Organisation Mondiale de la Santé Animale | World Organisation for Animal Health | Organización Mundial de Sanidad Animal

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September 2008

REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 23–25 September 2008

The OIE Biological Standards Commission met at the OIE Headquarters from 23 to 25 September 2008. Dr Gideon Bruckner, Deputy Director General and Head of the Scientific and Technical Department, on behalf of the Director General of the OIE, welcomed the Members of the Commission, Professor Steven Edwards, President, Dr Beverly Schmitt, Vice-President, Dr Mehdi El Harrak, Secretary General, as well as the other expert participant, Dr Peter Wright. The other members of the Commission (Dr Santanu K. Bandhopadhyay and Dr Vladimir Drygin) were invited but could not attend the meeting.

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

1. OIE Reference Laboratories and Collaborating Centres

1.1. New applications for Collaborating Centre and Reference Laboratory status:

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

OIE Collaborating Centre for Biotechnology-based Diagnosis of Infectious Diseases in Veterinary Medicine
The OIE Collaborating Centre for Application of Polymerase Chain Reaction Methods for Diagnosis of Viral Diseases in Veterinary Medicine, Uppsala, Sweden, had requested to extend its mandate to include the Swedish University of Agricultural Sciences (SLU) as a partner. Dr Sándor Belak will continue to be the contact point.

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The Commission was concerned at the number of applications for OIE Reference Laboratory status in which the activities and competence of the applicant were at the level of a national Reference Laboratory but which did not demonstrate the wider support role for other OIE Member Countries that is expected of an OIE Reference Laboratory.

A proposal to establish a regional Collaborating Centre network had been received. The Commission would request a policy statement from the OIE Administrative Commission on handling such applications. The Commission would also propose that the OIE consider adopting a procedure for officially recognising Reference Laboratory networks.

1.2. Updating the list of Reference Laboratories

The OIE has been notified of the following changes of experts at OIE Reference Laboratories. The Commission recommends their acceptance:

Rinderpest and Peste des petits ruminants
Prof. Tom Barrett to replace Dr John Anderson at the Institute of Animal Health, Pirbright, United Kingdom.

Bovine tuberculosis
Prof. Glyn Hewinson to replace Dr Keith Jahans at Veterinary Laboratories Agency (VLA), Weybridge, United Kingdom.

The Commission noted that Dr Vladimir Borisov would be the new contact point at the OIE Collaborating Centre for Diagnosis and Control of Animal Diseases in Eastern Europe, Central Asia and Transcaucasia in Vladimir, Russia, replacing Prof. K.N. Gruzdev. It was also noted that Dr Claes Enøe would be the new contact point at the OIE Collaborating Centre for Research and Training in Population Animal Health Diagnosis and Surveillance Systems at the International Epilab, Danish Institute for Food and Veterinary Research, Denmark, replacing Dr Håken Vigre.

1.3. Review of twinning applications

Since launching the OIE twinning initiative in 2007, nine twinning projects between OIE Reference Laboratories or OIE Collaborating Centres and candidate laboratories in developing or transitional countries have been approved and signed off, and are either underway or due to start imminently:

1. *Italy (IZSVe) and Russia	Avian influenza and Newcastle disease
2. UK (VLA) and China	Classical swine fever and rabies
3. UK (VLA) and South Africa	Avian influenza and Newcastle disease
4. Germany (FLI) and Egypt	Avian influenza and Newcastle disease
5. Italy (Teramo) and Eritrea	Brucellosis
6. Italy (Teramo) and Botswana	Contagious bovine pleuropneumonia
7. Italy (IZSVe) and Cuba	Avian influenza and Newcastle disease
8. Italy (Teramo) and Cuba	Epidemiology
9. UK (VLA) and Turkey	Brucellosis

*The Commission noted a mid-report that had been received for this twinning project.

The OIE Biological Standards Commission approved in principle a further three full applications for a twinning project, subject to final contractual agreements:

1. Canada (NCFAD) and Colombia	Avian influenza and Newcastle disease
2. UK (IAH-Pirbright) and Morocco	African horse sickness and bluetongue
3. USA (Ames) and Brazil	Avian influenza and Newcastle disease

The Commission agreed that a pre-project assessment by the parent laboratory is essential before a project proposal can be drafted and submitted. It also agreed that the annual progress reports submitted by the twinned laboratories would be published by the OIE along the annual reports of the activities of all OIE Reference Laboratories and Collaborating Centres.

Information on all aspects of twinning can be found in the twinning guide, which is available on the OIE website (http://www.oie.int/downld/LABREF/A_Guide.pdf).

1.4. Follow-up from January – Reference Laboratories that provided a poor annual report for 2007

The Commission reviewed those laboratory reports that showed little or no OIE-related activities in 2007. If this lack of OIE-related activity continues in the 2008 reports from these laboratories, the Commission will consider removing them from the list, as is the policy for laboratories that do not submit a report for 2 consecutive years.

1.5. Follow-up from January – Review of the Mandates for OIE Reference Laboratories and Collaborating Centres: letter from Dr Gajadhar

Further to his Technical Item and the accompanying resolution adopted by the International Committee in May 2007, Dr Alvin Gajadhar had sent a letter detailing his suggestions for amendments to the mandates for OIE Reference Laboratories and Collaborating Centres. Dr Gajadhar's suggestions would be given to the external auditor who has been contracted by the OIE to review all its statutes.

2. International standardisation of diagnostic tests and vaccines

2.1. OIE standardisation programmes for diagnostic tests

Highly pathogenic avian influenza (*HPAI*) *– Coordinator: Dr P. Selleck, Australian Animal Health Laboratory* (*AAHL*)*, Geelong, Victoria, Australia*

Dr Selleck had reported that a candidate reference serum for the avian influenza (AI) AGID[1] test had been prepared and sent to the other Reference Laboratories. He is currently evaluating their results for the purpose of submitting his final evaluation report in time for the February 2009 meeting of the Commission, with a view to adopting these sera.

Enzootic bovine leukosis (*EBL*) *PCR procedure – Coordinator: Dr T. Vahlenkamp, Friedrich Loeffler Institute, Greifswald-Insel, Germany*

The Commission noted the progress report submitted by Dr Vahlenkamp on the project to develop a standard PCR[2] protocol for EBL.

Caprine and ovine brucellosis – Coordinator Mrs J. Stack, VLA Weybridge, UK

An *ad hoc* Group of all the OIE Brucellosis experts and some other experts had met at the OIE Headquarters in July to analyse the results of the interlaboratory comparison of candidate sera that had been carried out. The final report and conclusions would be submitted shortly.

Porcine brucellosis – Coordinator: Dr K. Nielsen, Canadian Food Inspection Agency, Nepean, Canada

The *ad hoc* Group (see above) had also analysed the results for the candidate sera for porcine brucellosis. The final report and conclusions would be submitted shortly.

Dourine – Coordinator: Dr Noboru Inoue, National Research Center for Protozoan Diseases, Obihiro, Hokkaido, Japan

Dr Noboru Inoue informed the Commission about a research project he planned to carry out. The Commission is always interested in research initiatives and is grateful to Dr Inoue for this information. It stressed however, that the priority for this disease is to develop internationally validated standard sera and, given that there is no clear definition of what defines an isolate of *Trypanosoma equiperdum* as distinct from other strains, a recognised standard strain that is representative of currently circulating isolates.

2.2. Bovine serum evaluation panel for the NSP[3] tests for FMD[4] diagnosis

Dr Ingrid Bergmann provided a paper on a bovine serum evaluation panel that she had had published in the *Journal of Virological Methods*. The Commission commended her on the work she had carried out in developing and evaluating this panel for the detection of antibodies against FMD viral non-caspid proteins. Dr Bergmann was encouraged to ensure that the panel be made available to OIE Member Countries. The Commission would request her to draft guidelines on the use of such a panel. These guidelines would be reviewed by the *ad hoc* Group on NSP Tests for FMD Diagnosis, before being submitted to the Commission at its next meeting.

1 AGID: agar gel immunodiffusion
2 PCR: polymerase chain reaction
3 NSP: non-structural protein
4 FMD: foot and mouth disease

2.3. Serological tests for avian influenza in ostriches: application of ELISA[5]

Dr Ilaria Capua had sent data on serological tests for avian influenza in ostriches. The Commission suggested that she try to publish this information. In the meantime, it would be sent to the author of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*) chapter with the recommendation that it be included in the revised version of the chapter.

3. List of prescribed and alternative tests

3.1. Designate a prescribed test for Newcastle disease

Following the adoption of a new chapter on Newcastle disease in the *Terrestrial Animal Health Code* (*Terrestrial Code*), the need to adopt a prescribed test for trade had come to light. Following consultation with OIE experts, the Commission recommends that virus isolation be adopted. The PCR is not suitable as not all strains can be detected using this method; the Commission would encourage the experts to further develop a PCR so that this problem can be overcome.

3.2. Alternative to the mouse potency assay for rabies.

The Commission had received a request from the United States of America to approve in principle the use of an alternative to the mouse potency assay for testing rabies vaccines. The Commission is always keen to support alternatives to animal experimentation. Following advice from the OIE experts The Commission agreed to consider an *in-vitro* assay as an alternative when sufficient validation data were submitted.

