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REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 11–12 September 2013

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The OIE Biological Standards Commission (the Commission) met at the OIE Headquarters from 11 to 12 September 2013. As Prof. Vincenzo Caporale, President, could not attend because, upon his agreement to accept the request of the Director General of the OIE, he was participating in the "Global Microbial Identifier (GMI) Meeting – Meeting #6", in University College Davis Campus, California, USA, Dr Hualan Chen, Vice-President, was appointed Acting President.

Dr Bernard Vallat, Director General of the OIE, welcomed the Members of the Commission. During the General Session in May 2013, the Delegates had been informed of the proposal to potentially replace the current list of prescribed and alternative tests that can be found in both the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*) and the *Terrestrial Animal Health Code* (*Terrestrial Code*) with a table in the disease-specific chapters that lists the diagnostic methods available for the disease in question alongside the purpose for which the assay has been validated. Dr Vallat reminded the Commission that although the rationale for inclusion of a diagnostic test in the *Terrestrial Manual* is purely scientific, OIE Standards must also be used for international trade and have legal uses. A final decision on whether or not to phase out the list of prescribed tests for international trade would therefore be taken by the Council following consultation with other Specialist Commissions including the Commission for Aquatic Animals.

Dr Vallat went on to talk about an important revolution that is currently occurring globally in the area of new approaches using new technologies and bioinformatics for diagnostics and the creation of global sequence databases. The OIE must be involved as a leader in this revolution; participation in newly formed committees on this subject, for example Prof. Caporale's participation in the GMI Meeting, was one way to raise the OIE's profile internationally in this area. Dr Vallat stated that the topic would also be a key one on the programme of the Global Conference of the OIE Reference Centres, which will be held in Seoul, Korea (Rep. of), from 14 to 16 October 2014 (see agenda item 7.2).

On the topic of the OIE Twinning Programme, Dr Vallat informed the Commission that the selection criteria for twinning projects were not only scientifically based but also took into account donor, political and other geostrategic priorities. The Commission was requested to provide its opinion on the technical merit of projects, but the OIE's final decision would take into account other considerations and input from other entities, including donors.

Dr Vallat then brought up the coronavirus implicated in the Middle East respiratory syndrome (MERS), which has attracted a lot of media attention that is often not science based. He asked that the Commission encourage the *ad hoc* Group on Camelidae to work to provide a scientifically backed opinion on the diagnostic tests to be used in camelids.

Dr Vallat mentioned that the OIE is still open to suggestions of where to publish guidelines, for example the validation guidelines, in the *Terrestrial Manual* or elsewhere. A more flexible proposal would be to publish them on the OIE website with cross references to the *Terrestrial Manual* for formal recognition.

Finally, Dr Vallat spoke about equine influenza vaccines: the Expert Surveillance Panel on Equine Influenza Vaccine Composition make annual recommendations on the strains to be included in vaccines. These recommendations are not often taken up on time by the industry, probably for economic reasons. It seems that several Regulatory Authorities were already prepared to adapt the time needed for the licensing procedure as is the case for seasonal human influenza. He wondered if specific provisions should be made for this purpose in the *Terrestrial Manual* to resolve this issue.

1. Adoption of Agenda

The proposed agenda was presented and adopted.

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

2. OIE Reference Centres

2.1. Applications for the status of OIE Reference Centre

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

OIE *Reference Laboratory Avian chlamydiosis* (Chlamydia psittaci)
Laboratory for Immunology and Animal Biotechnology, Ghent University, Faculty of Bioscience Engineering, Department of Molecular Biotechnology, Coupure links, 653, 9000 Ghent, BELGIUM
Tel.: (+32) 09.264.59.72; Fax: (+32) 09.264.62.19;
E-mail: Daisy.Vanrompay@ugent.be
Designated Reference Expert: Prof. Daisy Vanrompay.

An application had been received from a European country for an OIE Collaborating Centre for Viral Genomics, Bioinformatics and Transmission Dynamics. The Commission believed that the Centre's activities would overlap with those of the existing OIE Collaborating Centre for Biotechnology-based Diagnosis of Infectious Diseases in Veterinary Medicine in Sweden. In light of the "one OIE Collaborating Centre per topic per region" rule, the Commission proposed that the applicant contact the Swedish Centre with a view to forming a consortium.

A country in the Americas region had submitted an application for an OIE Reference Laboratory for avian infectious bronchitis. The Commission requested more information on the laboratory's international activities and on its quality management system. Another country in the same region had submitted an application for an OIE Reference Laboratory for rabies. Again, the Commission requested more information on international activities and a list of recent publications on this important disease.

Applications had been received from a European country for designation of four OIE Reference Laboratories: for bovine spongiform encephalopathy (BSE) and atypical BSE, for scrapie and atypical scrapie, for Leishmaniosis and for *Babesia* and *Theileria*. The Commission requested more information on international activities. Noting that OIE Reference Laboratories are designated for named diseases, the Commission would encourage those applying for an OIE Reference Laboratory for *Babesia* and *Theileria* to choose one disease per application, e.g. theileriosis or bovine babesiosis. As an OIE Reference Laboratory for BSE and one for scrapie would be expected to diagnose atypical BSE and atypical scrapie, these mentions would not be included in the titles of the Reference Laboratories.

An application from a country in the Asia, the Far East and Oceania Region for an OIE Reference Laboratory for Rinderpest that was first received in January 2012 had been put on hold at that time until the Joint FAO[1]/OIE Advisory Committee on Rinderpest had finalised the procedure for applicants for approved holding biosecure facilities for rinderpest virus-containing material. Any laboratory

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

requesting recognition as an OIE Reference Laboratory for Rinderpest would need to first be identified by OIE and FAO as an approved rinderpest holding facility. The Commission therefore, agreed to keep the application 'on hold' and invites the applicant to submit a dossier for approved holding facility status to the Joint Advisory Committee.

Finally, an application had been received from a country in Asia for a Reference Laboratory for Equine piroplasmosis. The Commission requested more information on the laboratory's international activities, on its ability to receive samples from abroad and on its quality management system.

2.2 Changes of experts in the List of Reference Centres

The Delegate of the United Kingdom had submitted to the OIE the following nomination for a change of expert at two OIE Reference Laboratories. The Commission recommended its acceptance:

Foot and mouth disease and swine vesicular disease
Dr Donald King to replace Dr Jef Hammond at the Institute for Animal Health, Pribright, UNITED KINGDOM.

2.3. Creation of a database of former OIE designated experts: "OIE expertise"

When OIE designated experts at Reference Centres leave their positions, because of a change of job or retirement, their names are removed from the lists of OIE Reference Laboratories and Collaborating Centre. Prof. Caporale had proposed that the OIE create a database of former OIE designated experts, with the permission of the expert, so that they could continue their collaboration with OIE (missions, etc.) should the need arise. The Commission felt that such a database could be useful and agreed in principle to its development by the OIE Headquarters.

