Organisation Mondiale de la Santé Animale
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Organización Mundial de Sanidad Animal

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REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 12–14 September 2012

The OIE Biological Standards Commission (the Commission) met at the OIE Headquarters from 12 to 14 September 2012. On the afternoon of Wednesday 12 September, Dr Bernard Vallat, Director General of the OIE, joined the meeting to welcome and congratulate the members of the Commission on their election or re-election: Prof. Vincenzo Caporale, President, Dr Hualan Chen and Dr Rodolfo Rivero, Vice-Presidents, Dr Beverly Schmitt, Dr Paul Townsend and Dr Peter Daniels, Members of the Commission.

Dr Vallat reiterated the OIE's support to the Commission, the output of which contributes to fulfilling one of the key missions of the organisation: to improve animal health worldwide. He indicated that funds were available should the Commission require scientific support in the form of *ad hoc* Groups to address specific issues within its remit.

With regard to developing a laboratory component of the PVS[1] evaluation tool, Dr Vallat confirmed that an initial meeting had taken place of nominated experts already involved in the PVS programme. It was important that the end result be a tool that is useful, effective and beneficial; the Commission's opinion would be sought once the document was available. Should the Commission deem it important to participate in the PVS Technical Group discussions, one member could be proposed.

It was noted that the pilot PVS Laboratory gap analysis process/mission currently under development was not aiming at assessing the technical qualification/competency of national veterinary laboratories, but rather at assessing optimal options for addressing the priorities and strategies outlined in the PVS Evaluation report.

Dr Vallat reminded the Commission that for the first time at the General Session in May this year, the Assembly had adopted by Resolution those Reference Centres that the Commission had proposed be given official OIE status; this leant more weight to the Commission's decisions. In response to a request for clarification of the Commission's role in evaluation of twinning applications, Dr Vallat explained that the Commission was a consultative body in this field; its advice was one of several elements in the decision-making process that had also to take into consideration the conditions put forward by the donors.

Dr Vallat invited the Commission to provide the OIE with a framework for identifying priority topics for strengthening the global network of OIE Reference Centres.

1. Adoption of Agenda

The proposed agenda was presented and adopted.

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

1 PVS: Performance of Veterinary Services

2. OIE Reference Centres

2.1. Applications for the status of OIE Reference Centre

An application had been received from an African country for an OIE Collaborating Centre for Quality Control of Veterinary Vaccines. The Commission requested more detailed information on the training programme that the Centre would provide to OIE Member Countries, and a full list of its recent publications.

2.2 Changes of experts in the List of Reference Centres

The Commission observed that nominations for replacement experts at OIE Reference Laboratories were most often received from the Head of the Institute housing the laboratory. Some members of the Commission asked if the Delegate, who is responsible for submitting the initial application, should not also be responsible for notifying all changes at the Reference Laboratory, including proposals for changes of experts.

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

African horse sickness

Dr Javier Castillo-Olivares to replace Dr Chris Oura at the Institute of Animal Health, Pirbright, UNITED KINGDOM.

African swine fever

Dr Linda Dixon to replace Dr Chris Oura at the Institute of Animal Health, Pirbright, UNITED KINGDOM.

Bee diseases

Dr Marie-Pierre Chauzat to replace Dr Jean-Paul Faucon at the Laboratoire d'études et de recherches sur les ruminants et les abeilles, Anses Sophia Antipolis, FRANCE.

Bluetongue

Dr Peter Mertens to replace Dr Chris Oura at the Institute of Animal Health, Pirbright, UNITED KINGDOM.

Equine infectious anaemia

Dr Makoto Yamakawa to replace Dr Kenji Murakami at the National Institute of Animal Health, Ibaraki, JAPAN.

Equine viral arteritis

Prof. Dr Falko Steinbach to replace Dr Trevor Drew at the Animal Health and Veterinary Laboratories Agency, Weybridge, UNITED KINGDOM.

Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

Dr Akbar Dastjerdi to replace Dr Malcolm Banks at the Animal Health and Veterinary Laboratories Agency, Weybridge, UNITED KINGDOM.

Surra (Trypanosoma evansi)

Dr Philippe Büscher to replace Dr Filip Claes at the Institute of Tropical Medicine Antwerp, BELGIUM.

2.3. Review of new and pending applications for laboratory twinning

Dr Gounalan Pavade, Scientific and Technical Department of the OIE, provided an update on the OIE Laboratory Twinning programme. Eight twinning proposals were presented to the Commission for technical input and the Commission supported the technical content of three of them: United States of America–India for rabies; Spain–Kenya for African swine fever and Australia–Thailand for emerging infectious diseases. For four of the five remaining projects, the Commission recommended further review of the scope and purpose; the fifth project was not considered a priority on the basis that the disease was no longer listed by the OIE. Finally the Commission supported an extension of the Australia–Malaysia project for avian influenza and Newcastle disease.

2.4. Presentation of the proposed new annual report template

At its last meeting in February 2012, the Commission had recommended that the OIE Scientific and Technical Department continue to work on developing an improved annual report template and expanding the guidance notes for experts. Dr Raffaella Nisi, Scientific and Technical Department of the OIE, joined the meeting to present this work.

The new template would allow the automatic collection and compilation of key quantitative information on OIE Reference Centres. It should also facilitate networking between OIE Reference Laboratories through the easy online access to qualitative data, as well as allowing random surveys of laboratory performance and the fulfilment of the Terms of Reference of the growing number of OIE Reference Laboratories. The new template was designed for future integration in a web-based tool, linked to software that would allow data to be analysed for trends and be converted into maps and graphs. The reformatted template was structured around each Term of Reference for OIE Reference Laboratories. Questions were close-ended (yes/no answers) to generate more accurate and comparable information from the laboratories. Tables to allow for the collection of detailed information related to the activities carried out by the laboratories would also be included.

