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

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September 2010

REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 14–16 September 2010

The OIE Biological Standards Commission met at the OIE Headquarters from 14 to 16 September 2010. Dr Kazuaki Miyagishima, Head of the OIE Scientific and Technical Department, welcomed the Members of the Commission, Prof. Vincenzo Caporale, President, Dr Beverly Schmitt, Vice-President, Dr Mehdi El Harrak, Secretary General, and Dr Alejandro Schudel, Dr Chen Hualan, Dr Paul Townsend, Members of the Commission, and as well as the expert participants: Dr Adama Diallo from FAO/IAEA[1], and Dr Peter Wright, Canada; and an invited observer, Dr Benaouda Kadra, Hungary.

This meeting of the Biological Standards Commission received certain policy guidance from the OIE Council, which met from 13 to 15 September, at which Professor Caporale was invited to present the view of the Biological Standards Commission.

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

1. OIE Reference Laboratories and Collaborating Centres

1.1. Designation of OIE Reference Laboratories and Collaborating Centres

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

OIE Reference Laboratory for Swine influenza
National Veterinary Services Laboratories, 1920 Dayton Ave, Ames, IA 50010, UNITED STATES OF AMERICA
Tel: (+1-515) 337.75.51; Fax: (+1-515) 337.73.48; E-mail sabrina.l.swenson@aphis.usda
Designated Reference Expert: Dr Sabrina L. Swenson

OIE Reference Laboratory for Foot and mouth disease
Lanzhou Veterinary Research Institute, CAAS, National Foot and Mouth Disease Reference Laboratory, Xujiaping No.1, Yanchangpu, Lanzhou, Gansu province 730046, CHINA (PEOPLE'S REPUBLIC OF)
Tel: (+86-931) 834.25.85; Fax: (+86-931) 834.09.77; (+86-931) 834.20.52; E-mail hnxiangtao@hotmail.com
Designated Reference Expert: Dr Xiangtao Liu

OIE Reference Laboratory for Equine infectious anaemia
Laboratory of Equine Infectious Anemia, Harbin Veterinary Research Institute of Chinese Academy of Agricultural Sciences, 427 Maduan Street, Harbin 150001, CHINA (PEOPLE'S REPUBLIC OF)
Tel: (+86-189) 46.06.61.24; Fax: (+86-451) 82.73.31.32; E-mail: jianhua_uc@126.com
Designated Reference Expert: Dr Jianhua Zhou

1 FAO/IAEA: Food and Agriculture Organization of the United Nations/International Atomic Energy Agency

An application had been received for an OIE Reference Laboratory for rabies at Kansas State University in the USA. The Commission recalled that the USA was already hosting an OIE Reference Laboratory for this disease. The OIE Council, which met during the same week, had given direction, and the Biological Standards Commission agreed, that from now on there should only be one OIE Reference Laboratory for a given disease in a country. With this decree in mind, the Delegate of the USA would be asked to find a solution to this situation.

A laboratory in India had sent an application for an OIE Reference Laboratory for Bovine viral diarrhoea. Although the application revealed a high level of expertise, and scientific and technical excellence in the work being done at the institute, it did not include information on the laboratory's international activities. As the principal role of an OIE Reference Laboratory is to provide its services globally, the institute would be asked to provide information on its international activities and how it could fulfil the mandate of an OIE Reference Laboratory.

An application had been received for two OIE Reference Laboratories, one for Anaplasmosis and one for Babesiosis, in Mexico. The Commission agreed to seek further information about the institution. A decision on this application was postponed until the next meeting of the Commission.

The Commission reviewed again the application for an OIE Reference Laboratory for Porcine Cysticercosis in the USA. The application emphasised the laboratory's work on human diseases. The Commission agreed that the expert should be asked to provide more information on her work on *Taenia solium* infections in non-human mammals.

An application had been received for two OIE Reference Laboratories, one for Equine influenza and one for Equine rhinopneumonitis, in Germany. Similar to the application from the USA for a laboratory for porcine cysticercosis, the proposed expert was not a veterinarian. Before reaching a decision, the Commission would seek assurance that the teams working at the laboratories have the veterinary competence to sustain their role as an OIE Reference Laboratory. A decision on this application was postponed until the next meeting of the Commission.

Due to a shortage of time, the Commission postponed its decision on the applications for OIE Reference Laboratories for Bovine anaplasmosis and Piroplasmosis (Bovine babesiosis) in Italy until its next session.