2.4. Specific issues related to Reference Centres

Two instances of OIE Reference Laboratories apparently not fulfilling their mandates were brought to the attention of the Commission. While the Commission proposed appropriate actions to take in these particular cases, the broader issue of how to monitor OIE Reference Centres' activities and react to under-performing or other problematic Reference Centres was discussed. The Commission agreed to develop a structured approach to evaluating Reference Centres so that any future problems could be dealt with in a fair, timely, and coherent manner. The procedure would be based on the Terms of Reference, and the annual reports of OIE Reference Centre activities would be a key element in identifying a Reference Centre in difficulties. The Commission felt that initial steps to take would involve communication with the Reference Centre, keeping the Delegate of the host country involved. An on-site visit would be the last resort and the aim of such a visit would be to try first to resolve problems rather than to revoke the OIE designation.

2.5. Update on the template for annual reports of Collaborating Centre activities and feedback on Reference Laboratory quality management systems

Dr Min-Kyung Park, Scientific and Technical Department of the OIE, joined the meeting for this agenda item. The template for annual reports of Collaborating Centre activities, like its counterpart for Reference Laboratories, had also been reformatted in accordance with the Terms of Reference as a web-based tool. Dr Park presented an updated template and the Commission provided further proposals for improvement. For the 2013 reports, this updated template shall be used but as a Microsoft Word document rather than a web-based tool.

At the previous meeting, Dr Park had presented an analysis of the activities of the OIE Reference Centres collected through the annual reports for 2012. A number of laboratories had not responded satisfactorily to the question on the quality management system under which they operated and Dr Park had been asked to follow up on this question. The Commission reviewed the replies, which could be roughly divided into two: those laboratories that were in the process of achieving an internationally

recognised quality management system and those that were not. For the former group, the Commission agreed that a letter of encouragement should be sent with the request for an update on any progress that had been made during the year. The latter group was a concern as OIE Reference Laboratories are mandated to have a quality management system; the Commission agreed that a letter should be sent to those Laboratories requesting clarification of their situation and confirmation that the laboratory complies with Chapter 1.1.4 of the OIE *Terrestrial Manual* entitled: *Quality management in veterinary testing laboratories*. Laboratories that do not comply with the Terms of Reference could be proposed for delisting. The importance of a quality management system, and the proposal to delist those Reference Laboratories that do not maintain a quality system was highlighted during the 81st General Session of the OIE World Assembly in May this year.

2.6. Review of new and pending applications for laboratory twinning

Dr Gounalan Pavade, Scientific and Technical Department of the OIE, updated the Commission on the OIE Laboratory Twinning programme. As of August 2013, 16 projects have been completed, 27 are underway and 16 are approved and due to start. For the completed twining projects, twinning certificates were distributed to both parent and candidate laboratories.

Three twinning proposals were presented for the Commission's technical input: South Africa–Yemen for Rift Valley fever (RVF), Italy–Tanzania for *Trichinella*, and Brazil (Panaftosa)–Panama for Foot and mouth disease (FMD) and Vesicular stomatitis (VS).

Regarding the RVF project, the Commission suggested that the candidate laboratory should not handle live virus or carry out animal studies on its premises until the on-going construction of biosafety level 3 facility laboratory is completed and fully operational. For the *Trichinella* project, the Commission commented that the candidate laboratory should broaden its objective beyond that of serving as a regional laboratory for the disease. For the FMD/VS project, the Commission recognised the importance of the control of these diseases in the region and agreed on the technical contents of the project.

2.7. Development of criteria to determine twining priorities for use when reviewing applications

Dr Keith Hamilton, Scientific and Technical Department of the OIE, clarified the procedures for review and approval of twinning projects to the Commission. A checklist was circulated to the Commission describing the various criteria to be considered for the assessment of OIE laboratory twinning project 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, 4–6 September 2013

Dr Peter Daniels presented the report of the meeting of this *ad hoc* Group. He informed the Commission members that the Group reviewed the comments received on the draft Chapter 1.1.3 *Standard for managing biorisk in veterinary laboratories and animal facilities* and the draft Guideline 3.5 *Biorisk analysis: biological agent-specific risk assessments* and finalised these documents based on these comments.

The *Terrestrial Manual* chapter and the guideline proposed by the Group would be sent separately for Member Country comment.

The Commission adopted the report, which can be found at Annex 3 of this report.

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

3.2. *Ad hoc* Group on High Throughput Sequencing and Bioinformatics and Computational Genomics (HTS-BCG)

At its last meeting in February, Prof. Caporale had presented the report of the meeting of a Brainstorming Group on New Approaches to Diagnosis: Applied Genomics and a White Paper: *High-throughput Sequencing in Veterinary Infection Biology and Diagnostics*. The Commission agreed and supported in particular the recommendation in the report to convene an *ad hoc* Group on high throughput sequencing and bioinformatics and computational genomics (HTS-BCG). This had been added it to their work plan. In his welcoming address, Dr Vallat had also identified this topic as a priority.

The Commission discussed the Terms of Reference for this *ad hoc* Group. It identified the need for an OIE strategy on HTS-BCG. It would be important to clarify the role of the *Terrestrial Manual:* could Standards be included that addressed the various commercial systems available, both hardware and chemistries, their fitness for purpose, issues of data management, the validation of bioinformatics in different laboratories, sampling and sample preparation, etc. The range of purposes for which HTS-BCG could be used was also recognised as an important issue, and may include detection in various specimen types of previously unknown agents, definition of the spectrum of known infectious agents present, novel recombinants, other genetic variants or quasispecies populations, for the purposes of diagnosis, surveillance or notification. The problem posed by laboratories that use this technology but which do not have an accredited quality management system would also need to be addressed.

The Commission also looked forward to receiving feedback from Prof. Caporale on in the GMI Meeting he was attending from 10 to 11 September 2013.

3.3. *Ad hoc* Group on Camelidae

As Dr Vallat stated in his welcoming address, identification of animal reservoirs for the Middle East respiratory syndrome (MERS) coronavirus infection and transmission is an important and challenging issue on which OIE leadership is required. Given reports of uncoordinated testing in a range of species, with a particular focus on camels, there is an urgent need to have a scientifically based opinion on appropriate diagnostic tests for MERS-CoV in camels. The Commission agreed that the *ad hoc* Group on Camelidae should be reconvened to address this and other issues and should include along with experts on camelidae, experts on coronaviruses and on test validation to ensure a comprehensive consideration of issues.