The Commission enthusiastically welcomed the new annual report template and proposed amendments to further improve it. A non-interactive mock-up of the template was available on the web site at: http://www.oie.int/eng/sst/quest.htm. A fully working version of the template should be available for the 2013 reports. For the 2012 reports, this template would be used but as an Office document rather than a web-based tool.

3. *Ad hoc* Groups

■ **Past *ad hoc* Group meetings**

3.1. Report of the Meeting of the *ad hoc* Group on Vaccine Quality related to Rabies, 2–4 May 2012

Dr Susanne Münstermann, Scientific and Technical Department of the OIE, presented the report of the meeting of this *ad hoc* Group. The Commission noted that to test the efficacy of the rabies vaccines, the proposed chapter required that animals (dogs) be inoculated with the virus and subsequently killed. Given that immunity could be determined by antibody titration, the Commission requested that the *ad hoc* Group provide the scientific justification for animal inoculation. In the meantime, adoption of the report and draft chapter was postponed.

3.2. Report of the Third Meeting of the *ad hoc* Group on Biosafety and Biosecurity in Veterinary Laboratories, 17–19 July 2012

The Commission adopted the report, which can be found at Annex 3 of this report. The three *Terrestrial Manual* chapters proposed by the Group would be sent separately for Member Country comment.

3.3. Report of the Fourth Meeting of the *ad hoc* Group on Validation of Diagnostic Assays, 21–23 August 2012

The Commission adopted the report, which can be found at Annex 4 of this report. The *Terrestrial Manual* chapter proposed by the Group would be sent separately for Member Country comment. The chapter's seven appendices were being reformatted as guidelines; a final decision on where these guidelines would be published would be taken by the OIE Secretariat.

3.4. Report of the Meeting of the *ad hoc* Group on Vaccine Quality related to Classical Swine Fever, 4–6 September 2012

Dr Münstermann presented the preliminary report of the meeting of the *ad hoc* Group. She explained that the proposed updated vaccine section of the *Terrestrial Manual* chapter had not been finalised and discussions were ongoing; this work could continue at a future meeting.

■ **Planned *ad hoc* Groups**

3.5. Second meeting of the *ad hoc* Group on Validation of Diagnostic Tests for Wildlife, 15–17 January 2013

The Commission noted the meeting of the *ad hoc* Group.

3.6. Second meeting of the *ad hoc* Group on Rift Valley Fever, 9–11 October 2012

The Commission noted the meeting of the *ad hoc* Group.

3.7. Brainstorming on New Approaches to Diagnosis: Applied Genomics, 10–12 December 2012

At its February 2012 meeting, the Commission had identified the field of new diagnostic technologies, their potential importance and impact, as a priority. It proposed that the OIE should convene an *ad hoc* Group to draft an OIE White Paper on this topic. Since then, the Commission had identified an expert to write the first draft of the White Paper, and had proposed dates and membership for a brainstorming meeting to further develop and refine the policy document, identify issues for the Delegates arising from this technology. Rather than just a detailed description of the technologies themselves, the aim would be to reflect on their use and the consequence of their use, on how they can be deployed as part of emergency response preparedness schemes, etc.

The Commission had also determined that this issue would be the theme of the 1-day OIE Symposium to be held during the next WAVLD[2] conference in Berlin, Germany from 5 to 8 June 2013 (see item 7.1). The brainstorming meeting would also finalise the programme and list of speakers for the Symposium.

4. International Standardisation/Harmonisation

■ **Diagnostic tests**

4.1. Prescribed and Alternative Tests

The President of the Commission proposed to remove the current list of prescribed and alternative tests in the *Terrestrial Manual*. Instead, a statement would be added to each test described in the *Terrestrial Manual* indicating its designated fitness for purpose. The concept of including in the chapters a table listing the tests in use and the purpose for which they have been validated was proposed by the brainstorming meeting for modernising the *Terrestrial Manual*[3], and those experts contributing chapters to the *Terrestrial Manual* had been asked to provide such a table. In this way, it would be clear to users the purpose for which each test recommended by the OIE was intended.

The Commission noted this proposal, which was worth further study and agreed to analyse the implications of this proposal including in the light of the existing links between the *Terrestrial Manual* and the *Terrestrial Code*. The Code Commission would be informed of this proposal and would be asked to provide its views.

2 WAVLD: World Association of Veterinary Laboratory Diagnosticians

3 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.

4.2. Update on assay for the detection of *Campylobacter fetus*

At the last meeting in February, the Canadian developers of a monoclonal antibody-based antigen capture ELISA[4] 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 had been asked for a final review and decision on whether the test should be included in the *Terrestrial Manual,* and had responded positively. The Commission agreed that the developers should be asked to provide the OIE expert with a step-wise protocol in the *Terrestrial Manual* style, for inclusion in the chapter in the next revision cycle.

4.3. OIE Register of diagnostic kits: 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 two diagnostic kits (BioChek Avian Influenza Antibody test kit and Prionics AG - Check Western), added to the OIE Register in 2008, were 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 manufacturers had been contacted to indicate whether they wished to maintain the same purposes for which their kit had been certified as validated or to add new purposes. The OIE experts for the diseases targeted by the kits had also been contacted and asked their opinion on the need for a new evaluation of the purposes for which the kits had been certified as validated. Based on this information, the Commission decided to propose to the vote of the Assembly in May 2013 to renew the registration of the two kits in the OIE register for the same purposes and for 5 additional years.

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. Presentation of the seventh edition of the *Terrestrial Manual*

The seventh edition of the *Terrestrial Manual* was currently at the printing press and hard copies would be available within 8 to 10 weeks. The Commission was presented with the Table of Contents, which in accordance with the proposals of the brainstorming meeting (see footnote 3 below) now included a re-organised introductory section of general standards, a new section on general guidelines, and each chapter included a note on when it had last been adopted by the Assembly.