In regard to the general approach to evaluating applications, the Commission noted the request of the OIE Council that the Biological Standards Commission develop objective criteria to assess and select applications for Reference Laboratories and Collaborating Centres, document these criteria and apply them in a consistent manner. In the case of Reference Laboratories, due emphasis should be given to the existence of peer-reviewed articles by the proposed specialist on the pathogen or disease under consideration. Flexibility should be exercised in appreciating the guarantees given in terms of legal and budgetary provisions, as many governments and governmental entities are bound to operate on a yearly budget. The same criteria should be used by the Aquatic Animals Commission if applicable.

1.2. Review of annual reports of Reference Laboratory/Collaborating Centre activities for 2009

At the previous meeting in January, Prof. Steven Edwards, the Consultant Editor of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*), had been asked to assist the Commission by analysing the annual reports of OIE Reference Laboratory and Collaborating Centre activities. On completion of this task, Prof. Edwards had written a report on some of his observations. He noted that there is variation in the amount of detail given in response to some of the questions in the report template, and that certain questions are interpreted differently and sometimes incorrectly by some of the laboratories. The Commission undertook to clarify the explanatory notes that are given with each question in the template so as to resolve these issues.

The Commission also noted the request of the OIE Council to implement the 4-year re-designation scheme for Reference Laboratories and Collaborating Centres, in an effective, practicable and sustainable manner. Objective criteria were needed and should be documented. In addition to the assessment of their annual reports, site visits to Laboratories and Centres could also be arranged, where necessary.

1.3. Changes of experts in the List of Reference Laboratories and Collaborating Centres

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

African horse sickness, Bluetongue, Lumpy skin disease, Sheep pox and goat pox, and Rift Valley fever
Dr Baratang Alison Lubisi to replace Dr Truuske Gerdes at the Onderstepoort Veterinary Institute, South Africa.

Bluetongue and African horse sickness
Dr Chris Oura to replace Prof. Philip Mellor at the Institute for Animal Health, Pirbright Laboratory, UK.

Three other nominations had been received for replacement experts who were not veterinarians. While noting the view of the OIE Council that the designated OIE experts did not always have to be veterinarians if they had good technical knowledge and experience, the Commission held the view that OIE Reference Laboratories must demonstrate that they possess the veterinary competence to sustain their role as an OIE Reference Laboratory for a specific disease. These proposed experts would be requested to provide further information on the composition of the teams in which they work to ensure that they include veterinary pathologists, disease experts, etc.

1.4. Review of new and pending applications for laboratory twinning

Dr Keith Hamilton gave an update on the Twinning Programme. The Commission reiterated that efforts should be made to meet regional priorities and to synergise laboratory twinning and networking. It was agreed that because OIE Laboratory Twinning has multiple objectives, the Secretariat would provide a criteria-based guiding tool to assist the Commission in reviewing future twinning proposals.

The Commission reviewed six OIE Laboratory Twinning proposals and agreed that the technical principle for the following proposals was sound: Ireland with the People's Republic of China (equine influenza); Italy with Vietnam (animal salmonellosis); Italy with Tunisia (bluetongue); and Italy with Namibia (food safety). The Commission had not had enough time to fully review a proposal for twinning between Italy and Tunisia for food safety. However, based a preliminary review, the Commission sought assurances that none of the laboratories in the Tunisian Institute have ISO accreditation. If this is the case the Commission asked that the project proposal explicitly state that one of the measurable outputs of the twinning project is the accreditation of relevant tests in the Food Safety Laboratory at the Tunisian Institute to the ISO17025 standard**.** The Commission also sought clarification on a twinning proposal between UK and Egypt for bovine viral diarrhoea virus. The Commission felt that the impact of this disease in the region needed to be highlighted along with the reasons and benefits of building capacity for several ruminant viral diseases.

1.5. Identification of twinning projects for audit and review

Three twinning projects that have either been completed or are underway were randomly selected by Commission members for independent financial and technical audit. The three that were selected for audit are UK with Turkey (brucellosis); Italy with Eritrea (brucellosis), and South Africa with Nigeria (rabies). The OIE Headquarters would soon initiate audit missions.