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 “Biocheck - Newcastle Disease Virus antibody detection ELISA” 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 Biocheck - Newcastle Disease Virus antibody detection ELISA is fit to detect Newcastle Disease Virus specific IgG antibodies in chicken sera for the following purposes:

1. To demonstrate historical freedom from infection in a defined population (country/zone/ compartment/flock);

2. To determine immune status in individual animals or populations (post-vaccination);
3. To monitor infection or disease in unvaccinated populations;
4. To estimate prevalence of infection to facilitate risk analysis in non-vaccinated populations (surveys/flock health schemes/disease control).

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 2014.

4.2. Standardisation programme

The Commission has a procedure for designating OIE-approved International Standard Sera in accordance with the Commission's Guide 3: *International Reference Antibody Standards for Antibody Assays* (the current list of OIE-approved sera can be accessed on line at: http://www.oie.int/en/our-scientific-expertise/veterinary-products/reference-reagents/). However, few of the OIE Reference Laboratories are aware of this procedure and list (as ascertained from the responses received in the annual reports). Given that OIE Reference Laboratories are mandated to develop reference materials, and the vast majority of them comply with this mandate, but do not submit their materials for evaluation, the Commission agreed that its standardisation programme needs to be reviewed, updated and overhauled.

First, the Commission agreed that Guide 3 should be put on line on the OIE web site following review by an expert. A guide for antigen standards could usefully be developed; an expert was identified for the task. Other guidelines already exist under the OIE umbrella and could be cross referenced, e.g. OFFLU[1] guidelines on molecular tests.

Secondly, Prof. Caporale had requested the OIE Collaborating Centre on Cell Cultures to develop an itinerary of all materials currently available from the OIE Reference Centre network. A lot of this information could be obtained from the annual report.

At its next meeting, the Commission would review the guidelines and itinerary and identify priorities (diseases or materials). This is a crucial activity and the Commission would like it to be added to the programme for the Third Global Conference of OIE Reference Centres (see agenda item 7.2).

4.3. Prescribed tests for international trade

Following proposals that had been received from the experts updating the *Terrestrial Manual* chapters (see agenda item 5.1.) the Commission proposed three amendments to the list of prescribed tests for international trade: to add virus neutralisation as a prescribed test for bluetongue; to add polymerase chain reaction as a prescribed test for bovine babesiosis; and to remove the complement fixation text as a prescribed test for contagious caprine pleuropneumonia.

■ Biosafety/Biosecurity

4.4. International Federation of Biosafety Associations (IFBA) statement

IFBA had consulted its board (on which the OIE is represented) for their opinion on the future of the CEN Workshop Agreement on biorisk management CWA 15793, which is due to expire in 2014. Options included: 1) converting the document to a full International standard (ISO) status or other type of ISO deliverables; 2) Renewing CWA 15973 until 2018 in its current form as a CEN Workshop Agreement; 3) Developing the document into another international standard; or 4) Adopting the document as guidance issued by national, regional and/or international Biosafety Associations.

[1] OFFLU: Joint OIE-FAO Network of Expertise on Animal Influenza

The Commission discussed the options and agreed that a sensible approach would be to renew the CWA 15973 until 2018 in its current form. This would also allow time for feedback from countries and biosafety associations on their experiences in implementing CWA 15793. The Commission expressed concerns that adoption as an ISO standard may result in an additional burden on laboratories, because resources were required to achieve certification. The Commission also noted concerns that a proliferation in biosafety certification (including the certification of biosafety professionals) could also lead to an additional burden on laboratories.

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. Decision on proposals of the Enlarged Bureau Group

The Commission approved the proposals of the EBG Group, which met on 10 September 2013 (see Annex 4).

The Commission reviewed the outcome of the Enlarged Bureau Group (EBG) meeting. Twenty-three chapters were approved for circulation to Member Countries for first-round. The chapter and guideline on biorisk management that had been developed by the *ad hoc* Group and provided to the Commission members during their meeting (see agenda item 3.1) would also be included in the batch of draft chapters for Member Country comment.

Some chapters were identified for proposal for adoption in May 2015; these along with those that had been identified for adoption in May 2014 but which had been submitted too late for first round circulation or had yet to be received, would be reviewed at the next meeting.

The Commission reiterated its principle of removing from the *Terrestrial Manual*, whenever possible, reference to tests involving animal inoculation; the Commission recognises however, that in some cases there is not a clearly substantiated alternative, e.g. in avian influenza assessment of pathogenicity.

5.2. Vaccine terminology – proposal from Australia

Australia had submitted a proposed definition of the term "thermotolerant" for inclusion in the *Terrestrial Manual's* glossary and a paragraph for inclusion in the section on *Stability tests* of Chapter 1.1.6 *Principles of veterinary vaccine production*. The Commission agreed that the time factor would need to be specified, as indicated in the proposed text from the Member Country. A product could not be marketed as being heat tolerant without specifying the boundaries of the tolerance to be expected.

The proposed text can be found at Annex 5 of this report; Member Country comments are invited on this proposal.

5.3. OIE validation guidelines

In May this year, Chapter 1.1.5 *Principles and methods of validation of diagnostic assays for infectious diseases* of the *Terrestrial Manual* had been adopted by the Assembly and is available on line. The chapter included references to seven validation guidelines, but these had not been proposed for adoption as the experts were amending them in accordance with the Member Country comments that had been received. Six of these seven validation guidelines and a seventh guideline on validation of tests applicable to wildlife, were reviewed. The Commission agreed with the EBG that the guidelines were ready to be circulated in a second round as the versions that would be proposed for adoption in May 2014. At its previous meeting in February the Commission had proposed integrating the guideline on validation of tests applicable to wildlife into chapter 1.1.5. The Commission decided however that the guideline would be better kept separate from the chapter. The Commission reiterated its proposal that the guidelines be put in Part 3 of the *Terrestrial Manual* in the on line version only with hyperlinks from the chapter to the appropriated guideline.

The Commission identified a potential author for the remaining guideline.

6. Follow-up from the General Session

6.1. Excerpt from the Final Report of the 81st General Session, May 2013

At the General Session, the 27 European Union (EU) Member States noted that certain disease-specific chapters of the *Terrestrial Manual* contain a case definition, e.g. the current chapter on Newcastle disease. The EU was in agreement with the Code Commission that case definitions should rather be included in the *Terrestrial Code*, whereas the *Terrestrial Manual* should contain references to the case definition in the *Terrestrial Code*, when necessary, to avoid inconsistencies between the two OIE publications that might lead to trade difficulties. The Commission agreed that case definitions were more suited to the *Terrestrial Code* and would ensure that they were removed from those *Terrestrial Manual* chapters for which there is a corresponding *Terrestrial Code* chapter. Case definitions would be maintained in those *Terrestrial Manual* chapters for which there is no corresponding *Terrestrial Code* chapter.