5.2. Revised chapters for adoption in May 2013

The Commission reviewed the outcome of the Enlarged Bureau Group (EBG) meeting, namely its recommendations regarding the chapters identified for update and proposal for adoption in 2013, and the list of new chapters and chapters proposed for update in 2014. Fifty-four chapters had been identified for update of which twenty-four had been received; twenty-one chapters were recommended for circulation to Member Countries. The value of the EBG meeting was recognised. The Group's recommendations and the Commission's response to them are presented in table format (see Annex 5, which also includes the agenda and list of participants). The Commission agreed that the recommendations of the EBG would always be presented in table format and appended to the reports of the Commission.

4 ELISA: enzyme-linked immunosorbent assay

One of the chapters approved for circulation was Chapter 1.1.3 *Standard for managing biorisk in the veterinary laboratory and animal facilities*, which had been developed by the *ad hoc* Group. The chapter moved away from prescribing biosecurity levels for each pathogen and instead recommended that a risk assessment be carried out. Should this chapter be adopted in May 2013, all mention of biosecurity levels would be removed from the disease chapters and replaced with a cross reference to the risk assessment methods described in Chapter 1.1.3 as and when these chapters were to be revised.

The Commission recommended that the Consultant Editor carefully consider all mention in the *Terrestrial Manual* of commercial products. It reiterated that such mentions should be avoided where possible, but acknowledged that some methods had been validated using certain commercial products.

5.3. Selection of chapters to be revised for adoption in May 2014

The Commission approved the proposals of the EBG Group (see Annex 5).

5.4. Conversion of the guidelines in the OIE Quality Standard booklet into stand-alone chapters for the introductory part of the *Terrestrial Manual*

The Commission felt that it was timely to discontinue the work aiming at updating the OIE *Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Diseases* contained in the booklet "OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases" in line with the new ISO[5] series, and proposed that the OIE Secretariat consider a new approach.

It was noted that there were currently four OIE guidelines in the booklet: two on validation (of diagnostic assays and of PCR assays), which would be superseded by the new validation chapter and guidelines (see item 3.3); one on International Reference Antibody Standards for Antibody Assays, which would be superseded by one of the new validation guidelines (number 7, see item 3.3); and one on Laboratory Proficiency Testing, which could be replaced with the ISO Standard 17043.

The Commission discussed advantages and disadvantages of publishing these and other guidelines and the appendices to the validation chapter that were being reformatted as guidelines, in Part 3 of the *Terrestrial Manual* or in one or more separate booklets or on the web site. For the validation guidelines, the EBG had proposed publishing them on line in a first step, and elsewhere if deemed necessary or desirable at a later date. These proposals would be submitted to the OIE Secretariat for final decision.

6. Follow-up from General Session

6.1. Comments from Delegates on equine influenza vaccines following Prof. Caporale's presentation at the General Session

At the General Session in May 2012, a Delegate had asked if it would be possible to shorten the vaccine registration process when simply updating and incorporating relevant strains in equine influenza vaccines and proposed that the Biological Standards Commission and VICH[6] look at ways of speeding up the registration process. This request also came from the OIE Conference on Glanders organised in Dubai in 2012. The Commission questioned the scientific justification for imposing the whole registration process on a vaccine that had merely updated its antigen when all that would be needed would be to verify its safety and efficacy. The Commission proposed that the Director General convene an *ad hoc* Group on this issue composed of representatives from industry, from the regulatory agencies and from the Expert Surveillance Panel (ESP) on Equine Influenza Vaccine Composition.

5 ISO: International Organization for Standardization
6 VICH: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products

7. Conferences, Workshops, Meetings

7.1. WAVLD, 5–8 June 2013, Berlin, Germany

At its last meeting, the Commission had determined that the theme of the 1-day OIE Symposium to be held in the middle of the WAVLD Conference would be: New Approaches to Diagnosis: Applied Genomics. A brainstorming meeting had been planned at which the programme and list of speakers would be finalised (see item 3.7).

7.2. Laboratory PVS meeting

Prof. Caporale reiterated his request that the Biological Standards Commission participate in the development of a laboratory component of the PVS evaluation tool (see introduction to this report).

7.3. Update on OFFLU

Dr Pavade, Scientific and Technical Department of the OIE, updated the Commission on OFFLU – the joint OIE-FAO[7] network of expertise on animal influenza. OFFLU contributed 39 H5 sequences and 39 H9 sequences at the February 2012 WHO[8] Human Vaccine composition meeting in Geneva. Eight OIE Reference Centres had participated in the first OFFLU ring trial in 2011 to harmonise avian influenza diagnostic testing. The OIE Reference Laboratory for avian influenza in Germany had developed a universally usable RNA standard for H5 avian influenza virus targeted polymerase chain reaction assays. OFFLU collaborated with WHO and CDC[9] to study the WHO Pandemic Influenza Preparedness (PIP) framework and its implications for animal health laboratories. A publication entitled *Review of Influenza A Virus in Swine Worldwide: a Call for Increased Surveillance and Research* was submitted by the OFFLU Swine Influenza Virus Group (SIV) to the journal *Zoonoses and Public Health*. Finally OFFLU held two meetings: a) OFFLU SIV Group meeting, OIE headquarters, Paris, France, 27–28 March 2012; b) OFFLU Annual Technical Meeting, Royal Holloway, London, United Kingdom, 4–5 April 2012.

8. Liaison with other Commissions

8.1. Scientific Commission for Animal Diseases (Scientific Commission)

Update on on-going issues or issues from the last Biological Standards Commission meeting:

The Commission noted that the Scientific Commission would request the *ad hoc* Group on bovine tuberculosis to provide an opinion on the principle of using the DIVA strategy for that disease.