2. *Ad hoc* Groups

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

2.1 Report of the Meeting of the *ad hoc* Group on the Scientific Partnerships among OIE Reference Laboratories and Collaborating Centres

The Commission reviewed the report of the Meeting of the *ad hoc* Group on the Scientific Partnerships among OIE Reference Laboratories and Collaborating Centres and made further amendments to Appendix IV on the Mandate and Internal Rules for OIE Reference Laboratories. The report had also been reviewed by the OIE Council. The Council did not agree with the view expressed in the following paragraph from the *ad hoc* Group report:

> "The Group felt strongly that being an OIE Reference Laboratory implies a commitment that would be in conflict with membership in laboratory networks belonging to other international organisations, and such overlapping membership should therefore be avoided; collaboration and partnerships between organisations that consist of sharing of resources and assets is however, strongly recommended."

Instead, the Council supported an approach whereby FAO is invited to designate its Reference Centres from among the OIE Reference Laboratories and Collaborating Centres to avoid non-OIE Reference Laboratories being recognised by FAO, and a dialogue between FAO and OIE be maintained to harmonise, where possible, selection criteria and operating procedures regarding reference centres between the two Organisations.

The *ad hoc* Group had recommended that OIE Reference Laboratories be mandated to provide a number of services including the following:

- to develop and validate new procedures for diagnosis and control of the designated pathogens, diseases;

The Council had proposed to delete the words "and control" in the above to emphasise that the core mandate of OIE Reference Laboratories should focus on diagnosis of pathogen or disease. The Commission disagreed with this deletion.

The present Mandate for OIE Reference Laboratories allows for laboratories to be designated for a disease or a topic. The Council proposed deleting the reference to "a topic", again as OIE Reference Laboratories should focus on diagnosis of pathogen or disease. The Commission agreed to this amendment and necessary changes were made throughout the document for consistency. Should the World Assembly adopt the amended Mandate and Internal Rules, existing OIE Reference Laboratories that were designated for a topic would be asked if they agree to have their designation changed to that of OIE Collaborating Centre. No new laboratories would be designated for a topic.

Furthermore, the Commission agreed that establishing and maintaining of a network of laboratories, if there were more than one laboratory for the same pathogen or disease, should be part of the obligations of OIE Reference Laboratories.

In line with the guidance given by the Council, the Commission agreed to amend the "Guidelines for Applicants for Designation as OIE Reference Laboratory" to enable full and consistent evaluation of the nominated specialist, based on documented proofs.

The report of the *ad hoc* Group can be found at Appendix III of this report; comments on the appendices of this report, i.e. on proposed changes to the Mandate and Internal Rules for OIE Reference Laboratories, are welcome. As the Mandate and Internal Rules for OIE Reference Laboratories were integral part to the Basic Texts of the OIE, their amendments would be formally proposed by the OIE Council for adoption by the World Assembly of Delegates in May 2011.

The Commission decided to convene a second meeting of the *ad hoc* Group to review the Mandate and Internal Rules for OIE Collaborating Centres as well as criteria to be used for the selection of Members' applications for new Reference Laboratories and Collaborating Centres. The Commission also agreed to ask the Director General to entrust to the same *ad hoc* Group the task of drafting a form to be used when sending sample to OIE Reference Laboratories (material transfer agreements).

2.2. Report of the Second Meeting of the *ad hoc* Group on Diseases of Camelids

Dr Mehdi El Harrak briefed the Commission on the second meeting of this *ad hoc* Group, for which he was the chairman. In this meeting, the Group continued its work on updating the list of diseases of interest for camelids and identifying for each of these diseases the need for validated diagnostic test methods, vaccines and research. The Group discussed and agreed on the need to set up a network of laboratories for diseases of camelids with the main objective of exchanging information and of validating diagnostic tests that were currently used for the significant diseases in species other than camelids, for all the different species of camelids. Finally the Group reviewed the list of the disease-specific chapters in the *Terrestrial Manual* to identify the chapters of concern for camelids and enhancing, where relevant, these chapters by including specific requirements for camelids.

The Commission indicated that as the test methods were not yet validated for camelids, it was premature to include them in the *Terrestrial Manual* and that the network of laboratories should prioritise the issue of validating diagnostic methods for diseases of camelids. The report of the *ad hoc* Group can be found at Appendix IV of this report.