With regard to the future of prescribed and alternative tests, the EU also strongly suggested that the Commission collaborate closely with the Code Commission so as to agree on a coordinated approach for both OIE Standards. Dr Vallat had also mentioned this topic in his welcoming address. The Commission asserted that only prescribed tests should be included in the second column of Table 1, Purpose of test: *Individual animal freedom from infection prior to movement*. The tests listed in this column should be in blue to clarify that they are the prescribed tests for trade. The Commission agreed to remove the denomination "an alternative test for trade" where it appears in the *Terrestrial Manual* chapters and to delete that column from the table in the *Terrestrial Manual* and *Terrestrial Code.*

6.2. *Ad hoc* Group on Shortening the Vaccine Registration Process when simply updating and Incorporating Relevant Strains in Equine Influenza Vaccines

At the 80th General Session in May 2012, the Delegate of South Africa had mentioned the importance of timely updating of equine influenza vaccines. Prof. Caporale agreed with the Delegate and stated that a close consultation among the experts in the Expert Surveillance Panel, regulatory authorities and the vaccine manufacturers was a key to making progress. Lessons could be learned from the poultry sector, which had experienced a similar situation. Dr Vallat had also mentioned this topic in his welcoming address to this meeting of the Commission. The Commission could not identify any regulatory impediments either in the EU or the United States of America to the timely incorporation of new antigens as recommended by the Expert Surveillance Panel into equine influenza vaccines. As Dr Vallat had pointed out, Regulatory Authorities are prepared to adapt the licensing procedure to incorporate new antigens for animal influenza vaccines as is done for seasonal human influenza. Therefore, the Commission did not feel that the issue could be resolved by an *ad hoc* Group, but would urge the Director General of the OIE to contact vaccine producers to resolve this important issue.

6.3. Follow-up of the Resolution No. 18 Declaration of Global Eradication of Rinderpest and Implementation of Follow-up Measures to Maintain World Freedom from Rinderpest, adopted May 2011

Dr Keith Hamilton and Dr Dawid Visser from the Scientific and Technical Dept joined the Commission for this agenda item. In May 2011, the World Assembly adopted Resolution No. 18 Declaration of Global Eradication of Rinderpest and Implementation of Follow-up Measures to Maintain World Freedom from Rinderpest. An appendix to this Resolution, *Global Rinderpest Eradication: Guidelines for Rinderpest Virus Sequestration*, which had been endorsed by the Biological Standards Commission and by the Joint FAO/OIE Committee on Global Rinderpest Eradication, included the stipulation that all approved rinderpest holding facilities be biosafety level 3 (BSL3). However the Joint Advisory Committee decided that this criterion would create practical difficulties for manufacturing vaccine because some vaccine manufacturing plants would not operate at

BSL3. The Joint Advisory Committee agreed that guidance should be amended with a derogation allowing the regulated movement of attenuated vaccine seed stock out of a BSL3 facility to an FAO-OIE approved facility. To this end the Joint Advisory Committee suggested the following text be added to the Guidelines for Rinderpest Virus Sequestration:

- Seed stocks solely for the purpose to maintain stocks of rinderpest vaccine must be maintained under strict biosecurity and biosafety in an appropriate FAO and OIE approved vaccine facility.

- Where it is necessary to manufacture new vaccine to maintain stocks of rinderpest vaccine, this must take place under strict biosecurity and biosafety in an appropriate FAO and OIE approved vaccine facility.

With the following justification: This addition to the points already iterated in the Resolution is necessary to implant proper measures, specifically vaccination, against the possibility of re-occurrence of rinderpest. The rinderpest vaccine is a live attenuated vaccine; in some Member States it is not possible to produce vaccine without moving material from BSL3 before inactivating the virus. This will preclude the storage of seed stocks maintained for the purpose of vaccine manufacture in those member states at BSL3, and may hamper efforts to maintain emergency preparedness against rinderpest re-occurrence. Consequently it is advised that where necessary, seed stocks maintained solely for the purpose of vaccine manufacture to maintain rinderpest vaccine stocks, may be maintained at lower than BSL3, under the oversight and regulation of FAO and OIE to maintain an appropriate level of biosafety and biosecurity. It is also advised that production of new vaccine to maintain stocks of rinderpest vaccine may take place at lower than BSL3, under the oversight and regulation of FAO and OIE to maintain an appropriate level of biosafety and biosecurity.

The Commission accepted the proposal from the Joint FAO/OIE Committee on Global Rinderpest Eradication.

It was reiterated that before institutes made applications to become an OIE Reference Centre for rinderpest, they should first be approved by OIE and FAO as an approved rinderpest holding facility

7. Conferences, Workshops, Meetings

7.1. Feedback on 1-day OIE Seminar, 7 June 2013 (theme: New approaches to diagnosis: applied genomics) held during the WAVLD[2], 5–8 June 2013, Berlin, Germany

Dr Elisabeth Erlacher-Vindel, Acting Head, OIE Scientific and Technical Dept., updated the Commission on the 1-day OIE Seminar.

The 10th OIE seminar, which was opened by Dr Karin Schwabenbauer, President of the OIE and Delegate of Germany, comprised ten presentations. These presentations were followed by a screening of the OIE Rinderpest Eradication film, which was met with applause. The seminar was brought to a close by a short summary of the presentations and an overview on future OIE activities related to new diagnostic approaches and technologies in line with the Commission's current work plan (see agenda item 3.2.). This OIE seminar was attended by over 200 participants and the feedback was extremely positive. Participants found the seminar to be very practical, current and of high scientific importance. Many of the participants visited the OIE Stand discovering the OIE for the first time.

[2] WAVLD: World Association of Veterinary Laboratory Diagnosticians

Preparations are underway for the next WAVLD Symposium, which will be held in Saskatoon, Canada in June 2015. The OIE will continue its tradition of hosting a 1-day Seminar during the Symposium.

7.2. Third Global Conference of the OIE Reference Centres, Seoul, Korea (Rep. of), 2014

The Commission noted that the Third Global Conference of the OIE Reference Centres would be held in Seoul, Korea (Rep. of) from 14 to 16 October 2014. Work had begun on developing the programme, which would include, among other topics, HTS-BCG, quality management systems and accreditation, selection criteria and feedback from twinning projects, and the standardisation programme for the development of reference materials. Prof. Caporale, Dr Hualan Chen, Dr Beverly Schmitt and Dr Peter Daniels were appointed members of the Steering Committee. The Aquatic Animal Health Standards Commission would also propose topics and members of the Scientific Committee at its meeting in October. Once finalised, the programme would be made available on line in the near future.

8. Liaison with other Commissions

8.1. Scientific Commission for Animal Diseases (Scientific Commission)

Matters from the Scientific Commission to the Biological Standards Commission

The experts from the *ad hoc* Group on Porcine reproductive and respiratory syndrome (PRRS) noted that the chapter on PRRS in the *Terrestrial Manual* needed a revision to take into account the different types of vaccines available and the latest molecular tests. The Commission agreed to add it to the list of chapters for update in 2014.