Matters from the Scientific Commission to the Biological Standards Commission

The Commission noted the questionnaire on rinderpest virus-containing materials would be used to determine the locations and types of such material.

8.2. Terrestrial Animal Health Standards Commission (Code Commission)

Matters from the Code Commission to the Biological Standards Commission

The Commission agreed to seek the advice of the *ad hoc* Group on Bluetongue on the Member Country question transferred from the Code Commission.

On the issue of potentially designating a prescribed test for international trade for lumpy skin disease, the Commission agreed to seek the advice of the OIE experts at the Reference Laboratories.

7 FAO: Food and Agriculture Organization of the United Nations
8 WHO: World Health Organization
9 CDC: Centers for Disease Control and Prevention (United States of America)

9. Matters of Interest for Information

9.1. Pilot Focal Points on laboratories

Dr Elisabeth Erlacher-Vindel informed the Commission of a pilot training project that had taken place in the Asian region on Focal Points on Laboratory issues. Two members of the Commission had also taken part. The Commission agreed that it was a useful endeavour. The Commission requested that it be invited to be represented, from the earliest stage, in any future such schemes.

9.2. Antimicrobial resistance (update)

Dr Erlacher-Vindel updated the Commission on activities in the field of antimicrobial resistance: that the *ad hoc* Group had met to update *Terrestrial Code* chapters, that the list of critically important antimicrobials was under review, and that an OIE Global Conference on the Responsible and Prudent Use of Antimicrobial Agents for Animals would be held in March 2013.

10. Any Other Business

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

Prof. Caporale invited all the Commission members to bring to the next meeting in February 2013 their proposals for the Commission's programme of activities for the years 2013 to 2015. The work plan could then be established.

The current work plan can be found at Annex 6.

10.2. Dates of the next Biological Standards Commission meeting

The Commission noted the dates for its next meetings:
18–22 February 2013 and 9–13 September 2013.

11. Adoption of the Report

The report was adopted by the Commission.

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Annex 1

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 12–14 September 2012

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Agenda

1. Adoption of the Agenda

2. OIE Reference Centres

2.1. Applications for the status of OIE Reference Centre
2.2. Changes of experts at OIE Reference Centres
2.3. Review of new and pending applications for laboratory twinning
2.4. Presentation of the proposed new annual report template

3. *Ad hoc* Groups

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

3.1. Report of the Meeting of the *ad hoc* Group on Vaccine Quality related to Rabies, 2–4 May 2012
3.2. Report of the Third Meeting of the *ad hoc* Group on Biosafety and Biosecurity in Veterinary Laboratories, 17–19 July 2012
3.3. Report of the Fourth Meeting of the *ad hoc* Group on Validation of Diagnostic Assays, 21–23 August 2012
3.4. Report of the Meeting of the *ad hoc* Group on Vaccine Quality related to Classical Swine Fever, 4–6 September 2012

Planned *ad hoc* Groups:

3.5. Second meeting of the *ad hoc* Group on Validation of Diagnostic Tests for Wildlife, 15–17 January 2013
3.6. Second meeting of the *ad hoc* Group on Rift Valley fever, 9–11 October 2012
3.7. Brainstorming on New Approaches to Diagnosis: Applied Genomics, 10–12 December 2012

4 International Standardisation/Harmonisation

- **Diagnostic tests**

4.1. Prescribed and Alternative Tests
4.2. Update on assay for the detection of *Campylobacter fetus*
4.2. OIE Register of diagnostic tests: review of applications

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

5.1. Presentation of the seventh edition of the *Terrestrial Manual*
5.2. Revised chapters for adoption in May 2013
5.3. Selection of chapters to be revised for adoption in May 2014
5.4. Conversion of the guidelines in the OIE Quality Standard booklet into stand-alone chapters for the introductory part of the *Terrestrial Manual*

6. Follow-up from General Session

6.1. Comments from Delegates on equine influenza vaccines following Prof. Caporale's presentation at the General Session

7. Conferences, Workshops, Meetings

7.1. WAVLD, 5–8 June 2013, Berlin, Germany
7.2. Laboratory PVS meeting
7.3. Update on OFFLU

8. Liaison with other Commissions

8.1. Scientific Commission for Animal Diseases

Update on on-going issues or issues from last Biological Standards Commission meeting:

Validation of bovine tuberculosis DIVA test

Matters from Scientific Commission to Biological Standards Commission

Rinderpest questionnaire

8.2. Terrestrial Animal Health Standards Commission

Bluetongue

Lumpy skin disease (seek advice from BSC on the possibility of improving the recommendations on prescribed tests in the *Terrestrial Manual*)

9. Matters of Interest for Information

9.1. Pilot Focal Points on Laboratories
9.2. Antimicrobial resistance

10. Any Other Business

10.1. Workplan
10.2. Dates of the next Biological Standards Commission meetings

11. Adoption of Report

Annex 2

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION
Paris, 12–14 September 2012

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Annex 3

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

Paris, 17–19 July 2012

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1. Opening

The OIE *ad hoc* Group on Biosafety and Biosecurity in Veterinary Laboratories met from 17 to 19 July 2012 at the OIE Headquarters in Paris, France, to continue its work on the revision of three chapters from the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual)*. Dr Elisabeth Erlacher-Vindel, Deputy Head of the Scientific and Technical Department, welcomed the participants and introduced the two observers to the Group members. She reminded the observers to fill and sign the confidentiality undertaking. and recalled the objectives of the meeting based on the terms of reference. She further announced that the OIE Director General, Dr Bernard Vallat, would be available to answer and guide the Group on specific questions that might arise.