■ Proposed *ad hoc* Groups: prioritisation of work and draft ToRs

2.3. *Ad hoc* Group on the Quality of Foot and Mouth Disease Vaccines

The Commission agreed that the Terms of Reference for the proposed *ad hoc* Group on the Quality of Foot and Mouth Disease Vaccines would be to review Section C (vaccine matching tests) and Section D (requirements for vaccines and diagnostic biologicals) of Chapter 2.1.5 "Foot and Mouth Disease" of the *Terrestrial Manual* with the aim of providing the quality characteristics of FMD vaccines for different species and according to the requirements of the *Terrestrial Animal Health Code* (safety, potency, purity, etc.). A proposal was made that observers from the vaccine manufacturing industry be invited to ensure a thorough review.

2.4. *Ad hoc* Group on Diagnostic Tests Related to New and Emerging Technologies

The Commission decided to ask one of the OIE experts from the network of Collaborating Centres to review Chapter 1.1.7 "Biotechnology in the Diagnosis of Infectious Diseases and Vaccine Development" of the *Terrestrial Manual* with the aim of advising the Commission on whether or not it was necessary to convene an *ad hoc* Group on Diagnostic Tests Related to New and Emerging Technologies, to update the chapter.

3 International Standardisation/Harmonisation

■ Diagnostic tests

3.1. Progress on the on-going standardisation programmes for reagents

The Commission noted written reports on the following standardisation programmes:

- Highly pathogenic avian influenza (HPAI), project to prepare standard sera for use in the AGID[2] test; Coordinator: Dr P. Selleck, Australian Animal Health Laboratory (AAHL), Geelong, Victoria, Australia;
- Rabies, project to produce weak positive and negative OIE Standard Sera for the FAVN[3] test for rabies; Coordinator Dr A. Fooks, VLA Weybridge, UK;
- Rabies, production of a second set of OIE Standard Sera for rabies to replace the first set; Coordinator Dr F. Cliquet, Anses Nancy, France;
- Enzootic bovine leukosis (EBL), project to develop a standard PCR[4] protocol; Coordinator: Dr T. Vahlenkamp, Friedrich Loeffler Institute, Greifswald-Insel, Germany;

2 AGID: agar gel immunodiffusion
3 FAVN: fluorescent antibody virus neutralisation
4 PCR: polymerase chain reaction

Further information would be sought on the methods used to develop the sera and on evaluation of ring tests with the other OIE Reference Laboratories for the same diseases.

In follow-up to the last meeting when Prof. Caporale resolved to end the impasse encountered in the project to develop internationally validated standard sera for dourine testing, he informed the Commission that he had now received positive reference serum for the CFT[5] from Prof. Yurov at the OIE Reference Laboratory. The sera would be tested in collaboration with OIE Reference Laboratories and other laboratories.

Prof. Caporale pointed out that the data sheet that had been provided for the OIE International Standards anti-*Brucella melitensis* sera (ISaBmS) was difficult to understand. Once the sentence referring to the Rose Bengal plate agglutination test was deleted, along with the corresponding lines in the expected results table, the necessary clarification would be provided. This amendment would need to be shared with the publication unit of the OIE, which would publish a paper on these sera shortly.

3.2. Review of the list of Prescribed and Alternative Tests, including new application

At its last meeting, the Commission had decided to forward a dossier from the Canadian Food Inspection Agency, Ottawa Laboratory, entitled Application for Certification of a Monoclonal Antibody-Based Antigen Capture ELISA for Detection of *Campylobacter fetus* in Preputial Washings and Other Diagnostic Samples, to a validation expert and the OIE Designated disease expert for their opinion. If the test has been developed as a kit, the Commission agreed to propose that the laboratory consider sending an application for the diagnostic kit, through the OIE Procedure for validation and certification of diagnostic assays, to be evaluated for possible inclusion in the OIE Register of Diagnostic Tests. If the test had been developed as a new test method and not in kit form, the OIE expert and author of the *Terrestrial Manual* chapter on Bovine genital campylobacteriosis would be asked to consider whether it should be included in the *Terrestrial Manual.*

3.3. OIE Register of diagnostic tests: review of applications; discussion on possible improvements

An update on the applications submitted to the OIE Procedure for validation and certification of diagnostic assays was provided. The Commission was informed that one application had been fully evaluated and the final report of the panel of experts had been forwarded to the Commission for consideration. Taking into account this report and the original dossier, and some discussion, the Commission decided not to propose adoption of this diagnostic kit by the World Assembly. An official letter would be sent to inform the applicant of this decision, indicating the possibility for the applicant to appeal it.