4. Expert, *Ad hoc* and Working Groups

4.1. Report of the Meeting of the *ad hoc* Group on Validation of Diagnostic Assays

The *ad hoc* Group had met in June to review and revise the validation template for submissions to the OIE test register. The Group also planned to revise the chapters on validation from the *Terrestrial Manual* by merging the two chapters into a general one on validation to which could be added appendices on certain aspects, such as validation of PCR tests, TSE tests and statistical methods, etc. The Commission approved the report, which can be found at Appendix III.

4.2. Report of the Meeting of the *ad hoc* Group on Camelidae Diseases

Dr Mehdi El Harrak, Secretary General of the Biological Standards Commission, was appointed Chairman of the *ad hoc* Group on Camelidae Diseases, which comprised six experts in total. The Group met at the OIE Headquarters in July 2008 (see Appendix IV for the report of this meeting) and discussed bacterial, parasitic and viral diseases of camelids. The diseases were divided into significant diseases, diseases for which camelids are potential pathogen carriers, and minor or non-significant diseases. A table was developed listing for each disease, the available antigen detection methods and serological tests, followed by recommendations for diagnosis and prevention. This list of diseases was divided into three categories to cover dromedary camelids, Bactrian camelids and the New World camelids (Llama and Alpaca). Regarding international trade in camelids and camelid products, the Group recommended removing dromedary from the OIE list of animals susceptible to FMD, and also establishing specific guidelines for trade in camelids and camelid products.

The Biological Standards Commission recommended that the Group identify the priority diseases for each of the three categories of camelidae so that the relevant OIE Reference Laboratories can be contacted and asked for information on the disease in camelids and availability of diagnostic tests validated for camelids. The Group's report will be transmitted to the Terrestrial Animal Health Code Commission (Code Commission) and the Table of significant diseases of Camelidae will be added to the OIE Website. There is a meeting on camelidae in 2009 in Tunisia and this would present a good opportunity to meet other experts, to exchange information and to collaborate on this topic; the OIE will be asked to send an expert to attend the meeting.

5 ELISA: enzyme-linked immunosorbent assay

Finally, the Commission recommended that an introductory chapter on Camelid diseases of significance should be drafted by the *ad hoc* group for inclusion in the *Terrestrial Manual*.

4.3. Report of the Meeting of the *ad hoc* Group on Biotechnology

The report of the meeting held from 28 to 30 August 2008 was noted and is included as Appendix V of this report. In the future, work on biotechnology would be carried out by two *ad hoc* Groups: one focused on vaccinology and the other on molecular diagnostic tests. These two Groups would be limited to a maximum of six participants and each Group would determine, during its first meeting, its working programme based on its Terms of Reference and taking into account the last report of the meeting of this *ad hoc* Group on Biotechnology. It was agreed that one member of the Biological Standards Commission should, if possible, attend the meetings of these Groups.

4.4. Report of the Meeting of the *ad hoc* Group on Brucellosis (see also item 2.1)

The *ad hoc* Group had met in July to analyse the results of the interlaboratory comparison of candidate sera that had been carried out. The Group also revised all four chapters on brucellosis from the *Terrestrial Manual*. The Group would send its final report and conclusions to the Commission for its next meeting in February 2009.

4.5. Terms of Reference for the restructured *ad hoc* Group on Non-Tsetse Transmitted Animal Trypanosomoses (NTTAT)

The Commission determined that the proposed *ad hoc* Group on NTTAT should focus on the need to clearly define these diseases and the need for better diagnostic tests.

4.6. Proposed *ad hoc* Group on vaccine purity for FMD vaccines

Dr David Paton would be asked to write the Terms of Reference for this *ad hoc* Group. He would also be asked to identify areas in the *Terrestrial Manual* chapter on FMD that he believes should be revised.

5. OIE Register of diagnostic tests

5.1. Review of the current applications

Dr François Diaz reported on the state of progress of the dossiers submitted to the OIE and currently being assessed by panels of experts.

5.2. Questions related to the OIE Test Register

Following some questions on the relation between the OIE Register and the *Terrestrial Manual*, the Commission decided to include a generic sentence in the those chapters of the *Terrestrial Manual* for which a kit has been certified by the OIE for diagnosis of the disease. This proposal would be forwarded to the Aquatic Animal Health Standards Commission so that it could consider taking the same approach in the *Manual of Diagnostic Tests for Aquatic Animals* (*Aquatic Manual*).

In response to a question on the use of the OIE logo once a kit has been certified by the OIE, the Commission agreed to update the Standard Operating Procedure. The update would be reviewed at the next meeting.

5.3. Results of a proficiency test organised by Afssa Nancy on the Bio-Rad's Platelia Rabies II kit

Dr Diaz presented to the Commission with a report submitted by Afssa Nancy on the results of a proficiency test it had organised on the Bio-Rad's Platelia Rabies II kit along with comments from Bio-Rad on these results. The proficiency test included 43 laboratories of which 31 succeeded in the test. On the basis of these two reports no conclusion on the performance of the kit can be reached; a new proficiency test could help to assess the performance of the kit with regard to reproducibility.

5.4. Information on the updated OIE Register following adoption of Resolution No. XXVII during the General Session in May 2008

Dr Diaz presented the updated version of the OIE Register, which now includes four diagnostic kits. For each diagnostic kit certified, an abstract sheet has been developed that summarises the data collected during the validation studies of these kits. The abstract sheets as well as the kit insert can be downloaded from the Register webpage on the OIE website.

6. OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*mammals, birds and bees*)

6.1. Comments on the sixth edition

The sixth edition of the *Terrestrial Manual* had been published in May and distributed to the Delegates and the OIE experts. The Commission suggested that all recipients of the sixth edition should be sent a users' questionnaire as their comments might prove useful for future editions of the *Terrestrial Manual*.

6.2. Chapters for revision this year

The Commission identified 12 chapters for immediate revision:
1. Avian influenza
2. Bluetongue
3. Bovine brucellosis
4. Bovine tuberculosis
5. Caprine and ovine brucellosis (excluding *Brucella ovis*)
6. Dourine
7. Foot and mouth disease
8. Ovine epididymitis (*Brucella ovis*)
9. Porcine brucellosis
10. Rabies
11. Scrapie
12. Turkey rhinotracheitis (vaccine section)

The authors would be contacted shortly. It is envisaged that the draft updated chapters would be sent to Member Countries and Reviewers early in 2009 such that the comments can be considered and the chapters proposed for adoption in May 2009.

6.3. Review of the list of authors and reviewers

The Commission reviewed the list for authors and reviewers for those chapters for immediate update.

6.4. IETS[6] recommendations on CBPP[7] and CCPP[8]

The Commission had received information on recommendations adopted by the IETS concerning CCPP and CBPP. The OIE experts on these diseases would be consulted for advice on whether the *Terrestrial Manual* chapters need to be revised in the light of these recommendations.

6.5. Future revisions of the *Terrestrial Manual*

The Commission suggested that each year 10–15 chapters would be identified for immediate update and proposed for adoption by the International Committee. Every 4 years a new printed edition of the *Terrestrial Manual* would be published, which would include those chapters adopted since the last edition; this means that not all chapters would necessarily be updated in the 4-yearly edition. The web version would remain the most up to date version of the *Terrestrial Manual*. The Commission welcomes comments on this suggestion.

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6 IETS: International Embryo Transfer Society
7 CBPP: contagious bovine pleuropneumonia
8 CCPP: contagious caprine pleuropneumonia

7. Liaison with other Commissions and Groups

7.1. Scientific Commission for Animal Diseases

As stated previously in this report (see item 1.1.), the Biological Standards Commission proposes that the OIE consider adopting a procedure for officially recognising Reference Laboratory networks. Should this principle be adopted by the OIE, the Commission could draw up the Mandate and Terms of Reference, and take the lead role in co-ordinating such networks, liaising with other OIE Specialist Commissions as appropriate.

7.2. Terrestrial Animal Health Standards Commission

The Code Commission had received a number of Member Country comments on proposed chapters for the *Terrestrial Code*. The Biological Standards Commission provided advice on some of the issues; for other more technical comments, the Commission sought the advice of the relevant experts. On the issue of paratuberculosis, the OIE Scientific and Technical Dept would ask an OIE expert to draft a guidance document on how to manage the disease in animals using the available diagnostic tests. The Biological Standards Commission reiterated its earlier advice on paratuberculosis, that as there are still no robust and well validated diagnostic tests, a *Terrestrial Code* chapter on paratuberculosis cannot yet be drafted.

In the light of a letter that had been received earlier in the year, which exposed Member Country confusion on the relation between the *Terrestrial Manual* and the *Terrestrial Code*, and on how to interpret these texts, Prof. Edwards agreed to draft an explanatory note for inclusion on the OIE Website.

The Commission recommends that virus isolation be adopted as a prescribed test for Newcastle disease (see Item 3.1).

Further advice was provided to the Code Commission on rabies and other lyssaviruses, following up earlier discussions (the Item 9.6 of the Report of the meeting of the Biological Standards Commission, September 2007) on the status of countries free from infection in land animals but where the virus was known to circulate in bats.