Dr Vallat, who joined briefly the meeting at the second day, thanked the Group for their valuable contribution to the OIE as the standards on development were of high importance to the OIE. Regarding the standard on development for the transport of animal specimens, he mentioned that this topic was of concern to the three international organisations participating regularly in a joint meeting (tripartite meeting): FAO, OIE and WHO. He pointed out that the development of relevant standards by the OIE in coordination with sister organisations would help to improve the effective and safe transport of animal specimens from the field to the laboratory and between laboratories worldwide. He specified, however, that the OIE Standards should follow the existing regulations adopted at the international level and, as far as possible, be implementable by all Member Countries.

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

The adopted Agenda and the List of Participants are presented in Appendices I and II of this report, respectively.

4. Review and finalisation of draft Chapter 1.1.1. on Collection and storage of diagnostic specimens

The Group reviewed and produced a final working draft of the chapter with the addition of a section and appendix on Epidemiological Approaches for Sampling contributed by OIE epidemiology experts. The Group agreed to finalise the chapter via email communications following the meeting.

The Group noted that this chapter was an update of the current Chapter 1.1.1. of the *Terrestrial Manual* on Collection and shipment of diagnostic specimens. The section on shipment was further developed into a separate chapter entitled: Chapter 1.1.2. Transport of specimens of animal origin.

5. Review and finalisation of draft Chapter 1.1.3. on Standard for managing biorisk in veterinary laboratories and animal facilities

The Group reviewed and produced a final working draft of the chapter. The Group agreed to finalise the chapter via email communications following the meeting.

The Group pointed out that the aim of this chapter was to provide OIE Member Countries with a standard for managing biorisk in veterinary laboratories and animal facilities that is in line with existing standards, including the CEN[1] Workshop Agreement 15793 (CWA standard). For this reason, the Group adhered substantially to the content of the CWA standard, while incorporating key OIE risk analysis concepts and definitions that were appropriate to animal health.

Where differences existed between the OIE risk analysis and CWA (Public Health) approaches and definitions, the Group highlighted that the risk analysis approaches were based on the OIE risk analysis developed in Chapter 2.1. of the *Terrestrial Animal Health Code*. The Group also decided to provide readers with some concrete examples of risk assessment in fictitious situations using specific representative diseases. Additionally, text was included to provide examples and definitions needed for the biosecurity component of risk management.

The Group emphasised that this draft chapter would be a transition from a prescriptive to a risk-based approach and would provide guidance on how to select the appropriate control measures (administrative, operational and engineering controls as well as personnel protective equipment) to contain the laboratory biorisks identified in a biorisk assessment. The Group recognised that this would be a significant change from established practices, but would ultimately provide a more science-based approach to laboratory biorisk management. By Group consensus, the historical approach of using risk group and biosafety level designations were removed, and clarification on the importance of laboratory-specific risk control measures was added.

By adopting these approaches, a consideration for the Group was harmonisation of animal health standards with those being developed in the public health sector, while focusing on the issues and concerns critical to animal health.

6. Review and finalisation of draft Chapter 1.1.2. on Transport of specimens of animal origin

The Group reviewed and produced a final working draft of the chapter. The Group agreed to finalise the chapter via email communications following the meeting.

The Group highlighted that the aim of this draft chapter was to provide an applicable and a practical standard for the transport of biological substances (infectious and non-infectious) with references to the existing international transportation standards or guidance, when relevant. The Group agreed to the following content: (1) An introduction, definitions, and responsibilities; (2) a decision tree; (3) and text that did not include specific instructions for handling substances designated by the United Nations as Category A (as international regulations currently require the personnel in charge of sending these substances to be trained and certified, the Group decided not to incorporate this part and to make a reference to the exhaustive documentation available via the internet and through applicable international and national regulatory bodies). For the transport of Category B substances, the Group identified the current sections in the WHO Guidance that were extracted from the current regulations, and incorporated the relevant items into the *Transport of specimens of animal origins* chapter. Further clarification and definition of exempt substances relevant to animal-derived specimens were added. For the specimens from exotic animals and endangered species where CITES[2] agreement applies, the Group summarised the current regulations and added a link where all the regulations applying for these samples could be found. The Group was of the opinion of including a short statement to assist in the transport of these specimens when they are being shipped for laboratory testing purposes. Again, the intention of the Group was to harmonise animal health standards with those that apply to public health, while including the issues and concerns critical to animal health.

7. Finalisation of the report

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

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…/Appendices

1 European Committee for Standardisation
2 Convention on International Trade in Endangered Species of Wild Fauna and Flora

Appendix I

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

Paris, 17–19 July 2012

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Agenda

1. Opening
2. Appointment of chair and rapporteur
3. Adoption of the agenda
4. Review and finalisation of draft Chapter 1.1.1. on Collection and storage of diagnostic specimens
5. Review and finalisation of draft Chapter 1.1.3. on Standard for managing biorisk in veterinary laboratories and animal facilities
6. Review and finalisation of draft Chapter 1.1.2. on Transport of specimens of animal origin
7. Finalisation of the report

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Appendix II

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

Paris, 17–19 July 2012

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Annex 4

Original: English
August 2012

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON VALIDATION OF DIAGNOSTIC ASSAYS

Paris, 21 – 23 August 2012

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1. Opening

The OIE *ad hoc* Group on Validation of Diagnostic Assays met from 21 to 23 August 2012 at the OIE Headquarters in Paris, France. Dr Elisabeth Erlacher-Vindel, Deputy Head of the Scientific and Technical Department, welcomed the participants on behalf of Dr Bernard Vallat, Director General of the OIE. She informed the Group that the objective of the meeting was to address the comments received from Member Countries and experts on the proposed updated version of Chapter 1.1.4./5. and on the seven appendices developed. She mentioned that the priority was to finalise the chapter during this meeting and if time allowed, to finalise the appendices. She also mentioned that the chapter, once adopted by the World Assembly of Delegates, would be included as a standard in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*) and in the *Manual of Diagnostic Tests for Aquatic Animals* (*Aquatic Manual*), and that different options were possible concerning the appendices: available only on the OIE website, included in the *Manuals* but in a new section at the end, reserved for "guidelines", published separately as a paper booklet, or available both on the OIE website and as a separate publication. She specified that this would be further discussed by the Biological Standards Commission but the Group could suggest a specific option.