One application was still being reviewed; the final report of the panel of experts would be available at the next meeting in February 2011. Another application would shortly be received for the reassessment of the rabies kit that had been certified by the World Assembly in May 2007; each diagnostic kit included in the OIE Register is subject to a reassessment every 5 years.

3.4. Letter from India re: FPA[6] and brucellosis

A letter had been received from a laboratory in India asking if *Brucella abortus* strain 99 could be used for the preparation of FPA antigen. Following consultation with all the OIE Reference Experts on Brucellosis, the Commission concluded that strain 99 could indeed be used. This information would be included in the *Terrestrial Manual* chapter on Bovine brucellosis.

4. *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 CFT: complement fixation test
6 FPA: Fluorescence polarisation assay

4.1. Production time table, Group of experts

During the General Session in May 2010, one Delegate had commented that the *Terrestrial Manual* production and management procedures were not transparent. To address this issue and to improve production standards, the Commission reviewed and approved a revised production schedule. This new time table provided for sending the amended chapters for comment a second time prior to the General Session such that the Delegates would receive the texts that will be proposed for adoption and eventual publication. This implied that the production cycle for a new or revised chapter would be extended to 18–24 months, which was similar to the *Terrestrial Code*.

The *Terrestrial Manual* was now in its seventh edition, and there was still several inconsistencies among the chapters in terms of the content and detail provided in each section. In addition, the level of validation of the tests described was not always known. The Commission agreed that the Consultant Editor would go through the contents of the current edition and provide a preliminary report on problem areas to the Commission, including clarification of which are the prescribed tests and that these have all been validated according to the procedure described in the *Terrestrial Manual*. The President of the Commission indicated that it was difficult to accept the existence of alternative tests in the absence of a corresponding prescribed one. The Commission agreed that the matter should be addressed.

The Consultant Editor's preliminary report would assist the Commission and the Consultant Editor to improve the quality of the information given in the *Terrestrial Manual* and to harmonise the contents across chapters. To accomplish this task, a new mechanism should be created to support the Consultant Editor. This matter being under the mandate of the OIE Director General, it will be discussed with him during the next meeting of the Commission so that a decision can be reached. It should remain the role of the Commission to approve all the chapters before submission to the World Assembly.

4.2. Review of chapters proposed for adoption in May 2011 before they are sent to Members

The Commission was reminded that of the 19 draft chapters that were circulated for comment last year, 17 were adopted by the World Assembly in May 2010. The remaining two were the chapters on rabies and on African horse sickness. The Rabies chapter had received a large number of comments, and these would be sent to the author and all the other OIE Reference Experts for rabies, to obtain a consensus view. The African horse sickness chapter had been heavily amended by the *ad hoc* Group on African horse sickness. The author would be requested to send assurances that the proposed new tests have been validated to OIE standards. Should the amended texts be received and approved by the Commission at its next meeting, they would be circulated a second time for Member comments.

The Consultant Editor had a small number of general comments left over from last year's mailing on which he sought the Commission's views. A suggestion that a section entitled "the View of Vaccine Manufacturers" be added to Chapter 1.1.7a. "The Application of Biotechnology to the Development of Veterinary Vaccines" was rejected as the *ad hoc* Group responsible for drafting that chapter had consulted industry partners while developing the chapter. A comment that there is little mention of *Trypanosoma evansi* (surra) disease in dogs was referred to the *ad hoc* Group on Diagnostic Tests for Trypanosomoses. Despite overlap and duplication, it was decided not to create a new chapter on capripox infections but to leave as two separate chapters the chapters on Lumpy skin disease and Sheep pox and goat pox. Finally, detailed comments on the chapter on porcine reproductive and respiratory syndrome were referred to the authors of the chapter.

4.3. Review of author/reviewer list

This item was postponed to the next meeting of the Commission.

4.4. Selection of chapters for proposal in May 2012

See item 4.2 above.

4.5. Seventh edition, due to be published in 2012

The Commission noted that the next paper edition of the *Terrestrial Manual* would be published at the end of 2012 so as to include any chapters that are adopted in May of that year.

5. Resolutions

The Commission noted Resolution No. 24 on the draft *Terrestrial Manual* chapters that had been adopted at the General Session in May 2010. A similar resolution would be proposed in May 2011 should the two chapters mentioned in item 4.2 above be ready.