8. Any other business

8.1. Update on OFFLU[9]

Dr Keith Hamilton updated the Commission on the activities of OFFLU.

There has been significant activity in the OFFLU network during 2008. Eight OFFLU technical activities have been initiated to address pertinent issues. The OFFLU Biosafety technical activity has drafted guidelines for handling highly pathogenic avian influenza viruses in veterinary laboratories; this will be published on the OFFLU website (see Appendix VI). The OFFLU secretariat moved to OIE in January 2008 and since then has developed the website (www.offlu.net) and supported OFFLU meetings. The inaugural OFFLU annual meeting of heads of avian influenza Reference Laboratories was held in March 2008 in Paris, these meetings aim to coordinate activities of the OFFLU network – a further meeting will be held in 2009. Two OFFLU Scientists are now in place – one at VLA and one at FAO[10], Rome – they support the technical activities of OFFLU, including evaluating publicly available sequence databases and encouraging their use.

At the 76th OIE General Session held in May, a resolution on virus sharing was adopted. This demonstrated the commitment of the OIE International Committee to virus and information sharing in support of the global effort to control the disease, it was supported by OFFLU.

OFFLU continues to strengthen functional links with WHO[11].

9 OFFLU: OIE/FAO Network on Avian Influenza
10 FAO: Food and Agriculture Organization of the United Nations
11 WHO: World Health Organization

8.2. Biosafety guidelines for handling highly pathogenic avian influenza in veterinary diagnostic laboratories

Dr Beverly Schmitt presented guidelines that had been drafted by an OFFLU Technical Group on biosafety guidelines for handling highly pathogenic avian influenza in veterinary diagnostic laboratories. The Commission reviewed the guidelines and commended Dr Schmitt and the Group on its excellent work. These guidelines can be found at Appendix VI and will be presented for adoption as a text in the *Terrestrial Manual* by the International Committee in May 2009.

8.3. Second Conference for OIE Reference Laboratories and Collaborating Centres, 2010

Dr Bruckner informed the Commission that it is planned to hold the Second Conference of OIE Reference Laboratories and Collaborating Centres in 2010. The venue has yet to be decided as there is a need to hold a number of side meetings so that the experts can take the opportunity to network.

8.4. Guidelines for harmonising the labelling systems used in veterinary medicines

The Commission reviewed some draft guidelines on labelling systems. Such systems usually fall under the responsibility of national legislation. The Commission would refer these guidelines to VICH for advice.

8.5. WAVLD[12] and the OIE Symposium

The next WAVLD conference will be held in Madrid, Spain from 18 to 20 June 2009. As usual, there will be a 1-day OIE Symposium in the middle of the Conference, on 19 June. The Commission determined that the theme of this Symposium would be 'Veterinary Laboratory Networks and Networking'. The programme and speakers would be determined at the next Commission meeting.

8.6. First Meeting of National Veterinary Services Laboratories in the Americas, Panama City, Panama from 9 to 11 December 2008

The goal of this conference is to promote the coordination of national reference laboratories, liaison with OIE Reference Laboratories and the twinning concept amongst laboratories in the Americas. Members of the Commission had been invited to speak on OIE Standards and the Twinning concept.

8.7. Dates of next Biological Standards Commission meeting

The next full meeting is planned for 3–5 February 2009.

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.../Appendices

12 WAVLD: World Association of Veterinary Laboratory Diagnosticians

Appendix I

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 23–25 September 2008

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Agenda

1. OIE Reference Laboratories and Collaborating Centres
2. International Standardisation of Diagnostic Tests and Vaccines
3. List of Prescribed and Alternative Tests
4. Expert, *ad hoc* and Working Groups
5. OIE Register of diagnostic tests
6 *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
7. Liaison with other Commissions
8. Any Other Business

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MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 23–25 September 2008

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List of participants

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Appendix III

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

Paris, 3–5 June 2008

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The meeting of the OIE *ad hoc* Group on Validation of Diagnostic Assays was held at the OIE Headquarters in Paris from 3 to 5 June 2008.

The meeting was chaired by Dr Rich Jacobson, Dr Kath Webster acted as rapporteur. The Agenda and the list of participants are presented as Appendices I and II, respectively.

1. Introduction

Dr Gideon Brückner, Deputy Director General of the OIE, welcomed the members on behalf of the OIE Director General, Dr Bernard Vallat, and invited the Group to also keep in mind the discussions and proposals made related to diagnostic assays during the 1-day Symposium held in Melbourne, Australia in November 2007.

2. Assay validation – proposed future directions for the introductory chapters in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual)* and the template(s) and guidelines for the OIE validated test register

Chapter on assay validation for the OIE *Terrestrial Manual*

The Group discussed the principles of assay validation. The essential validation criteria required are virtually the same for all test types although the evaluation processes used may differ. The Group recommended a single chapter that incorporates the core principles. There are currently two chapters, 1.1.4 and 1.1.5, which separately address aspects of validation for immunological and nucleic acid detection systems. These two chapters will be merged into one chapter to reflect all the relevant aspects of validation.

To provide enhanced guidance the Group recommended the development of a series of appendices to the new chapter that will describe best practices for several different subject areas associated with test development and optimisation and test validation.

Template for the OIE validated test register

The Group discussed the core aspects of validation and agreed on the essential criteria that should be used as headings in the template and recommended that the OIE create the status of provisional approval (completion of Stage 1). This would represent the minimal acceptable criteria for entry onto the register provided that additional data would be submitted within an agreed time frame. The Group concluded that it will encourage developers to submit data that reflect situations for some diseases and/or applications where it is difficult to complete the full field validation requirement (i.e. Stages 2 and 3). This will be accomplished by completing the essential criteria of the analytical Stage 1, which has been expanded to include both a comparison with an index test on a smaller group of defined animals or populations and preliminary estimates of reproducibility among laboratories in a relatively close vicinity.

Some categories in the template have been moved to a new section: *Essential prerequisites*. The Group recommended that the template should simply request assurance from the test developer that the best practices described in new appendices to the chapter have been followed. For example, under best practices, developers will be advised to use international/national standard reagents to calibrate their assays. However, if they are not available, the test developer should prepare and describe in-house reference reagents that have been used to develop and optimise the assay. Developers should be able to provide detailed information relative to this best practice, if requested by the review committee.

The Group agreed to clarify the explanations (currently in italicised text) in the template.

In conclusion, the template has been reorganised, but the Group recommended that a single generic template be applicable to all diagnostic test types.

Guidelines

Information will be provided to test developers (in the format of guidelines developed for different test types), which will describe approaches (processes) that may be used to generate, analyse and present the required data (essential criteria). Guidelines will follow the format of the template. It was agreed that the use of examples in these guidelines should be encouraged as this aids transparency.

The Group concluded that it was not useful to have a specific guideline only for reviewers because the latter could consult the guidelines used by the submitters as they would be far more detailed and prescriptive.

If required, specific guidelines may be developed for specific diseases and applications (e.g. for TSEs, AI, FMD or other relevant diseases).

3. Progress and timetable for the future work of the *ad hoc* Group

The *ad hoc* Group will submit a new prototype template to the Biological Standards Commission (BSC) for consideration at its next meeting. The following timetable and responsibilities were proposed in order to:

- Revise Chapter 1.1.4 and meld the relevant parts of the Chapter 1.1.5: Dr Rich Jacobson in collaboration with the participants of the *ad hoc* Group and Dr Sandor Belak – first draft.

- Produce draft appendix(ces) on best practices for the merged chapter:

    1. Development and optimisation of immunological assays: Dr Axel Colling
    2. Development and optimisation of NADs: Dr Sandor Belak and Dr Kath Webster
    3. Measurement of uncertainty: Dr Axel Colling
    4. Statistical approaches to validation: Dr Ian Gardner

- Produce draft guidelines to accompany the template:

    1. Immunological-based assays (ELISA, CFT, Luminex – Ag/Ab): Dr Peter Wright and Dr Ian Gardner
    2. Nucleic acid detection assays: Dr Kath Webster, Dr Sandor Belak and Dr Ian Gardner
    3. TSE agents: Dr Kath Webster and Dr Ian Gardner

The Group recommended a follow-up meeting early in 2009 (2–4 February) to discuss the draft documentation described above. This would also present an opportunity to discuss progress directly with BSC members who will also be meeting at OIE Headquarters that week.

…/Appendices

Appendix I

REPORT OF THE FIRST MEETING OF THE OIE *AD HOC* GROUP
ON VALIDATION OF DIAGNOSTIC ASSAYS
Paris, 3 – 5 June 2008

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Agenda

1. Introduction

2. Assay validation – proposed future directions for the introductory chapters in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual)* and the template(s) and guidelines for the OIE validated test register

3. Progress and timetable for the future work of the *ad hoc* Group

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Appendix II

REPORT OF THE FIRST MEETING OF THE OIE AD HOC GROUP

ON VALIDATION OF DIAGNOSTIC ASSAYS

Paris, 3 – 5 June 2008

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List of Participants

MEMBERS

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Appendix IV

Original: English
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REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON CAMELIDAE DISEASES

Paris, 8–10 July 2008

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The *ad hoc* Group on Camelidae Diseases met at the OIE Headquarters from 8 to 10 July 2008.

