016

Ad hoc Groups		
Vaccine Quality related Rabies (Second Meeting: section on oral vaccine)	SST: SM Member of the BSC who will attend: VC	Dates: 2–4 May 2012
Vaccine Quality related Classical swine fever (urgent)	SST: SM Member of the BSC who will attend: VC	Dates: 12–14 June 2012
Validation of diagnostic assays (SE must provide his analysis of the Member Country comments)	SST: FD Member of the BSC who will attend: VC	Dates: End April/Early May 2012
Validation of Diagnostic Tests for Wildlife (Second Meeting) (the outcome of the AHG on Validation meeting [above] will feed into this)	SST: FD Member of the BSC who will attend: VC	Dates: after September 2012
Vaccine Quality related Rift Valley fever (Second Meeting)	SST: FD Member of the BSC who will attend: VC	Dates: after GS, maybe August 2012
Brainstorming Group on new approaches to diagnosis in animal health (whole genome sequencing); outcome White Paper + programme for the WAVLD meeting	SST: EEV + FD + SL Member of the BSC who will attend: VC	Dates: week of 8 or 19 October 2012
Meetings		
1-day seminar to be held during WAVLD meeting in Berlin in June 2013. Theme: validation or "(New approaches to diagnosis: applied genomics). Need to decide, programme and speakers	SST & BSC	Validate with organisers/confirm officially by DG letter/ Use ad hoc Group on brainstorming as internal "scientific committee

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