6. Biosafety/biosecurity

6.1. Work on a roadmap for OIE guidance on biosafety/biosecurity of veterinary laboratories

For this agenda item, the Commission was joined by Dr Nicoletta Previsani of the WHO[7].

The Commission identified the benefit of developing OIE guidance on biosafety and on biosecurity of veterinary laboratories, starting with biosafety, i.e. the safety veterinary laboratory personnel. Dr Previsani explained that although the WHO had been organising workshops on biosafety and biosecurity, to which the OIE was regularly invited to participate, there were no adopted WHO standards on biosafety or biosecurity, mainly due to the divergence in national legislation and regulations. A few years before, the European Committee for Standardisation had published a workshop agreement and this was often used by laboratories undergoing internal audits. Dr Schmitt, who had chaired an OIE *ad hoc* Group on Biosafety and Biosecurity, expressed the view that because of different approaches and conditions and testing purposes and even terminology, drafting a global harmonised biosafety standard would be a difficult task. The *ad hoc* Group had written an introductory chapter on this topic, which was found in the *Terrestrial Manual* (Chapter 1.1.2. - Biosafety and Biosecurity in the Veterinary Microbiology Laboratory and Animal Facilities) in which all the different approaches were considered.

Given the volume and diversity of material currently being used (national health and safety regulations, risk assessments etc.), it was agreed that some international standards were desirable. The Commission agreed to request the Director General of the OIE to re-convene the *ad hoc* Group to review relevant existing documents with the aim of proposing them for adoption by the OIE or of adapting them to OIE Standards. Dr Previsani stated that the WHO would collaborate on this project; the WHO was already involved in training, education, competence and awareness raising in several developing countries and countries in transition economy.

The Commission noted that the OIE Collaborating Centre for Veterinary Training, Epidemiology, Food Safety and Animal Welfare in Teramo, Italy is working on a training programme on biosafety in veterinary laboratories in collaboration with WHO. It was agreed that the output of this work could be of interest when developing a definition of OIE biosafety standards.

6.2. Other international initiatives on biosafety, biosecurity, biocontainment, etc.

The Commission examined a number of documents from a selection of different regional and global groups working on and organising meetings on biosafety, biosecurity, biocontainment, etc. The Commission agreed that the OIE with its structure and democratic processes was well placed to develop international standards on these topics in relation to veterinary laboratories.

7 WHO: World Health Organization

7. Conferences, Workshops, Meetings

7.1. Second Global Conference for OIE Reference Laboratories and Collaborating Centres, 21–23 June 2010, OIE Headquarters

The Second Global Conference for OIE Reference Laboratories and Collaborating Centres, which had been held earlier in the year, was deemed to be a success. All the power point presentations that had been given by the participants were now available on line along with the adopted recommendations. The Commission noted that Recommendation No. 15 stated that:

> *The Director General of the OIE encourages OIE Member Countries to consider, when evaluating laboratories, to include an evaluation of activities as an OIE Reference Laboratory so as to officially recognise these activities.*

The Commission expanded on this and suggested developing a PVS (Performance of Veterinary Services) tool to evaluate veterinary laboratories, including OIE Reference Laboratories, either as a separate programme or as part of a PVS mission.

7.2. Participation of the OIE in the OIE/FAO/IAEA Consultants meeting to develop a roadmap for the implementation of modern OIE principles and methods of diagnostic test validation

Dr François Diaz briefly updated the Commission on the outcome of the Consultants meeting, which had taken place in the IAEA Headquarters (Vienna) from 6 to 9 September 2010. Dr Mehdi El Harrak participated in the meeting on behalf of the Biological Standards Commission. The OIE *ad hoc* Group on Validation of Diagnostic Assays had made a significant technical contribution to this meeting as well as the subsequent roadmap and training materials. Once finalised, the meeting report would be provided to the Commission, which could then decide on follow-up actions as appropriate.