Dr Gideon Brückner, Deputy Director General of the OIE, welcomed the Members on behalf of Dr Bernard Vallat, Director General of the OIE, presented the provisional agenda and explained the Terms of Reference. He emphasised that the *ad hoc* Group should focus on determining what are the most significant diseases of camelids. The *ad hoc* Group should list these diseases and describe the available diagnostic tests. In this way a quick reference guide could be developed on important camelid diseases and the available diagnostic tests that could be used when deciding if a chapter should be included in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*. The drafted text will be presented to the Biological Standards Commission.

Dr Medhi El Harrak thanked Dr Brückner for his helpful guidance and then took over as Chairman of the *ad hoc* Group. Dr Bernard Faye and Dr Mohammed Bengoumi volunteered to act as rapporteurs.

The Agenda and List of Participants are given at Appendices I and II, respectively, and the Terms of Reference at Appendix III.

Discussion

Dr Reuven Yagil, veterinarian and camel farmer, gave a short presentation on the diseases associated with camel husbandry and their physiological manifestations.

The *ad hoc* Group then discussed viral diseases of camelids. The diseases were divided into three groups: 1) Significant diseases; 2) Diseases for which camelids are potential pathogen carriers; 3) Minor or non-significant diseases. For each disease, the available antigen detection methods and serological tests were added, followed by recommendations for diagnosis and prevention. These lists of diseases were developed for the dromedary camel, the Bactrian camel and the New World camelids (Llama and Alpaca).

The *ad hoc* Group then discussed bacterial and parasitic diseases, and drafted overviews of the significant bacterial and parasitic diseases of camelids, as it had done for viral diseases. A list of abbreviations used for the different diseases was added.

The *ad hoc* Group was of the opinion that knowledge of camelid diseases is limited and that more research is necessary to elucidate the role of some of the pathogens mentioned in the epidemiology and pathogenesis of these diseases in camelids:

- Viral diseases: bluetongue, African horse sickness, Rift Valley fever, bovine viral diarrhoea, West Nile fever, herpesvirus infection, Crimean–Congo haemorrhagic fever.
- Bacterial diseases: pasteurellosis, leptospirosis, Q fever, chlamydiosis.
- Parasitic diseases: toxoplasmosis, sarcosporidiosis, trypanosomes.
- Multifactorial diseases: neonatal diarrhoea, respiratory syndrome, abortion, unknown mortalities.

Camelid susceptibility and epidemiological investigations should be carried out for the following diseases: bluetongue, Rift Valley fever, West Nile fever, bovine viral diarrhoea, pasteurellosis, leptospirosis, Q fever, toxoplasmosis.

Existing vaccines for camelpox, rabies and foot and mouth disease (used in the Bactrian camel) should be validated and, if necessary, new vaccines should be developed (see Table given at Appendix IV).

The *ad hoc* Group also made the following recommendations:

For diagnostic purposes:

- c-ELISA[1] and PCR[2] are available for some pathogens, but need to be validated for use in camelids;
- When they are not available, specific tests should be developed;
- For serological validation, there is a need for positive and negative camelid reference sera;
- For direct and indirect ELISA, commercial anti-camelid conjugate must be validated and used (Triple J Farms USA: www.kentlabs.com/triplej.html);
- OIE Reference Laboratories should develop diagnostic tests for camelid diseases where relevant;
- There is a need for specimens from camelids (dromedary, Bactrian and New World camelids): OIE should encourage Delegates from camelid-rearing countries to collect specimens to send to OIE Reference Laboratories for diagnostic test validation;
- OIE should encourage the Delegates from camelid-rearing countries, to submit applications for the designation of their national reference laboratories for camelid diseases as OIE Reference Laboratories or Collaborating Centres.

For international trade in camelids and camelid products:

- Remove the dromedary from the OIE list of foot and mouth disease susceptible animals;
- Establish specific guidelines for trade in camelids and camelid products.

For the purpose of promoting the inclusion of camelids in the scientific literature and to the international veterinary community:

- Special issue of the OIE *Scientific and Technical Review*;
- Other text books, website, etc.;
- Include camel diseases in veterinary education and professional training;
- Presentation of the recommendations of the OIE *ad hoc* Group on Camelidae Diseases at the 2nd International Conference of the International Society of Camelid Research and Development (ISOCARD) at Djerba (Tunisia), 11–14th March 2009, and at other meetings and in camel disease journals.

The Chairman thanked the Group for its insightful contributions and the very positive spirit exhibited by all participants.

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…/Appendices

1 c-ELISA: competitive enzyme-linked immunosorbent assay
2 PCR: polymerase chain reaction

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON CAMELID DISEASES

OIE Headquarters, Paris, 8 - 10 July 2008

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Agenda

1. Opening and purpose of the meeting
2. Designation of chairperson and rapporteur
3. Presentation and adoption of the Agenda and Terms of Reference
4. Short oral presentation: Overview of the main camelid diseases
5. Finalisation of the working procedure for the *ad hoc* Group
6. *Viral diseases of camelidae:*
   - Rinderpest and peste des petits ruminants; Rift Valley fever; foot and mouth disease; rabies; bluetongue; West Nile fever; bovine viral diarrhoea and border disease; infectious bovine rhinotracheitis/infectious pustular vulvovaginitis; camelpox; contagious ecthyma; Crimean–Congo haemorrhagic fever; herpesvirus infection
7. *Bacterial diseases of camelidae:*
   - brucellosis; pasteurellosis; anthrax; tuberculosis; paratuberculosis (Johnes disease); salmonellosis; chlamydia pyogenic diseases (lymphadenitis and cutaneous necrosis); glanders; plague; Q fever
8. *Protozoal diseases of camelidae:*
   - Trypanosomosis
9. Recommendations
10. Finalisation of the draft report

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Appendix II

MEETING OF THE OIE *AD HOC* GROUP ON CAMELIDAE DISEASES

Paris, 8–10 July 2008

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List of participants

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Appendix III

TERMS OF REFERENCE

1. Of the OIE listed diseases, decide which are considered significant in Camelidae (and in which species of Camelidae). This may include pathogens that cause disease in Camelidae, or pathogens of other domestic animals where Camelidae are significant carriers.

2. Identify any important infectious diseases of Camelidae that are not on the OIE List.

3. Draft a position paper for the OIE Biological Standards Commission on the diseases that have been chosen outlining the diseases and providing information on diagnostic tests suitable for use in Camelidae. The paper should indicate to what extent the tests have been validated in Camelidae. A second part of the paper should discuss the scope for control of disease in Camelidae by the use of vaccination.

4. The Biological Standards Commission would then decide whether this information is more suitable as a standalone chapter for the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, or whether it should be incorporated into the corresponding disease-specific chapters.

Appendix IV

SIGNIFICANT DISEASES OF CAMELIDAE

A) Viral diseases in camelids

Group I = Significant diseases
Group II = Diseases for which camelids are potential pathogen carriers
Group III= Minor or non-significant diseases

Dromedary camels

Diseases	Identification of the agent	Serological tests	Recommendations for diagnostic	Recommendations for prevention
Group I				
Camelpox	OIE *Terrestrial Manual* 2008, Chapter 2.9.2, Page 1177	ELISA not available VNT*	Preparation of an ELISA kit by Dr Wernery in collaboration with Dr El-Harrak for validation	Vaccination
Contagious ecthyma	TEM IHC	None	Contact with Dr Albina (CIRAD) for PCR validation on Parapox strains from different animal species	
Rabies	OIE *Terrestrial Manual* 2008, Chapter 2.1.13, Page 304	ELISA not available VNT*	Vaccination with cattle dose	Vaccination
Group II				
BT, AHS, EHD	OIE *Terrestrial Manual* 2008, Chapter 2.5.1 (AHS), Page 823; Chapter 2.1.3 (BT and EHD), Page 158	c-ELISA	Investigation of susceptibility for virulent strains and serotypes. Investigation of duration of viraemia	
RVF	OIE *Terrestrial Manual* 2008, Chapter 2.1.14, Page 323	c-ELISA VNT*	Investigation on susceptibility and duration of viraemia	
BVD	rt-PCR Virus isolation as for other ruminants OIE *Terrestrial Manual* 2008, Chapter 2.4.8, Page 698	ELISA not available VNT*	Validation of serological tests in blood and milk Investigation on susceptibility	
Group III				
West Nile fever	PCR and virus isolation OIE *Terrestrial Manual* 2008, Chapter 2.1.20, Page 377	c-ELISA	Investigation on susceptibility for the two strains	
Herpes	PCR, Virus isolation, Immunofluorescence OIE *Terrestrial Manual* 2008, Chapter 2.5.9 (EHV), Page 894; Chapter 2.4.13 (IBR), Page 752	ELISA not available VNT*	Investigation on susceptibility for EHV 1 and 4, and BHV 1 Validation of serological tests	