The Scientific Commission submitted comments it had received on the *Terrestrial Manual* chapters on Bluetongue and Epizootic haemorrhagic disease (EHD). There are extensive validation data for the competitive enzyme-linked immunosorbent assay (C-ELISA) for bluetongue, but considerably less data for its validation for EHD. The Commission would request that the OIE Reference Laboratory for EHD coordinate a study with the Reference Laboratories for Bluetongue to validate the C-ELISA for EHD.

At its last meeting, the Scientific Commission had referred a request to the Biological Standards Commission for an internationally agreed upon and validated polymerase chain reaction (PCR) method for African horse sickness virus (AHSV). The OIE Reference Laboratories all agreed with the principle that at present it would not be prudent to recommend a single real-time reverse-transcription PCR test for molecular diagnosis of AHSV as more work is needed to identify such a method(s). The laboratories recommended that an inter-laboratory comparison between different molecular diagnostic methods be performed before designating a specific test as ‘prescribed’. The Commission agreed with this recommendation.

8.2. Terrestrial Animal Health Standards Commission (Code Commission)

For this agenda item, the Commission was joined by the Dr Masatsugu Okita, OIE International Trade Department.

At its February 2013 meeting, the Code Commission had suggested that the OIE should nominate one of the Specialist Commissions as responsible for initiating specific categories of work and invite the other Commissions to align with it once adopted by the OIE Member Countries. Although there was agreement in principle with the Code Commission, the Biological Standards Commission noted that the Code Commission had proposed that the Scientific Commission should address the category of taxonomy. The Biological Standards Commission did not agree with this proposal as it could delay updating of certain *Terrestrial Manual* chapters. At present, issues relating to taxonomy are referred to the appropriate OIE Reference Laboratories and the Biological Standards Commission believed this is the correct action to take.

In May 2013, an updated chapter on avian influenza that had been amended to remove reference to "notifiable avian influenza" had been adopted and included in the *Terrestrial Code*. The *Terrestrial Manual* chapter was being similarly amended (see agenda item 5.1). The Code Commission would review the revised *Terrestrial Manual* chapter before it is sent for Member Country comment.

Matters from the Code Commission to the Biological Standards Commission

The Biological Standards Commission referred comments on two bee disease chapters to the experts for consideration. It also referred a question on *Trichinella* taxonomy to the OIE Reference Laboratories for advice.

Matters from the Biological Standards Commission to the Code Commission

The Biological Standards Commission requested the Code Commission's official opinion on the proposal to replace the current list of prescribed and alternative tests that can be found in both the *Terrestrial Manual* and the *Terrestrial Code* with a table in the disease-specific chapters that lists the diagnostic methods available for the disease in question alongside the purpose for which the assay has been validated (see agenda item 6.1. and Dr Vallat's welcoming address).

At its last meeting, the Code Commission had requested the Biological Standards Commission's opinion on delisting paratuberculosis. The Biological Standards Commission had consulted the OIE Reference Laboratories and concluded that the lack of an accurate diagnostic test makes diagnosis difficult in subclinically infected animals and thus the disease did not meet the listing criteria and should be delisted.

9. Matters of Interest for Information

9.1. Update on OFFLU

Prof. Steven Edwards, Chairman of OFFLU Steering Committee, updated the Commission on OFFLU – the joint OIE-FAO network of expertise on animal influenza. OFFLU is currently undergoing some changes to its managerial committees. After 8 years, Prof. Edwards will step down at the end of 2013 as founding Chairman of the OFFLU Steering Committee. He will be replaced by Dr Peter Daniels, who will take over the role from the beginning of 2014. Other new changes include the appointment of Prof. Ian Brown (UK) as a member of the Steering Committee, of Dr David Swayne (United States of America) as Chairman of the OFFLU Executive Committee, and of Dr Giovanni Cattoli (Italy) as a member of OFFLU Executive Committee. In February 2013, a WHO[3] Meeting on Vaccine Composition in the Southern Hemisphere was held in Geneva; the OFFLU network contributed 93 H5 sequences and 14 H9 sequences to help WHO in pandemic preparedness. OFFLU swine influenza virus group experts met at FAO Headquarters, Rome in April 2013 for their third annual technical meeting. The experts exchanged research findings and data on the global influenza situation in swine. In response to the emergence of novel avian influenza A(H7N9) virus in China (People's Rep. of) in March 2013, OFFLU collaborated with the public and animal health sectors for coordination, compiled laboratory algorithms, protocols and validation data for the detection and characterisation of H7N9 and posted all this information on the OFFLU website.

9.2. OIE PVS[4] Laboratory Mission Manual and potential participation by members of the BSC in PVS laboratory missions

Dr Erlacher-Vindel updated the Commission on this topic. The PVS Laboratory Mission Manual had now been completed. The Members of the Commission would be invited to participate in the training session for experts that will be organised before April 2014. Members would start to be invited as soon as the dates are available. Members of the Commission could also be invited to participate in the training of the OIE National Focal Points for Veterinary Laboratories on a regional basis.

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[3] WHO: World Health Organization

[4] PVS: Performance of Veterinary Services

9.3. FAO/WHO Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications

The Commission noted this publication.

10. Any Other Business

10.1. Work plan and activities (as of September 2013)

The updated work plan was agreed and can be found at Annex 6.

10.2. Dates of the next Biological Standards Commission meeting

The Commission noted the dates for its next two meetings: 17–21 February 2014 and 10–12 September 2014.

11. Adoption of the Report

The report was adopted by the Commission.

.../Annexes

Annex 1

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 11–12 September 2013

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. Creation of a database of former OIE designated experts: "OIE expertise"
2.4. Specific issues related to Reference Centres
2.5. Update on the template for annual reports of Collaborating Centre activities and feedback on Reference Laboratory quality management systems
2.6. Review of new and pending applications for laboratory twinning
2.7. Development of criteria to determine twining priorities for use when reviewing applications

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, 4–6 September 2013

Future *ad hoc* Groups: scheduling and drafting ToRs

3.2. *Ad hoc* Group on High Throughput Sequencing and Bioinformatics and Computational Genomics (HTS-BCG)
3.3. *Ad hoc* Group on Camelidae

4. International Standardisation/Harmonisation:

- **Diagnostic tests**

4.1. OIE Register of diagnostic tests: update and review of applications [opinion]
4.2. Standardisation programme
4.3. Prescribed tests for international trade

- **Biosafety/Biosecurity**

4.4. International Federation of Biosafety Associations statement

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

5.1. Decision on proposals of the Enlarged Bureau Group
5.2. Vaccine terminology – Proposal from Australia
5.3. OIE validation guidelines