7.3. Update on OFFLU

Dr Keith Hamilton provided an update on OFFLU, the joint OIE-FAO network of expertise on animal influenzas. OFFLU continued to grow in terms of scope – now actively engaging experts from avian, equine, swine and companion animal influenza networks – and geographical representation. The OIE twinning programme continued to be an important means of expanding the geographical scope of OFFLU with nine projects for avian influenza underway or complete. OFFLU continued to deliver concrete outputs including an OFFLU animal influenza surveillance strategy document. Ten OFFLU technical activities (small working groups) continued to address pertinent influenza related technical issues and several joint OFFLU-WHO technical projects were due to be initiated. The link with WHO remained strong and WHO was looking to OFFLU as a key source of information on animal influenza viruses; OFFLU was regularly participating in the WHO vaccine strain selection meetings, WHO PCR working group, and WHO working group on nomenclature. FAO were leading OFFLU projects in Egypt and Indonesia to provide advice on selection of viral strains for vaccines to protect against H5N1 HPAI. Dr David Swayne had joined the OIE on a one-year secondment to review global avian influenza control measures with a focus on vaccines. The annual OFFLU technical meeting would take place at FAO Headquarters in November 2010.

8. Liaison with other Commissions

8.1. Scientific Commission for Animal Diseases

Requests for consideration/noting by the Biological Standards Commission:

The Scientific Commission had requested that the OIE Scientific and Technical Department enquire, via the Biological Standards Commission, of the OIE *ad hoc* Group on Diseases of Camelids, the feasibility and need for a specific chapter in the *Terrestrial Code* on Brucellosis in camelids and to advise the Scientific Commission accordingly. The Biological Standards Commission requested that the OIE Headquarters put this enquiry directly to the OIE *ad hoc* Group on Diseases of Camelids.

A number of other requests and enquiries had been made by the Scientific Commission to the Biological Standards Commission. Given that the primary responsibility for diagnostics lies with the Biological Standards Commission and that many of the *ad hoc* Groups convened under the authority of the Scientific Commission often also consider diagnostic aspects of disease due to close relations between the diagnostics and the control of disease, the Biological Standards Commission requested the OIE Headquarters to inform its members in advance of a meeting of an *ad hoc* Group when the Group might touch on the area of diagnostics. This would facilitate coordination between the two Commissions with due regard to their respective mandate. Likewise, the Scientific Commission should be informed in advance of any work been carried out by the Biological Standards Commission that would have implications to its work.

The Biological Standards Commission considered that the subject of diagnostic tests for diseases of wildlife fell within its remit rather than that of the Scientific Commission. Consequently, any *ad hoc* Group convened to study the issue should report to the Biological Standards Commission.

9. Matters of Interest for Information

9.1. VICH[8] Conference

Dr Elisabeth Erlacher-Vindel updated the Commission on the VICH Conference that had been held at the OIE Headquarters immediately following the Second Conference for OIE Reference Laboratories and Collaborating Centres in June 2010. The Director General of the OIE had agreed to host this meeting at the OIE Headquarters in an attempt to keep non-VICH member countries informed of the activities of VICH. One major barrier that became apparent at the Conference was that VICH did not have an established mechanism to integrate non-member countries in its work; the OIE would maintain a dialogue with VICH to find ways to enlarge the scope of VICH work and its country participation.

9.2. Analysis of the WHO/OIE/FAO/IAEA questionnaire on Laboratory Quality Standards and External Quality Assessment Schemes (EQAS)

Dr François Diaz updated the Commission on the analysis of replies received to this questionnaire. The Second report on the elaboration of a database from the Global Survey of Laboratory Quality Standards and External Quality Assessment Schemes would be provided to Commission members.

The Commission noted that more and more OIE Reference Laboratories were accredited to ISO 17025. The secretariat from the OIE Headquarters emphasised that the OIE Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases was a useful tool for use as a specific interpretation of the ISO standard for veterinary laboratories.

9.3. Training of focal points on veterinary products

The Commission noted that the OIE was carrying out training of national focal points in different regions. The aim of the training on veterinary products was to provide guidance to the focal points on what information they need to provide to their Delegates and what feedback they need to send to the OIE. The training also assisted in increasing awareness on VICH and its activities. The OIE Collaborating Centre for Veterinary Medicinal Products would continue to participate in this programme.

10. Other Business

10.1. Standards/Guidelines on needle and vaccine vials waste

The OIE had received a query asking if the OIE had standards or guideline on how to dispose of used needles and vaccine vials on the farm. The Commission felt that this was a very specific topic that would best be addressed in a training course whose programme could be developed by the *ad hoc* Group on Biosafety (see item 6.1).