PPR, RP	PCR, virus isolation OIE *Terrestrial Manual* 2008, Chapter 2.7.11 (PPR) and 2.1.15 (RP), Pages 1036 and 334	c-ELISA	Investigation on susceptibility for virulent strains. Validation of PCR for PPR. Production of negative and positive sera for reference laboratories	
CCHF	Virus isolation** PCR	None	Validation of ruminant c-ELISA Serological survey	
FMD	PCR & Virus isolation OIE *Terrestrial Manual* 2008, Chapter 2.1.5, Page 190	NSP & c-ELISA	Remove dromedary from the OIE list of FMD susceptible animals	

*need to work in BSL3 level lab security; **need to work in BSL4 level lab security

Bactrian camels

Diseases	Identification of the agent	Serological tests	Recommendations for diagnostic	Recommendations for prevention
Group I				
Camelpox	OIE *Terrestrial Manual* 2008, Chapter 2.9.2, Page 1177	ELISA not available VNT*	Preparation of an ELISA kit by Dr Wernery in collaboration with Dr El-Harrak for validation	Vaccination
Contagious ecthyma	TEM IHC	None	Contact with Dr Albina (CIRAD) for PCR validation on Parapox strains from different animal species	
Rabies	OIE *Terrestrial Manual* 2008, Chapter 2.1.13, Page 304	ELISA not available VNT*	Vaccination with cattle dose	Vaccination
FMD	PCR Virus isolation OIE *Terrestrial Manual* 2008, Chapter 2.1.5, Page 190	NSP c-ELISA	Recommended test. More investigations needed (blood and milk)	Vaccination
Group II				
BT, AHS, EHD	OIE *Terrestrial Manual* 2008, Chapter 2.5.1 (AHS), Page 823; Chapter 2.1.3 (BT and EHD), Page 158	c-ELISA	Investigation on susceptibility for virulent strains and serotypes. Investigation on duration of viraemia	
RVF	PCR and virus isolation	c-ELISA VNT*	Investigation on camel susceptibility and duration of viraemia	
BVD	rt-PCR Virus isolation as for other ruminants -OIE *Terrestrial Manual* 2008, Chapter 2.4.8, Page 698	ELISA not available VNT*	Validation of serological tests in blood and milk. Investigation on camel susceptibility	

Group III				
West Nile fever	PCR and Virus isolation OIE *Terrestrial Manual* 2008, Chapter 2.1.20, Page 377	c-ELISA	Investigation on camel susceptibility for the two strains	
Herpes	PCR, Virus isolation, Immunofluorescence OIE *Terrestrial Manual* 2008, Chapter 2.5.9 (EHV), Page 894; Chapter 2.4.13 (IBR), Page 752	ELISA not available VNT*	Investigation on susceptibility for EHV 1 and 4, and BHV 1 Validation of serological tests	
PPR, RP	PCR, virus isolation OIE *Terrestrial Manual* 2008, Chapter 2.7.11 (PPR) and 2.1.15 (RP), Pages 1036 and 334	c-ELISA	Investigation on camel susceptibility for virulent strains. Validation of PCR for PPR. Production of negative and positive sera for reference laboratories	
CCHF	Virus isolation** PCR	None	Validation of ruminant c-ELISA Serological survey	

New World Camelids

Diseases	**Identification of the agent**	**Serological tests**	**Recommendations for diagnostic**	**Recommendations for prevention**
Group I				
BVD	rt-PCR Virus isolation as for other ruminants -OIE *Terrestrial Manual* 2008, Chapter 2.4.8, Page 698	ELISA not available VNT*	Validation of serological tests in blood and milk	
Contagious ecthyma	TEM IHC	None	Contact with Dr Albina (CIRAD) for PCR validation on Parapox strains from different animal species	
Rabies	OIE *Terrestrial Manual* 2008, Chapter 2.1.13, Page 304	ELISA not available. VNT*	Vaccination with cattle dose	Vaccination
Herpes	PCR, Virus isolation, Immunofluorescence OIE *Terrestrial Manual* 2008, Chapter 2.5.9 (EHV), Page 894; Chapter 2.4.13 (IBR), Page 752	ELISA not available VNT*	Investigation on susceptibility for EHV 1 and 4, and BHV 1 Validation of serological tests	
Group II				
BT, AHS, EHD	OIE *Terrestrial Manual* 2008, Chapter 2.5.1 (AHS), Page 823; Chapter 2.1.3 (BT and EHD), Page 158	c-ELISA	Investigation on susceptibility for virulent strains and serotypes Investigation on duration of viremia	
RVF	PCR and virus isolation	c-ELISA	None	

FMD	PCR Virus isolation OIE *Terrestrial Manual* 2008, Chapter 2.1.5, Page 190	NSP c-ELISA VNT*	Investigation on different susceptibility in llama and alpaca	
Equine encephalo-myelitis	PCR Virus isolation OIE *Terrestrial Manual* 2008, Chapter 2.5.5, Page 858	CF, HI, PRN	Investigation on small camelid susceptibility for virulent strains and serotypes. Investigation on duration of viraemia	
Group III				
West Nile fever and other flaviviruses	PCR and Virus isolation OIE *Terrestrial Manual* 2008, Chapter 2.1.20, Page 377	c-ELISA VNT*	Investigation on small camelid susceptibility for the two lineages	
Camelpox	OIE *Terrestrial Manual* 2008, Chapter 2.9.2, Page 1177	ELISA not available VNT*	None	
PPR, RP	PCR, virus isolation OIE *Terrestrial Manual* 2008, Chapter 2.7.11 (PPR) and 2.1.15 (RP), Pages 1036 and 334	c-ELISA	None	
CCHF	Virus isolation** PCR	None	None	

b) Bacterial diseases in camelids

Group I = Significant diseases
Group II = Diseases for which camelids are potential pathogen carriers
Group III= Minor or non-significant diseases

Dromedary camels

Diseases	**Identification of the agent**	**Serological tests**	**Recommendations for diagnostic**	**Recommendations for prevention**
Group I				
Brucellosis (*abortus* and *melitensis*)	OIE *Terrestrial Manual* 2008, Chapter 2.4.3, Page 624	CF, RBT, SAT	Validation of c-ELISA test for *B. abortus* and *B. melitensis.* Tests validation in milk. Specificity and sensitivity evaluation	Eradication of seropositive animals and vaccination according to the species (*B. abortus* or *B. melitensis*)
Tuberculosis	OIE *Terrestrial Manual* 2008, Chapter 2.4.7, Page 683	RT test	Investigation should be conducted with serological test. Need of further investigation on skin test	Eradication of positive animals after validation of the tests
Johne's disease	OIE *Terrestrial Manual* 2008, Chapter 2.1.11, Page 276	ELISA not available	Validation of serological tests in blood and milk.	Eradication of seropositive animals after validation of the tests
Anthrax	OIE *Terrestrial Manual* 2008 Chapter 2.1.1, Page 135	None	None	Vaccination in endemic area Need for vaccine field trial

Pyogenic diseases (Caseous lymphadenitis)	Isolation and typing of bacteria	None	Development of serological test for *Corynebacterium pseudotuberculosis*	Development of vaccines
Pasteurellosis (haemorrhagic scepticaemia)	OIE *Terrestrial Manual* 2008, Chapter 2.4.12, Page 739	None	Controversial data on susceptibility and aetiology. Investigation on susceptibility	Not yet
Salmonellosis	OIE *Terrestrial Manual* 2008, Chapter 2.9.9, Page 1267	None	Identification of the most prevalent biovars. Development of serological tests	Development of vaccines
Colibacillosis	OIE *Terrestrial Manual* 2008, Chapter 2.9.11, Page 1294	None	Identification of the most pathogenic biovars. Development of serological tests	Development of vaccines
Group II				
Plague (Yersiniosis)	Isolation of bacteria	None	Development of serological test	Eradication of infected animals
Leptospirosis	OIE *Terrestrial Manual* 2008, Chapter 2.1.9, Page 251	MAT	Identification of the most prevalent biovars. Investigation on susceptibility	Development of vaccines
Q fever	OIE *Terrestrial Manual* 2008, Chapter 2.1.12, Page 292	CF ELISA not available	Validation of serological tests in blood and milk. Investigation on susceptibility	Development of vaccines
Group III				
Glanders (Melioidosis)	OIE *Terrestrial Manual* 2008, Chapter 2.5.11, Page 919	CF	Validation of serological tests	Eradication of seropositive animals
Chlamydiosis	Isolation and identification of the agent	c-ELISA	Validation of serological tests	None

Bactrian camels

Diseases	**Identification of the agent**	**Serological tests**	**Recommendations for diagnostic**	**Recommendations for prevention**
Group I				
Brucellosis (*abortus* and *melitensis*)	OIE *Terrestrial Manual* 2008, Chapter 2.4.3, Page 624	CF, RBT, SAT	Validation of c-ELISA test for *B. abortus* and *B. melitensis.* Tests validation in milk. Specificity and sensitivity evaluation	Eradication of seropositive animals and vaccination according to the species (*B. abortus* or *B. melitensis*)
Tuberculosis	OIE *Terrestrial Manual* 2008, Chapter 2.4.7, Page 683	RT test	Investigation should be conducted with serological test. Need of further investigation on skin test	Eradication of positive animals after validation of the tests
Johne's disease	OIE *Terrestrial Manual* 2008, Chapter 2.1.11, Page 276	ELISA not available	Validation of serological tests in blood and milk	Eradication of seropositive animals after validation of the tests