The members of the Group expressed their sincere thanks to Drs Peter Wright and Richard Jacobson, prior *ad hoc* Group members, for their leadership and vision in developing the current version of chapter1.1.4./5. and the associated appendices. Their contribution was highly valued and was used as basis for the Group discussions.

2. Designation of chairperson and rapporteur

The meeting was chaired by Dr Mehdi El Harrak and Prof. Ian Gardner acted as rapporteur.

3. Adoption of the Agenda

The adopted Agenda and the List of Participants are presented in Appendices I and II of this report, respectively.

4. Review of the technical OIE Member comments on the proposed Chapter 1.1.5. "Principles and Methods of Validation of Diagnostic Assays for Infectious Diseases" and its appendices of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*

Chapter 1.1.5.

The Group reviewed the comments from OIE Member Countries and experts on Chapter 1.1.5. and proposed changes to the chapter text as appropriate. A final version of the chapter was developed and agreed to by the Group during the meeting.

The review of the Group and actions taken are summarised below:

Many reviewer comments proposed additions or deletions in the text. The Group accepted these proposals when they added clarity to the text or avoided redundancy with the appendices, and were in line with the focus of the chapter.

The revision included rewording consistent with formatting the chapter as a standard along with moving specific examples or materials to the appendices. The text boxes in the chapter were also removed as part of this aim and the text moved into the chapter when relevant. The Group suggested that the definitions from these text boxes be included in the glossary of the *Terrestrial* and *Aquatic Manuals*.

As the essential prerequisites were covered in quality management, point A.2.a) "Essential prerequisites: factors that impact assay validation" was renamed "Quality management" and developed without sub-headings. After further editing of the text, this section was moved and included under the section titled "Preliminary considerations in assay development and validation".

The section on "Direct and indirect methods that require validation" was deleted and replaced with a single sentence indicating that all tests should be validated.

Point A.2.e) "Inhibitory factors in sample matrix" was rephrased to state the recommendations in "positive" rather than in negative language.

To avoid the use of different terms for the same concept, the terms robustness and ruggedness were removed and replaced by repeatability and reproducibility, respectively. The part dedicated to robustness was renamed "Preliminary study of the repeatability" and rewritten with the aim to provide concise information on the topic.

For more clarity and consistency, the term "allowable error" was removed and replaced by "error margin".

In the introduction of point B.2., the recommendation to perform stage 1 studies for repeatability, reproducibility and assessment of analytical sensitivity (limit of detection) in a blinded fashion with random selection of samples was removed as this was considered essential for stages 2 and 3, but not for stage 1.

In part B, Stage 1 Analytical performance characteristics, items b) "Analytical specificity" and c) "Analytical sensitivity" were revised. The definitions of these concepts were rewritten to be clearer and the examples provided removed to be included in the relevant appendices.

In part B, Stage 2 Diagnostic performance of the assay, item b) "Reference animal infection status" was revised and renamed ("Samples from animals of unknown status") for clarity since this is common when data are analysed with latent class models. The text was re-ordered to put more emphasis on latent class models as the preferred approach.

In part B, stage 4 – Programme implementation, section a) on interpretation of test results was expanded to include more description of predictive values and economic consequences of test errors in disease control programmes.

Figure 1, "The assay development and validation pathways", was revised and updated to harmonise with the changes made in the chapter text.

Appendices

The Group reviewed the comments from OIE Member Countries and experts on the 7 appendices. The Group proposed these appendices be designated in the future as validation guidelines. Based on the comments submitted, the Group did some rephrasing and editorial work in the text of all chapters to harmonise their content with changes in the chapter and improve clarity of presentation. However, for Validation Guidelines 3 on Development and optimisation of nucleic acid detection assays and 5 on Statistical approaches to validation, the Group was of the opinion that the documents needed substantial changes. The Group proposed therefore to send these documents to the original authors or to another expert to propose a new version that would take the comments into account. For Validation Guideline 4 on Measurement Uncertainty, the Group decided to send the document to the author of Validation Guideline 5 to see if the two guidelines could be merged. For Validation Guideline 6, the Group decided to ask to the author whether it could be included as a part of the three first Validation Guidelines for the different types of test methods (Development and optimisation of antibody detection assays, antigen detection assays by immunological means, and of nucleic acid detection assays respectively) or whether it was preferable to keep it separate. In this case, revision would be necessary as the guideline was for the time being only focused on nucleic acid detection tests.

The Group was of the opinion that a follow-up meeting was not necessary and the finalisation of the validation guidelines could be done electronically before the meeting of the Biological Standards Commission early in 2013.

The Group proposed that the validation guidelines be published on the OIE website when finalised. The Group also proposed that the OIE consider publishing the chapter and validation guidelines as an ebook and the paper version would depend on Member Countries' interest.

5. Adoption of the report

The Group adopted the report.