6. Follow-up from the General Session

6.1. Excerpt from the Final Report of the 81st General Session, May 2013
6.2. *Ad hoc* Group on Shortening the Vaccine Registration Process when simply updating and Incorporating Relevant Strains in Equine Influenza Vaccines
6.3. Follow-up of the Resolution No. 18 Declaration of Global Eradication of Rinderpest and Implementation of Follow-up Measures to Maintain World Freedom from Rinderpest, adopted May 2011

7. Conferences, Workshops, Meetings

7.1. Feedback from the 1-day OIE Seminar, 7 June 2013 (theme: New approaches to diagnosis: applied genomics) held during the WAVLD, 5–8 June 2013, Berlin, Germany
7.2. Third Global Conference of the OIE Reference Centres, Seoul, Korea, 2014

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. Update on OFFLU
9.2. OIE PVS Laboratory Mission Manual and potential participation by members of the BSC in PVS laboratory missions
9.3. FAO/WHO Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications

10. Any Other Business

10.1. Work plan and activities
10.2. Dates of the next Biological Standards Commission meetings

Annex 2

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION
Paris, 11–12 September 2013

List of participants

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Annex 3

Original: English
September 2013

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

Paris, 4–6 September 2013

_____

1. Opening of the meeting

The OIE *ad hoc* Group on Biosafety and Biosecurity in Veterinary Laboratories met from 4 to 6 September 2013 at the OIE Headquarters in Paris, France. Dr Elisabeth Erlacher-Vindel, Acting Head of the Scientific and Technical Department, welcomed the participants on behalf of the Director General of the OIE, Dr Bernard Vallat.

She informed the Group that the main objective of the meeting was to review the comments received on draft Chapter 1.1.3. *Standard for managing biorisk in veterinary laboratory and animal facilities* and draft Guideline 3.5. *Biorisk analysis: biological agent-specific risk assessments* from the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual)* with the aim of finalising both documents.

2. Designation of chairperson and rapporteur and adoption of the agenda

The meeting was chaired by Dr Peter Daniels, and Dr Uwe Mueller-Doblies acted as rapporteur. The adopted Agenda and the List of Participants are presented at Appendices I and II of this report, respectively.

3. Review of the technical comments received on the proposed draft Chapter 1.1.3. *Standard for managing biorisk in veterinary laboratories and animal facilities* and draft Guideline 3.5. *Biorisk analysis: biological agent-specific risk assessments*

Technical comments had been received from OIE Member Countries and from the International Federation of Biosafety Associations (IFBA).

The Group reaffirmed that an important objective in redrafting this draft chapter was to promote and encourage the more thoughtful and appropriate approach of biorisk analysis in managing matters relating to laboratory biosafety and biosecurity. Conversely the intention was to discourage any misunderstandings that encouraged an automated approach to the management of biorisk in laboratories and animal handling facilities through a simplistic pairing of pre-ranked organisms with predefined levels of "containment".

The Group noted that most of the comments from OIE Member Countries were in agreement with this risk-based approach for managing biorisk in veterinary laboratories. However there were a number of concerns and issues raised or implicit in the feedback received that the Group discussed in detail.

1. Removal of reference to the established numeric risk group classification and biocontainment levels:

   - As facilities become more used to applying the risk control systems, facility risk communication can advance to a higher level and provide more reassurance to stakeholders than reference to containment levels of the same numeric value but with very different effective performance. The Group therefore continued to support the concept of not including agent risk group and facility biosafety levels within the document. The use of a biorisk management system as described in this draft chapter can identify an appropriate combination of controls that are commensurate with the risk

presented by biological materials and activities in a given setting. The Group attempted, in considering the Member Country comments, to identify sections of the chapter where the recommended biorisk analysis approach would benefit from a clearer form of words and made changes accordingly throughout the chapter.

2. Competence and resources required to implement the new approach may not be available in all countries or laboratories:

   - The Group noted that risk analysis approaches were used in the veterinary area more frequently and more broadly. The intention in drafting the chapter as submitted for Member Country consultation was to have the proposed risk analysis process closely aligned with the risk analysis processes adopted by OIE Member Countries for other purposes, such as for Import Risk Analyses (Chapter 2.1. of the *Terrestrial Animal Health Code*) while being consistent with approaches in the CEN[1] Workshop Agreement 15793 (CWA standard). To this end, wording similar or identical to *Terrestrial Code* Chapter 2.1, and as much as possible consistent with CWA 15793, has been adopted in the proposed *Terrestrial Manual* chapter. The Group also pointed out that documents were referenced at the end of the chapter to provide helpful guidance for this particular application of risk analysis. In its consideration of specific Member Countries comments on the draft chapter, the Group attempted to ensure that the wording used in each section would provide clarity.

3. A process for validation of individual laboratories' risk analysis is not described:

   - The risk analysis process described requires clear and complete documentation of the process and should provide the level of confidence to those seeking it. This is the basic process also required in the use of the management systems approach to quality assurance systems and associated specific activities such as test validation. The processes of documentation of an evidence-based approach to substantiation of matters relating to laboratory management should be familiar to laboratory managers.

4. The background information on which to base the risk analysis is not uniformly available (that includes information on biological material properties and on possible mitigation measures) in the OIE *Terrestrial Manual* and others scientific references:

   - For 33 disease agents, the hazardous biological properties are detailed in the technical disease cards and further relevant information can be obtained from the disease chapter in the OIE *Terrestrial Manual* and others scientific references. However, the Group acknowledges that there are gaps in the information available for many biological agents (e.g. infectious dose, environmental survival, and parameters required to quantify the consequences of a disease such as welfare implications, loss in productivity, trade restrictions). Efforts should continue to further strengthen data supporting the risk analysis process. These may include (1) expanding the technical disease cards to support the risk assessment processes at the national and facility levels; (2) improving the available data on performance and validation of alternative control measures.

5. Criteria for assessing likelihood and consequences are not sufficiently detailed:

   - The concept of risk pathways was re-emphasised to address this concern. A revised Table A will provide additional directions to Member Countries.

The Group discussed in detail all the comments received and accepted, where appropriate, proposed amendments with the overall objective of keeping the current approach that had attracted considerable Member Country support and to clarify and improve the text where other comments suggested that better clarity was required.

A summary of the Group's review of draft chapter 1.1.3. is given below.

1 European Committee for Standardisation

The Group suggested that the Biological Standards Commission include definitions of laboratory biosafety and laboratory biosecurity in the glossary of the *Terrestrial Manual* as these terms are used in the chapter but are not defined. The Group proposed the following definitions:

Laboratory biosafety describes the principles and practices for the prevention of unintentional exposure to biological materials, or their accidental release.

Laboratory biosecurity describes the controls on biological materials within laboratories, in order to prevent their loss, theft, misuse, unauthorised access, or intentional unauthorised release.