Anthrax	OIE *Terrestrial Manual* 2008, Chapter 2.1.1, Page 135	None	None	Vaccination in endemic area Need for vaccine field trial
Pyogenic diseases (Caseous lymphadenitis)	Isolation and typing of bacteria	None	Development of serological test for *Corynebacterium pseudotuberculosis*	Development of vaccines
Pasteurellosis (haemorrhagic scepticaemia)	OIE *Terrestrial Manual* 2008, Chapter 2.4.12, Page 739	None	Controversial data on susceptibility and aetiology Investigation on susceptibility	Not yet
Salmonellosis	OIE *Terrestrial Manual* 2008, Chapter 2.9.9, Page 1267	None	Identification of the most prevalent biovars.Development of serological tests	Development of vaccines
Colibacillosis	OIE *Terrestrial Manual* 2008, Chapter 2.9.11, Page 1294	None	Identification of the most pathogenic biovars. Development of serological tests	Development of vaccines
Group II				
Plague (Yersiniosis)	Isolation of bacteria	None	Development of serological test	Eradication of infected animals
Leptospirosis	OIE *Terrestrial Manual* 2008, Chapter 2.1.9, Page 251	MAT	Identification of the most prevalent biovars. Investigation on susceptibility	Development of vaccines
Q fever	OIE *Terrestrial Manual* 2008, Chapter 2.1.12, Page 292	CF ELISA not available	Validation of serological tests in blood and milk. Investigation on susceptibility	Development of vaccines
Group III				
Glanders (Meloidosis)	OIE *Terrestrial Manual* 2008, Chapter 2.5.11, Page 919	CF	Validation of serological tests	Eradication of seropositive animals
Chlamydiosis	Isolation and identification of the agent	c-ELISA	Validation of serological tests	None

New World Camelids

Diseases	**Identification of the agent**	**Serological tests**	**Recommendations for diagnostic**	**Recommendations for prevention**
Group I				
Brucellosis *abortus* and *melitensis*	OIE *Terrestrial Manual* 2008, Chapter 2.4.3, Page 624	CF, RBT, SAT	Validation of c-ELISA test for *B. abortus* and *B. melitensis.* Tests validation in milk. Specificity and sensitivity evaluation	Control for exported animals
Tuberculosis	OIE *Terrestrial Manual* 2008, Chapter 2.4.7, Page 683	RT test	Investigation should be conducted with serological test. Need of further investigation on skin test	Eradication of positive animals after validation of the tests

Johne's disease	OIE *Terrestrial Manual* 2008, Chapter 2.1.11, Page 276	ELISA not available	Validation of serological tests in blood and milk	Eradication of seropositive animals after validation of the tests
Anthrax	OIE *Terrestrial Manual* 2008, Chapter 2.1.1, Page 135	None	None	Vaccination in endemic area Need for vaccine field trial
Pyogenic diseases (internal abcesses)	Isolation and typing of bacteria	None	Development of serological test for *Corynebacterium pseudotuberculosis*	Development of vaccines
Enterotoxaemia	Isolation and typing of bacteria	None	ELISA and PCR tests available for toxinotyping. Application to determine dominant types	Development of toxoid bacteria vaccines
Salmonellosis	OIE *Terrestrial Manual* 2008, Chapter 2.9.9, Page 1267	None	Identification of the most prevalent biovars Development of serological tests	Development of vaccines
Colibacillosis	OIE *Terrestrial Manual* 2008, Chapter 2.9.11, Page 1294	None	Identification of the most pathogenic biovars. Development of serological tests	Development of vaccines
Group II				
Leptospirosis	OIE *Terrestrial Manual* 2008,Chapter 2.1.9, Page 251	MAT	Identification of the most prevalent biovars, Investigation on susceptibility	Development of vaccines
Q fever	OIE *Terrestrial Manual* 2008, Chapter 2.1.12, Page 292	CF ELISA not available	Validation of serological tests in blood and milk. Investigation on susceptibility	Development of vaccines
Group III				
Pasteurellosis (haemorrhagic scepticaemia)	OIE *Terrestrial Manual* 2008, Chapter 2.4.12, Page 739	None	Controversial data on susceptibility and aetiology. Investigation on susceptibility	Not yet
Chlamydiosis	Isolation and identification of the agent	c-ELISA	Validation of serological tests	Not yet

c) Parasitic diseases in camelids

Group I = Significant diseases
Group II = Diseases for which camelids are potential pathogen carriers
Group III= Minor or non-significant diseases

Dromedary camels

Diseases	Identification of the agent	Serological tests	Recommendations for diagnostic	Recommendations for prevention
Group I				
Trypanosomosis	OIE *Terrestrial Manual* 2008, Chapter 2.4.8, Page 352	CATT, Indirect ELISA, c-ELISA (Neither ELISA is commercially available)	Preparation of an ELISA kit by Dr Wernery in collaboration with Dr El-Harrak and Dr Bengoumi for validation. Validation of c-ELISA from Morocco	Systematic control for trade. Treatment of positive animal (for example melarsomine)
Mange (*Sarcoptes scabiei*)	OIE *Terrestrial Manual* 2008, Chapter 2.9.8, Page 1255	c-ELISA	Identification of the parasite for differential diagnosis from other skin diseases (psoroptes, ringworm, etc.)	Quarantine and good drug for treatment Development of vaccine
Hydatidosis Echinococcosis	OIE *Terrestrial Manual* 2008, Chapter 2.1.4, Page 175	ELISA	Validation of ELISA	Treatment of the dogs. Development of vaccine
Ticks	Agent identification	None	Identification of the parasite	Development of vaccine
Cephalopinosis	Agent identification	None	Identification of the parasite	Research for new treatment
Group III				
Myasis	Agent identification	None	Identification of the parasite	Avermectines
Screw-worm	OIE *Terrestrial Manual* 2008, Chapter 2.1.10, Page 261	None	Identification of the parasite	Avermectines
Coccidiosis	Agent identification	None	Identification of the parasite. Development of serological tests and PCR	Research for new treatment and development of vaccine
Toxoplasmosis	OIE *Terrestrial Manual* 2008, Chapter 2.9.10, Page 1284	SAT ELISA	Investigation on susceptibility	None

Bactrian camels

Diseases	Identification of the agent	Serological tests	Recommendations for diagnostic	Recommendations for prevention
Group I				
Trypanosomosis	OIE *Terrestrial Manual* 2008, Chapter 2.4.8, Page 352	CATT, Indirect ELISA, c-ELISA (neither ELISA is commercially available)	Preparation of an ELISA kit by Dr Wernery in collaboration with Dr El-Harrak and Prof. Bengoumi for validation. Validation of c-ELISA from Morocco	Systematic control for trade Treatment of positive animal (for example melarsomine)

Mange (*Sarcoptes scabiei*)	OIE *Terrestrial Manual* 2008, Chapter 2.9.8, Page 1255	c-ELISA	Identification of the parasite for differential diagnosis from other skin diseases (psoroptes, ringworm, etc.)	Quarantine and good drug for treatment. Development of vaccine
Hydatidosis Echinococcosis	OIE *Terrestrial Manual* 2008, Chapter 2.1.4, Page 175	ELISA	Validation of ELISA	Treatment of the dogs. Development of vaccine
Ticks	Agent identification	None	Identification of the parasite	Development of vaccine
Group III				
Coccidiosis	Agent identification	None	Identification of the parasite. Development of serological tests and PCR	Research for new treatment and development of vaccine
Cephalopinosis	Agent identification	None	Identification of the parasite	Research for new treatment

New World Camelids

Diseases	**Identification of the agent**	**Serological tests**	**Recommendations for diagnostic**	**Recommendations for prevention**
Group I				
Mange (*Sarcoptes scabiei*)	OIE *Terrestrial Manual* 2008, Chapter 2.9.8, Page 1255	c-ELISA	Identification of the parasite for differential diagnosis from other skin diseases (psoroptes, ringworm, etc.)	Quarantine and good drug for treatment. Development of vaccine
Hydatidosis Echinococcosis	OIE *Terrestrial Manual* 2008, Chapter 2.1.4, Page 175	ELISA	Validation of ELISA	Treatment of the dogs. Development of vaccine
Ticks	Agent identification	None	Identification of the parasite	Development of vaccine
Sarcocystosis	None	ELISA	Validation of ELISA	Development of vaccine
Coccidiosis	Agent identification	None	Identification of the parasite. Development of serological tests and PCR	Research for new treatment and development of vaccine
Group III				
Trypanosomosis	OIE *Terrestrial Manual* 2008, Chapter 2.4.8, Page 352	CATT, Indirect ELISA, ELISA (neither ELISA is commercially available)	Preparation of an ELISA kit by Dr Wernery in collaboration with Dr El-Harrak and Prof. Bengoumi for validation. Validation of c-ELISA from Morocco	Systematic control for trade. Treatment of positive animal (for example melarsomine)
Neosporosis	PCR IF	ELISA	Investigation on susceptibility	Evaluation of available vaccine