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…/Appendices

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON VALIDATION OF DIAGNOSTIC ASSAYS

Paris, 21 – 23 August 2012

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Agenda

1. Opening
2. Appointment of chairperson and rapporteur
3. Adoption of the agenda
4. Review of the technical OIE Member comments on the proposed Chapter 1.1.5. "Principles and Methods of Validation of Diagnostic Assays for Infectious Diseases" and its appendices of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
5. Other matters
6. Adoption of the report

_____

Appendix II

OIE *AD HOC* GROUP ON VALIDATION OF DIAGNOSTIC ASSAYS

Paris, 21 – 23 August 2012

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MEETING OF THE ENLARGED BUREAU GROUP OF THE OIE BIOLOGICAL STANDARDS COMMISSION
Paris, 10–11 September 2012

Status of the chapters identified for update and proposal for adoption in 2013

No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
1.1.1	Collection of diagnostic specimens	RECEIVED	Add a section on post-mortem samples. Approved in principle to be sent to Member Countries (MCs).	Agree
1.1.2.	Transport of specimens of animal origin	RECEIVED	Approved to be sent to MCs	Agree
1.1.3.	Standard for managing biorisk in the veterinary laboratory and animal facilities	RECEIVED	Glossary should be removed from the chapter and added to the *Manual*'s glossary. Appendix 1.1.3.2 should be removed from chapter and published elsewhere as guidelines. Approved in principle to be sent to MCs.	Agree. Reformat appendix as a guideline that will be added to Part 3 of the *Manual*.
1.1.5.	Principles and methods of validation of diagnostic assays for infectious diseases + seven appendices	RECEIVED	Approve to be sent to MCs. Need text on in-house validation, which can be added at revision stage 2. Appendices, reformatted as guidelines, could be published elsewhere, with the OIE website favoured.	Agree
1.1.6.	Principles of veterinary vaccine production (re-write as a standard)	To be drafted by an AHG		
1.1.10.	International standards for vaccine banks	Not yet received		
2.1.3.	Bluetongue	Received first draft (vaccine section not reformatted)		
	Crimean–Congo haemorrhagic fever	RECEIVED	Back to author. Reduce number of references. Shorten the introduction. Remove mention of commercial products. Move most of text in Section C to introduction, leaving just sentence that there are no vaccines for animals. Ask BSC if bioweapons should be mentioned in *Manual*.	Agree. Bioweapons should not be mentioned in the *Manual*
	Epizootic haemorrhagic disease	Not yet received		
2.1.4.	Echinococcosis/Hydatidosis	Not yet received	.	
2.1.6.	Heartwater	Not yet received		

No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
2.1.8.	Leishmaniosis	Not yet received		
2.1.10.	Screwworm (*Cochliomyia hominivorax* and *Chrysomya bezziana*)	RECEIVED	Change "Diagnostic Biologicals" to "Biological Control" in title of Section C. Change references to commercial products to footnotes. Approved in principle to be sent to MCs.	Agree
2.1.11.	Paratuberculosis (Johne's disease)	Not yet received		
2.1.13.	Rabies (Vaccine section)	AHG on Vaccine Quality revised vaccine section (2012). RECEIVED	Remove Table 2. Approved to be sent to MCs.	Adoption of draft chapter was postponed while awaiting the scientific justification for animal inoculation and subsequent killing as immunity can be determined by antibody titration.
2.1.14.	Rift Valley fever	AHG to revise in particular the vaccine section		
2.1.20.	West Nile fever	RECEIVED	Reduce number of references. Approved in principle to be sent to MCs.	Agree
2.2.1	Acarapisosis of honey bees	AHG revising all bee disease chapters (coor. by Ritter). Not yet received		
2.2.2.	American foulbrood of honey bees	Not yet received		
2.2.3.	European foulbrood of honey bees	Not yet received		
2.2.4.	Nosemosis of honey bees	RECEIVED	Approved to be sent to MCs	Agree
2.2.5.	Small hive beetle infestation (*Aethina tumida*)	RECEIVED	In the section on manual colony examination regroup the three notes and put at the beginning. Approved in principle to be sent to MCs.	Agree
2.2.6.	*Tropilaelaps* infestation of honey bees (*Tropilaelaps* spp.)	Not yet received		
2.2.7.	Varroosis of honey bees	Not yet received		
2.3.2.	Avian infectious bronchitis	RECEIVED	Reduce number of references in the diagnostic section. Approved in principle to be sent to MCs.	Agree
2.3.5.	Avian mycoplasmosis (*M. gallisepticum, M. synoviae*)	Not yet received		

No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
2.3.9.	Fowl cholera	Received first draft (but the vaccine section unchanged)		
2.3.10.	Fowl pox	Not yet received		
2.3.12.	Infectious bursal disease (Gumboro disease)	Not yet received		
2.4.5.	Bovine genital campylobacteriosis	Asked to be moved to 2014 r	Put on the 2014 list	Agree
2.4.8.	Bovine viral diarrhoea	Not yet received		
2.4.9.	Contagious bovine pleuropneumonia	Not yet received		
2.4.15.	Malignant catarrhal fever	RECEIVED	Remove mention of commercial products. Shorten section on disease control and move to introduction. Approved in principle to be sent to MCs.	Agree
2.4.16.	Theileriosis	Not yet received		
2.4.18.	Trypanosomosis (Tsetse-transmitted)	RECEIVED	Approved to be sent to MCs.	Agree
2.5.3.	Dourine	RECEIVED	Clarify the definition of a confirmed case of dourine (is it one of the four conditions or the first two and one of either three or four), and move out of the vaccine section (to before title C). Approved in principle to be sent to MCs.	Check the definition of a confirmed case and ask the experts to review the molecular methods. Once clarified, send chapter to MCs.
2.5.5.	Equine encephalomyelitis (Eastern & Western)	RECEIVED	Approved to be sent to MCs.	Agree
2.5.6.	Equine infectious anaemia	RECEIVED	Approved to be sent to MCs.	Consult expert on use of a vaccine. Once clarified, send chapter to MCs.
2.5.8.	Equine piroplasmosis	Not yet received		
2.5.9.	Equine rhinopneumonitis	Received first draft (but vaccine section unchanged)		
2.5.10.	Equine viral arteritis	RECEIVED	Approved in principle to be sent to MCs.	Agree.
2.5.11.	Glanders	RECEIVED	Remove mention of commercial products. Propose deleting section on other tests as they are not for diagnosis. Approved in principle to be sent to MCs.	Agree. Re-word text on mallein test. Consult expert on the complement fixation test in donkey sera
2.5.13.	Venezuelan equine encephalomyelitis	RECEIVED	Approve to be sent to MCs.	Agree
2.6.1.	Myxomatosis	Not yet received		