The Group noted that although the chapter was focused on biorisk associated with the manipulation of biological materials in the laboratory, as the title referred specifically to animal facilities, animals used in such facilities were also included in the scope. In this sense some research laboratories might hold and manipulate potential arthropod vectors. The Group agreed that biorisk associated with such life forms should also be considered within the scope of the chapter. Emphasis on these issues was specifically addressed in the introduction section, making it clear that this breadth of scope applies throughout the chapter. To this end the term "biological material" has been proposed throughout the chapter rather than the more narrowly defined term "agents and toxins".

As part of the overall process of making the chapter clearer and better structured wherever possible, the Group proposed moving from Section B: *Biorisk Analysis and Biorisk Management System*, that part of point 2 *Risk Assessment* that deals with resourcing and cost effectiveness of the application of the risk analysis to that part of point 3 *Risk Management* that deals with the risk management process. This change has been implemented in the current, resubmitted, draft.

Based on the comments received from a Member Country, the Group updated flow chart 1 for clarity and to be more in line with chapter 2.1. of the *Terrestrial Code* on import risk analysis.

Similarly, based on the comments received, the Group proposed revisions of tables A and B with the aim of being more comprehensive and consistent with the content of the chapter. The flow of material in table A has been standardised and more explanatory wording has been included without making the table too detailed. Table B had initially been included to give users of the chapter who were familiar with the old rankings of biocontainment facilities a point of reference. However comments indicated that the table did not sufficiently complement the risk analysis approach so a modification has been proposed that more clearly links examples of different mitigation strategies to the risk pathways that were already included in the text. The intent of table B is to provide examples of different mitigation or risk management measures that can be considered applicable to different types of risk without comprehensively including every type of strategy. Such an approach would be beyond the scope of the *Terrestrial Manual*.

In reply to comments received requesting a minimal standard for the essential requirements for all laboratory work, the Group proposed inclusion of a paragraph from the current version of chapter 1.1.3. of the *Terrestrial Manual* on biosafety and biosecurity in veterinary laboratories and animal facilities. This text was included in Section B point 3 of the newly submitted draft that has the heading "Risk Management". The Group was of the opinion that this would make the current draft a better and more useable Standard.

The Group also reviewed draft guideline 3.5. based on the OIE Member Country comments received. The changes introduced into the draft were mainly to give a better clarity to the text.

4. Finalisation of the report

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

…/Appendices

Appendix I

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

Paris, 4–6 September 2013

Agenda

1. Opening of the meeting

2. Designation of chairperson and rapporteur and adoption of the agenda

3. Review of the technical comments received on the proposed draft Chapter 1.1.3 *Standard for managing biorisk in veterinary laboratories and animal facilities* and draft Guideline 3.5 *Biorisk analysis: biological agent-specific risk assessments*

4. Finalisation of the report

Appendix II

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

Paris, 4–6 September 2013

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MEETING OF THE ENLARGED BUREAU GROUP OF THE OIE BIOLOGICAL STANDARDS COMMISSION
Paris, 10 September 2013

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

No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
1.1.3.	Standard for managing biorisk in the veterinary laboratory and animal facilities; Guideline 3.5 Managing biorisk: examples of aligning risk management strategies with assessed biorisks	**RECEIVED**	AHG has now addressed Member Country (MC) comments, approved the chapter and guideline to be sent to MCs for second-round comments	Agree
1.1.6.	Principles of veterinary vaccine production (re-write as a standard)	Collaborating Centre for Veterinary Medicinal Products has undertaken to draft the texts in collaboration with other OIE Centres working on vaccines	Awaiting text	
1.1.8.	Minimum requirements for vaccine production facilities		Awaiting text	
1.1.9.	Quality control of vaccines		Awaiting text	
1.1.10.	International standards for vaccine banks	Not yet received	Awaiting text	
2.1.3.	Bluetongue	**RECEIVED**	Approved to be sent to MCs for first-round comments	Agree. The BSC also proposed to include virus neutralisation on the list of prescribed tests
2.1.4x	Crimean–Congo haemorrhagic fever	**RECEIVED**	Chapter too human oriented; needs to be reviewed from an animal health perspective, and to include information on the situation in Europe. Authors of the *Bulletin* article are reviewing it. Awaiting text.	
2.1.6x.	Epizootic haemorrhagic disease	**RECEIVED**	Approved to be sent to MCs for first-round comments	Agree
2.1.4.	Echinococcosis/Hydatidosis	Not yet received	Awaiting text	
2.1.6.	Heartwater	Not yet received	Awaiting text	
2.1.8.	Leishmaniosis	**RECEIVED**	Approved to be sent to MCs for first-round comments	Agree
2.1.9.	Leptospirosis	**RECEIVED**	Approved to be sent to MCs for first-round comments	Agree
2.1.11.	Paratuberculosis (Johne's disease)	**RECEIVED**	Approved to be sent to MCs for first-round comments subject to clarification of some points by the authors	Agree

No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
2.1.14.	Rift Valley fever	**RECEIVED** chapter from AHG	Approved to be sent to MCs for second-round comments	Agree
2.2.1	Acarapisosis of honey bees	AHG revising bee disease chaps (coor. Ritter). Not yet received	Awaiting text	
2.2.2.	American foulbrood of honey bees	**RECEIVED**	Arrived after EBG meeting	Approved to be sent to MCs for first-round comments
2.2.3.	European foulbrood of honey bees	Not yet received	Awaiting text	
2.2.6.	*Tropilaelaps* infestation of honey bees (*Tropilaelaps* spp.)	Not yet received	Awaiting text	
2.2.7.	Varroosis of honey bees	Not yet received	Awaiting text	
2.3.5.	Avian mycoplasmosis (*M. gallisepticum, M. synoviae*)	Not yet received	Awaiting text	
2.3.3.	Avian infectious laryngotracheitis	**RECEIVED**	Approved to be sent to MCs for first-round comments	Agree
2.3.4.	Avian influenza	**RECEIVED**	Approved to be sent to MCs for first-round comments subject to clarification of some points by the authors	Agree
2.3.6.	Avian tuberculosis	**RECEIVED**	Approved to be sent to MCs for first-round comments	Agree
2.3.9.	Fowl cholera	Received diagnostic section. Awaiting vaccine section	Awaiting text	
2.3.10.	Fowl pox	Not yet received	Awaiting text	
2.3.12.	Infectious bursal disease (Gumboro disease)	Received diagnostic section. Awaiting vaccine section	Awaiting text	
2.4.2.	Bovine babesiosis	**RECEIVED**	Arrived after EBG meeting	Approved to be sent to MCs for first-round comments subject to clarification of some points by the authors. BSC also proposed to include PCR on the list of prescribed tests
2.4.5.	Bovine genital campylobacteriosis	Asked to be moved to 2014	Awaiting text	
2.4.8.	Bovine viral diarrhoea	Not yet received	Awaiting text	