List of Abbreviations:

AHS:	African horse sickness
BT:	Bluetongue
BVD:	Bovine viral diarrhoea
CCHF:	Crimean–Congo haemorrhagic fever
c-ELISA:	Competitive enzyme-linked immunosorbent assay
CF:	Complement fixation
CIRAD:	Centre de Coopération Internationale pour la Recherche Agronomique en Développement
EHD:	Epizootic haemorrhagic disease
FMD:	Foot and mouth disease
HI:	Haemagglutination inhibition
IHC:	Immunohistochemistry
MAT:	Microscopic agglutination test
NSP:	Nonstructural protein
OIE:	World Organisation for Animal Health
PPR:	Peste des petits ruminants
PRN:	Plaque reduction neutralisation
RBT:	Rose-Bengal test
rt-PCR:	Real-time polymerase chain reaction
RP:	Rinderpest
RT:	Rapid test
RVF:	Rift Valley fever
SAT:	Sero-agglutination test
TEM:	Transmission electron microscopy
Terrestrial Manual	*Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
VNT:	Virus neutralisation test

Appendix V

Original: English
August 2008

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON BIOTECHNOLOGY

Paris, 26–28 August 2008

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A meeting of the OIE *ad hoc* Group on Biotechnology was held at the OIE Headquarters in Paris from 26 to 28 August 2008. The meeting was chaired by Prof. Sándor Belak. Dr Cyril G. Gay acted as rapporteur. The Agenda and List of Participants are given at Appendices I and II, respectively. This was the last meeting of the OIE *ad hoc* Group on Biotechnology in its current format.

1. Introduction

The *ad hoc* Group on Biotechnology was welcomed by Dr Gideon Brückner, Deputy Director General, OIE, on behalf of Dr Bernard Vallat, Director General of the OIE.

Dr Brückner identified the task of the *ad hoc* Group for the current meeting:

- To discuss and propose Terms of Reference for the formation of two new *ad hoc* Groups to focus on diagnostics and vaccines related to new and emerging biotechnologies.

The *ad hoc* Group was encouraged not to focus too much of its time on background papers as its main focus should be to consider issues related to biotechnology that would eventually be adopted as chapters or guidelines for inclusion in either the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Manual Terrestrial*) or *Terrestrial Animal Health Code* (*Terrestrial Code*). However, should the information or current knowledge on a specific subject not be sufficient to guide the discussions, the Group should feel free to request a supporting background paper. The *ad hoc* Group in reviewing the Terms of Reference for the *ad hoc* Groups on diagnostics and vaccines should identify priority areas that could be developed into guidelines for OIE Members.

2. List of priority topics for future consideration by the OIE

The *ad hoc* Group discussed and agreed on the direction provided by Dr Brückner, and identified the following topics that should also be considered by the OIE.

Following an e-mail message sent in July by one member of the Group regarding cloned and transgenic animals, a detailed discussion followed. The Group resolved the following points:

- The *ad hoc* Group respects the direction set by the Biological Standards Commission, i.e. that it should focus on molecular diagnostics and vaccinology, however, the Group believes that cloned and transgenic animals should not be ignored by OIE.

- In the context of animal health, the technologies used to produce clones and transgenic animals are at the core of biotechnology.

- The development of cloning and transgenesis is currently quite advanced in various developing and developed countries. In addition, international movements to further develop these technologies are beginning to occur. Indeed, commercial ventures are now among the stakeholders attracting the attention of national regulatory bodies. Such developments have several facets including breeding traits (such as disease-resistant animals, special products for nutritional purposes [milk, meat, etc.], and novel products particularly for pharmaceutical use) or other traits.

- New breakthroughs in these technologies, such as targeted manipulation of the zygote, will increase further the number of applications.

- These reproductive biotechnologies imply inter-relationships with a number of issues ranging from traceability (see cloned livestock monitoring systems) to welfare, health, food safety, and the risks from pathogens associated with cloned and transgenic animals either as individuals or embryos. This includes, for example, transgenic animals that failed to express the targeted function but that can be numerous and susceptible to becoming a candidate for entrance to the livestock production and later the food chain.

Hence there is a clear need for IGOs[1] to develop guidelines as has been requested by the Codex Task Force, and the OIE could be the ideal organisation to do so. It is fortunate that the industry, as seen during a recent meeting of the IETS[2], holds such a view, but it needs to be further discussed and approved by the OIE.

Resolution XXVIII adopted by the International Committee during the 73rd General Session in May 2005 recommended that the OIE should consider this as a priority issue. The Group recognises that a horizontal approach is needed, involving several OIE Specialist Commissions and at least two departments of OIE. It was suggested that a horizontal *ad hoc* Group be established responsible for the many items involved with such animals either as zygotes/embryos or as living individuals.

3. Future work plan and Terms of Reference for the two proposed *ad hoc* Groups

The draft of Terms of Reference provided by the OIE was reviewed by the *ad hoc* Group.

The *ad hoc* Group recommends that the current *Terrestrial Manual* Chapter 1.1.7 Biotechnology in the diagnosis of infectious diseases and vaccine development, be separated into two new chapters, one on new and emerging diagnostic technologies that would be managed by the new *ad hoc* Group on Molecular Diagnostic Tests, and the other on vaccine technologies for innovative applications that would be managed by the new *ad hoc* Group on Vaccinology.

The new chapter on new and emerging diagnostic technologies should integrate part of Chapter 1.1.5 Validation and quality control of polymerase chain reaction (PCR) methods used for the diagnosis of infectious diseases, and the parts of chapter 1.1.7 that specifically address diagnostics.

The new chapter on vaccine technologies for innovative applications should integrate relevant information in the current chapter 1.1.7 and Chapter 1.1.8 Principles of veterinary vaccine production, as appropriate. The new chapter should initially focus on the following three applications: 1) vaccines for disease control in domestic animals; 2) vaccines for food safety; and 3) vaccines for wildlife.

Where applicable, the *Manual of Diagnostic Tests for Aquatic Animals* should reference the new chapters.

3.1. *Ad hoc* Group on Molecular Diagnostics

The *ad hoc* Group recommended that the Terms of Reference for the *ad hoc* Group on Molecular Diagnostics be as follows: develop guidelines for new technologies that have current and relevant applications for early disease detection, surveillance, and recovery from disease outbreaks to enable the transfer of these molecular diagnostic technologies to OIE Reference Laboratories and national veterinary laboratory networks.

Criteria that should be taken into consideration when determining whether a new diagnostic technology is ready and in need of an OIE guideline would be that the technology has a specific application (e.g. early detection) and that it has been validated to at lease the bench level.

1 IGO: Inter-governmental organisations
2 IETS: International Embryo Transfer Society

The following new molecular diagnostic methodologies were identified:

Direct diagnostic assays

- PCR-based assays
  - Real time;
  - Rapid detection in a disease outbreak;
  - Multiplex;
  - PCR robotics.
- Isothermal amplification assays;
- Microarray technologies;
- Rapid sequencing technologies, phylogenic analysis/bioinformatics;
- Genomic technologies to determine virulence;
- Complete full length genome sequencing technologies;
- Pen-side test technologies (lateral flow devices);
- Portable PCR technologies for field use;
- Nanotechnology;
- Proximity ligation technologies;
- *In-situ* hybridisation;
- Proteomics (detection of proteins).

Indirect diagnostic test (antibody-based assays)

- Bioluminometry;
- Fluorescence polarisation;
- Chemoluminescence technologies;
- Biosensors;
- Biomarkers;
- Recombinant proteins;
- Synthetic proteins;
- Improved monoclonals for enzyme-linked immunosorbent assays (ELISA).

Applications of these new molecular diagnostics include, but are not limited to, the following: 1) disease surveillance; 2) early detection; 3) detection during an outbreak; 4) detection during the recovery phase (to regain OIE disease-free status); 5) molecular epidemiological investigations; 6) implementation of DIVA[3] strategies.

In addition, these technologies will have important applications in the identification of clinical parameters for use in animal production and animal welfare, such as phenotypes (including non-infectious diseases), physiological conditions, and genotypes.

The *ad hoc* Group identified the priority topics that will benefit from guidelines by experts on the *ad hoc* Group on molecular diagnostics:

a) Early detection and identification

- PCR-based technologies
  - Issues:
    - Strategies to identify the most appropriate sequences for the purpose intended;
    - Positive results and test interpretation.
- Isothermal nucleic acid detection technologies
  - Issues:
    - Instrumentation;
    - Further development is required;
    - Positive results and test interpretation;
    - Bench and field validation is required.