No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
2.7.5.	Contagious agalactia	RECEIVED	Vaccine section does not conform to the requirements of the *Manual*. Return to author	Agree
2.7.10.	Ovine pulmonary adenomatosis (adenocarcinoma)	Not yet received		
2.7.11.	Peste des petits ruminants	RECEIVED	Reinstate the C-ELISA. Define positive cut-off for VN test. Approved in principle to be sent to MCs.	Agree
2.8.3.	Classical swine fever (hog cholera)	RECEIVED from AHG on vaccine section in 2012	Need to receive the references from AHG. Update diagnostic section to include DIVA test (Ref. Lab. Experts)	Agree
2.8.9.	Swine vesicular disease	RECEIVED	Define cut-off value for VN test. Provide a generic method for the RT-PCR so as not to endorse particular commercial products. Approved in principle to be sent to MCs.	Agree
2.9.1.	Bunyaviral diseases of animals (excluding Rift Valley fever)	RECEIVED	Send to other experts to review. Reduce the number of references.	Agree
2.9.2.	Camelpox	RECEIVED	Vaccine section does not conform to the requirements of the *Manual*. Remove mention of commercial products. Return to author.	Agree
2.9.4.	Cryptosporidiosis	Not yet received		
2.9.5.	Cysticercosis	Not yet received		
2.9.7.	*Listeria monocytogenes*	Not yet received		
2.9.8.	Mange	RECEIVED	Approved to be sent to MCs.	Agree
2.9.11.	Verocytotoxogenic *Escherichia coli*	Not yet received		

New chapters and chapters proposed for update in 2014

No.	Title
New chapter	Management of Veterinary Laboratories (to include sections on quality and biorisk management)
1.1.8	Minimum requirements for vaccine production facilities
1.1.9	Quality control of vaccine
1.1.6.	Principles of veterinary vaccine production (re-write as a standard)
2.1.9.	Leptospirosis
2.1.19.	Vesicular stomatitis
2.3.3.	Avian infectious laryngotracheitis
2.3.6.	Avian tuberculosis
2.4.3.	Bovine brucellosis
2.4.5.	Bovine genital campylobacteriosis
2.4.10.	Dermatophilosis
2.5.4.	Epizootic lymphangitis
2.7.2.	Caprine and ovine brucellosis (excluding *Brucella ovis*)
2.7.6.	Contagious caprine pleuropneumonia
2.7 9.	Ovine epididymitis (*Brucella ovis*)
2.8.5.	Porcine brucellosis
2.8.10.	Teschovirus encephalomyelitis (previously enterovirus encephalomyelitis or Teschen/Talfan disease)
2.9.10.	Toxoplasmosis

MEETING OF THE ENLARGED BUREAU GROUP OF THE OIE

BIOLOGICAL STANDARDS COMMISSION

Paris, 10–11 September 2012

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Agenda

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

1.1. Introduction and Presentation of the seventh edition of the *Terrestrial Manual* (table of contents, publishing dates, etc.)
1.2. Presentation of updating procedure and format of reporting of recommendations from the EBG to the BSC for agreement
1.3. Update on the status of the chapters identified for update and proposal for adoption in 2013
1.4. Review of chapters proposed for adoption in May 2013: chapters ready to be sent for first round of comments
1.5. Selection of chapters for proposal in May 2014

2. Outcome: recommendations of the Enlarged Bureau Group to the BSC (table from point 1.3 adapted according to discussions)

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MEETING OF THE ENLARGED BUREAU GROUP OF THE OIE

BIOLOGICAL STANDARDS COMMISSION

Paris, 10–11 September 2012

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Annex 6

BSC Work Plan: September 2012 to February 2013

Topic/Issue	Responsible(s)	Deadline
Manual of Diagnostic Tests and Vaccines for Terrestrial Animals		
Circulate the chapters approved by the Enlarged Bureau Group and the Commission	SL	By end October 2012
Remind authors of the chapters identified by the Enlarged Bureau Group and the Commission for adoption in 2013 but not yet received	SL	On going
Commission the chapters identified by the Enlarged Bureau Group and the Commission for proposal for adoption in 2014	SL	On going
Update all the disease-specific chapters of the *Manual* according to the new template	BSC/SST	Continuing implementation with the aim to finalise all these modifications for the publication of the paper version of the *Manual* in 2016
Ad hoc Groups		
Vaccine Quality related Rift Valley fever (Second Meeting)	SST: FD, SM Member of the BSC who will attend: VC (invited but didn't attend)	Dates: 9–11 October 2012
Validation of Diagnostic Tests for Wildlife (Second Meeting)	SST: FD, EEV Member of the BSC who will attend: VC	Dates: 15–17 January 2013
Brainstorming on New Approaches to Diagnosis: Applied genomics; outcome White Paper + programme for the WAVLD meeting	SST: EEV, FD, SL Member of the BSC who will attend: VC, PD	Dates: 10–12 December 2012
Vaccines to update chapter 1.1.6 *Principles of veterinary vaccine production*, and to draft two chapters: 1.1.8 *Minimum requirements for vaccine production facilities*, 1.1.9 *Quality control of vaccines*	SST: SM, FD	Ad hoc Group to be established
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 finalise programme and speakers	SST & BSC	Use Brainstorming members as internal "scientific committee