No.	Chapter title	Experts' draft	EBG recommendation	BSC decision
2.4.9.	Contagious bovine pleuropneumonia	**RECEIVED**	Approved to be sent to MCs for first-round comments	Agree
2.4.16.	Theileriosis	**RECEIVED**	Approved to be sent to MCs for first-round comments	Agree
2.5.8.	Equine piroplasmosis	**RECEIVED**	Approved to be sent to MCs for first-round comments	Agree
2.5.9.	Equine rhinopneumonitis	Received diagnostic section. Awaiting vaccine section	Awaiting text	
2.6.1.	Myxomatosis	**RECEIVED**	Arrived after EBG meeting	Approved to be sent to MCs for first-round comments
2.7.6.	Contagious caprine pleuropneumonia	**RECEIVED**	Approved to be sent to MCs for first-round comments	Agree. The BSC also proposed to remove CFT from the list of prescribed tests
2.7.10.	Ovine pulmonary adenomatosis (adenocarcinoma)	**RECEIVED**	Approved to be sent to MCs for first-round comments subject to clarification of some points by the authors	Agree
2.8.3.	Classical swine fever (hog cholera)	**RECEIVED** chapter from AHG	Approved to be sent to MCs for second-round comments	Agree
2.9.1.	Bunyaviral diseases of animals (excluding Rift Valley fever)	**RECEIVED**	Approved to be sent to MCs for first-round comments subject to clarification of some points by the authors	Agree
2.9.2.	Camelpox	**RECEIVED**	Approved to be sent to MCs for first-round comments	Agree
2.9.4.	Cryptosporidiosis	**RECEIVED**	Approved to be sent to MCs for first-round comments	Agree
2.9.5.	Cysticercosis	**RECEIVED**	Approved to be sent to MCs for first-round comments	Agree
2.9.7.	*Listeria monocytogenes*	**RECEIVED**	Approved to be sent to MCs for first-round comments subject to clarification of some points by the authors	Agree
2.9.11.	Verocytotoxogenic *Escherichia coli*	Not yet received	Awaiting text	

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

No.	Chapter title	EBG recommendation	BSC decision
Validation Guideline 3.5.1	Development and optimisation of antibody detection assays	Approved to be sent to MCs for second-round comments	Agree
Validation Guideline 3.5.2	Development and optimisation of antigen detection assays	Approved to be sent to MCs for second-round comments	Agree
Validation Guideline 3.5.3	Development and optimisation of nucleic acid detection assays	Approved to be sent to MCs for second-round comments	Agree
Validation Guideline 3.5.4	Measurement uncertainty	Approved to be sent to MCs for second-round comments	Agree
Validation Guideline 3.5.5	Statistical approaches to validation	Approved to be sent to MCs for second-round comments	Agree
Validation Guideline 3.5.6	Selection and use of reference samples and panels	Approved to be sent to MCs for second-round comments	Agree
Validation Guideline 3.5.7	Principles and methods for the validation of diagnostic tests for infectious diseases applicable to wildlife	Approved to be sent to MCs for second-round comments	Agree

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

No.	Title
New chapter	Management of Veterinary Laboratories (to include sections on quality and biorisk management)
2.1.19.	Vesicular stomatitis
2.4.3.	Bovine brucellosis*
2.4.5.	Bovine genital campylobacteriosis
2.4.10.	Dermatophilosis
2.5.4.	Epizootic lymphangitis
2.7.2.	Caprine and ovine brucellosis (excluding *Brucella ovis*)*
2.7 9.	Ovine epididymitis (*Brucella ovis*)*
2.8.5.	Porcine brucellosis*
2.8.10.	Teschovirus encephalomyelitis (previously enterovirus encephalomyelitis or Teschen/Talfan disease)
2.9.10.	Toxoplasmosis

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

The following five chapters were added to this list:

1.1.7.	Tests for sterility and freedom from contamination of biological materials (2008)
2.4.7.	Bovine tuberculosis (2009)
2.8.7.	Porcine reproductive and respiratory syndrome (2010)
2.8.8.	Swine influenza (2010)
2.8.11.	Transmissible gastroenteritis (2008)
2.9.6.	Hendra and Nipah virus diseases (2010)

Remaining chapters and guidelines and date last adopted.

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

For information: chapters adopted since 2012

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

No.	Title	Year adopted
2.8.1.	African swine fever	May 2012
2.8.2.	Atrophic rhinitis of swine	May 2012
2.8.9.	Swine vesicular disease	May 2013
2.9.8.	Mange	May 2013
Guideline 3.1.	Laboratory methodologies for bacterial antimicrobial susceptibility testing	May 2012
Guideline 3.2.	Biotechnology in the diagnosis of infectious diseases	May 2012

MEETING OF THE ENLARGED BUREAU GROUP OF THE OIE

BIOLOGICAL STANDARDS COMMISSION

Paris, 10 September 2013

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

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

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

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

Paris, 10 September 2013

List of participants

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Annex 5

Proposed text

GLOSSARY OF TERMS

The definitions given below have been selected and restricted to those that are likely to be useful to users of this OIE Terrestrial Manual.

- **Thermotolerant**

The term used to describe the ability of a vaccine and/or the parent virus/strain to retain a level of infectivity after exposure to heat, that is, the delayed heat degradation of the virus. For example, for the thermotolerant I-2 Newcastle disease vaccine, it is defined by the length of time the vaccine will retain an infectivity titre sufficient to induce a protective immune response, at a particular temperature. The term "delayed heat degradation" may also be encountered, but the term "thermotolerant" is preferred. The terms "heat resistant" and "thermostable" are considered to create unrealistic expectations of a vaccine's properties and should be avoided.

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CHAPTER 1.1.6.

PRINCIPLES OF VETERINARY VACCINE PRODUCTION

STABILITY TESTS

All vaccines are sensitive to heat to some extent, but some are more sensitive than others. There is increasing interest in the development of vaccines that can tolerate adverse storage conditions. In this *Terrestrial Manual,* thermotolerant is defined as the ability of vaccine and the parent virus to retain a level of infectivity after exposure to heat, that is, the delayed heat degradation of the virus at temperatures above 8°C. It is defined by the length of time the vaccine will retain a potency sufficient to induce a protective immune response, at a particular temperature and can be applied to both killed and live vaccines.

Rationale

Australia suggests the addition of a paragraph on thermotolerant vaccines along with a definition for the term "thermotolerant" in the Glossary of the *Terrestrial Manual*. Thermostability has been used in the past in association with certain rinderpest and peste des petits ruminants vaccines. We suggest that thermotolerant would also be better term for these particular vaccines

Annex 6

BSC Work Plan: to September 2013 to February 2014

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