3 DIVA: Differentiating infected from vaccinated animals

- Microarrays
  - Issues:
    - Instrumentation;
    - Further development is required;
    - Positive results and test interpretation;
    - Reproducibility;
    - Increase detection sensitivity;
    - Bench and field validation is required.
- Nanotechnologies
  - Issues:
    - Nanoparticle residues in *in vivo* diagnostic testing;
    - Characterisation of the nanomaterial;
    - Instrumentation.
- Rapid sequencing technologies
  - Issues:
    - Instrumentation;
    - Sample information;
    - Building genome databases;
    - Data processing (validation of software);
    - Sharing sequencing data;
    - Harmonisation of data.
- Complete full-length genome sequencing technologies (e.g. metagenomics for previously unidentified and emerging pathogens)
  - Issues:
    - Instrumentation;
    - Sample information;
    - Data processing;
    - Bioinformatics.

b) DIVA diagnostics

- Improved monoclonals and recombinant proteins
  - Issues:
    - Sensitivity;
    - Specificity;
    - Link with vaccine discovery to identify appropriate markers;
    - Field validation.
- PCR-based technologies
  - Issues:
    - Identification of unique sequences to differentiate live vaccine strains from wild-type pathogens;
    - Field validation.

c) Rapid detection in the field (pen-side of flock-side tests)

- Pen-side test technologies (lateral flow devices)
  - Issues:
    - Sensitivity;
    - Specificity;
    - Detection range.
- Portable PCR technologies for field use
  - Issues:
    - Field validation;
    - DIVA applications.
- Isothermal technologies
  - See above.

d) Molecular epidemiology for tracing routes of infections

- Rapid sequencing technologies, phylogenic analysis/bioinformatics
  - Issues:
    - Identification of useful sequences;
    - Identification of correct samples;
    - Data processing.

3.2. *Ad hoc* Group on Vaccinology

The *ad hoc* Group recommended that the Terms of Reference for the *ad hoc* Group on Vaccinology, which would include the use of various types of vaccines and their implications for animal and public health, be as follows: to develop guidelines for new vaccines that have been specifically designed for disease control, food safety, and wildlife, including all aspects of efficacy, potency, safety, and purity (i.e. quality) as well as the risk assessment of the release of biotechnology-derived vaccines and the food derived from animals vaccinated with these vaccines.

Criteria that should be taken into consideration when determining whether a vaccine technology is ready and in need of an OIE guideline are those technologies that have achieved proof-of-concept in a target host animal species and sufficient published information is available.

Where applicable, the *ad hoc* Group on Vaccinology should take into consideration guidelines from relevant international standard-setting bodies.

The following vaccine technologies were identified as needing new or improved guidelines:

- DNA vaccines (completed);
- Reverse genetics;
- Chimerics;
- Gene-deleted vaccines;
- Marker vaccine technologies (DIVA vaccines);
- Recombinant vectors;
- Virus like particles;
- Nanotechnology (nanoemulsions);
- Adjuvant formulations for targeted immune responses.

The *ad hoc* Group identified the priority topics that will benefit from these new technologies and recommended the preparation of the following guidelines by experts on the *ad hoc* Group on Vaccinology:

Vaccines for disease control

- Prevention of pathogen transmission;
- DIVA vaccines;
- Delivery systems for mass immunisation;
- Onset of immunity;
- Duration of immunity;
- Cross-protection.

Vaccines for food safety

- Efficacy in carrier hosts (e.g. *Escherichia coli* 0157 in cattle);
- Acceptable standards of efficacy specific for the food safety issues;
- Acceptable potency standards.

Vaccines for use in wildlife worldwide

1. Classical swine fever;
2. Brucellosis;
3. Tuberculosis;
4. Porcine reproductive and respiratory syndrome (PRRS);

5. Rabbit haemorrhagic disease;
6. Rabies;
7. Immunocastration;
8. The needs are not limited to the above diseases.

4. Review and discussion of drafts of background papers

4.1. Transgenic animal technologies in farm animals

The Group completed a background document on transgenic farm animals authored by Dr Harpreet Kochhar, which could form the basis for a future document on animal health issues associated with this biotechnology (i.e. transgenesis).

4.2. Appendix entitled "Animal Health Guidelines for Transgenic Animals" inclusion in Part 3 of the *Terrestrial Animal Health Code*

No document was presented for review. The Group discussed the possibility of preparing a guideline depending on the review by the OIE of the recommendations in Item 2 above.

4.3. Other background papers as planned at the November 2007 meeting

Reference is made to the November 2007 Report of the *ad hoc* Group on Biotechnology and the proposed list of guidelines and background papers. The Group offered to prepare any of the documents that do not fall under the scope of the new *ad hoc* Groups on Molecular Diagnostics and Vaccinology as OIE sees fit.

5. Other Issues

5.1. Follow-up from the International Symposium on 'Animal Genomics for Animal Health

The proceedings of the Symposium were published in August 2008 and include a Report and 'Roadmap' with recommendations as endorsed by the *ad hoc* Group on Biotechnology. The recommendations include many of the aspects that will be affected by genomics, such as therapeutics (RNA-based technologies), transgenic animals (disease-resistant traits), marker-assisted selection of animals with desirable health and production traits, selection of good responders to vaccination, etc.

At the last meeting, the *ad hoc* Group endorsed the development of a 'Roadmap' and recommendations to advance the use of animal genomics to improve animal health and animal welfare.

The *ad hoc* Group also recommended that a second International Symposium on Animal Genomics for Animal Health be held to review the progress made with the 'Roadmap' and to facilitate future progress.

The *ad hoc* Group requested OIE guidance on how best to progress the 'Roadmap'.

5.2. Emerging technologies

Increasingly emerging technologies are being used in the area of therapeutics; for example, nanocarbon molecules are being used to target drugs to specific areas of the body. Once the pharmacological effect has been achieved, the residual nanoparticles must be absorbed or excreted. This may evolve as an area of concern in food-producing animals.

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…/Appendices

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON BIOTECHNOLOGY

Paris, 26–28 August 2008

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Agenda

1. Introduction

2. List of priority topics for future consideration by the OIE

3. Future work plan and Terms of Reference for the two proposed *ad hoc* Groups:

3.1. *Ad hoc* Group on Molecular Diagnostics

3.2. *Ad hoc* Group on Vaccinology

4. Review and discussion of drafts of background papers

4.1. Transgenic animal technologies in farm animals

4.2. Appendix entitled "Animal Health Guidelines for Transgenic Animals" inclusion in Part 3 of the *Terrestrial Animal Health Code*

4.3. Other background papers as planned at the November 2007 meeting

5. Other issues

5.1. Follow-up from the International Symposium on 'Animal Genomics for Animal Health

5.2. Emerging Technologies

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Appendix II

MEETING OF THE OIE *AD HOC* GROUP ON BIOTECHNOLOGY

Paris, 26–28 August 2008

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World Organisation for Animal Health (OIE) Biosafety Guidelines for Handling Highly Pathogenic Avian Influenza Viruses in Veterinary Diagnostic Laboratories

The spread of highly pathogenic H5N1 avian influenza throughout Asia, Africa and Europe has led to an increase in the number of laboratories performing diagnostics for this pathogen. Highly pathogenic avian influenza (HPAI) is a serious threat to birds and mortality is often 100% in susceptible chickens. In addition, the agent can also pose a serious zoonotic threat, with over 50% mortality reported in humans. In recognition of the need for guidance on how to handle HPAI viruses safely, the OIE has established the following biocontainment level guidelines for handling specimens that may contain HPAI virus. They are based on biosafety guidelines published in the OIE *Terrestrial Manual* (1) and the World Health Organization (2).

HPAI samples that are tested using the following techniques can be processed using the OIE containment level for group 2 pathogens:

- Polymerase chain reaction (PCR)
- Antigen-capture assays
- Serology

Virus isolation and identification procedures for handling specimens that may contain HPAI should be performed at the OIE containment level for group 3 or group 4 pathogens, and the following procedures should be followed:

- Personnel protective equipment should be worn, including solid-front laboratory coats, gloves, safety glasses and respirators with a 95% efficiency.
- Specimens from potentially infected birds or animals should only be processed in type II or type III biological safety cabinets (BSC).
- Necropsies of birds should be performed in a Type II BSC while wearing respiratory protection, such as a N95 respirator or in a Type III biological safety cabinet.
- Centrifugation should be performed in sealed centrifuge cups.
- Centrifugation rotors should be opened and unloaded in a BSC.
- Work surfaces and equipment should be decontaminated after specimen processing.
- Contaminated materials should be decontaminated by autoclaving or disinfection before disposal or should be incinerated.

If chickens or other birds are inoculated with HPAI viruses, it should be done in a containment level for group 4 pathogens and the following procedures should be followed:

- Inoculated chickens should be held in isolation cages.
- Cages should be in a separate facility that is equipped to handle containment level for group 3 pathogens.
- The room should be under negative pressure to the outside and the cages should be under negative pressure to the room.
- Cages should have HEPA-filtered inlet and exhaust air.
- Biosafety cabinet should be available in the animal facility to perform post-mortem examinations and to collect specimens.

References

1. World Organisation for Animal Health (OIE) (2008). Chapter 1.1.2 Biosafety and biosecurity in the veterinary microbiology laboratory and animal facilities. *In:* Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, OIE, Paris, France, 15–26. http://www.oie.int/eng/normes/en_mmanual.htm

2. World Health Organisation (WHO) (2005). WHO laboratory biosafety guidelines for handling specimens suspected of containing avian influenza A virus, 12 January 2005. WHO, Geneva, Switzerland.