8 VICH: International Co-operation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

10.2. Other matters – communication from Argentina

The OIE Reference Laboratory for FMD in Argentina had expressed the difficulty it was experiencing in receiving samples and materials and its willingness to better collaborate with other laboratories in the region given its competence and status as an OIE Reference Laboratory. The Commission considered that the *Ad hoc* Group on the Quality of Foot and Mouth Disease Vaccines (see item 2.3 above) would be able to address some of the issues raised in the communication, such as vaccine matching. The President declared that a mission to the region would be of use to understand better the situation that could become a difficult one if not addressed in a timely fashion.

10.3. Dates of the next Biological Standards Commission meeting

The Commission noted that the tentative dates for its next meeting (8–10 February 2011) pending confirmation in due course.

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.../Appendices

Appendix I

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 14–16 September 2010

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Agenda

1. OIE Reference Laboratories and Collaborating Centres

1.1. Designation of OIE Reference Laboratories and Collaborating Centres
1.2. Review of annual reports of Reference Laboratory/Collaborating Centre activities for 2009
1.3. Changes of experts in the List of Reference Laboratories and Collaborating Centres
1.4. Review of new and pending applications for laboratory twinning
1.5. Identification of twinning projects for audit and review

2. *Ad hoc* Groups

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

2.1 Report of the Meeting of the *ad hoc* Group on the Scientific Partnerships among OIE Reference Laboratories and Collaborating Centres
2.2. Report of the second Meeting of the *ad hoc* Group on Diseases of Camelids

Proposed *ad hoc* Groups: prioritisation of work and draft ToRs

2.3. *Ad hoc* Group on the Quality of FMD Vaccines
2.4. *Ad hoc* Group on Diagnostic Tests Related to New and Emerging Technologies

3 International Standardisation/Harmonisation:

a) Diagnostic tests

3.1. Progress on the ongoing standardisation programmes for reagents
3.2. Review of the list of Prescribed and Alternative Tests, including new application
3.3. OIE Register of diagnostic tests: review of applications; discussion on possible improvements
3.4. Letter from India re: FPA and brucellosis

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

4.1. Production time table, proposed *ad hoc* Group of experts
4.2. Review of chapters proposed for adoption in May 2011 before they are sent to Members
4.3. Review of author/reviewer list
4.4. Selection of chapters for proposal in May 2012
4.5. Seventh edition, due to be published in 2012

5. Resolutions

6. Biosafety/biosecurity

6.1. Work on a roadmap for OIE guidance on biosafety/biosecurity of veterinary laboratories
6.2. Other international initiatives on biosafety, biosecurity, biocontainment, etc.

7. Conferences, Workshops, Meetings

7.1. Second Global Conference for OIE Reference Laboratories and Collaborating Centres, 21–23 June 2010, OIE Headquarters
7.2. Participation of the OIE in the OIE/FAO/IAEA Consultants meeting to develop a roadmap for the implementation of modern OIE principles and methods of diagnostic test validation
7.3. Update on OFFLU

8. Liaison with other Commissions

8.1. Scientific Commission for Animal Diseases

Requests for consideration/noting by the Biological Standards Commission

9. Matters of Interest for Information

9.1. VICH Conference
9.2. Analysis of the WHO/OIE/FAO/IAEA questionnaire on Laboratory Quality Standards and External Quality Assessment Schemes (EQAS)
9.3. Training of focal points on veterinary products

10. Other Business

10.1. Standards/Guidelines on needle and vaccine vials waste
10.2. Other matters – communication from Argentina
10.3. Dates of the next Biological Standards Commission meeting

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 14–16 September 2010

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Appendix III

Original: English
May 2010

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

Paris, 6–7 May 2010

1. Opening and adoption of the Agenda

The meeting of the OIE *ad hoc* Group on the Scientific Partnerships among OIE Reference Laboratories and Collaborating Centres was held from 6 to 7 May 2010, at the OIE Headquarters in Paris. The participants were welcomed by Dr Bernard Vallat, Director General of the OIE, and Dr Kazuaki Miyagishima, Deputy Director General of the OIE and Head of the OIE Scientific and Technical Department.

Dr Vallat stated that the main purpose of this *ad hoc* Group was to act as a 'think-tank' to reflect on how to maintain and improve the quality of OIE Reference Laboratories and Collaborating Centres. Given the large number of existing laboratories and centres, and the growing number of new applications, the OIE needed a new approach and a quality control policy. The Group was asked to review the mandate and internal rules for OIE Reference Laboratories and Collaborating Centres to clarify procedures, roles and commitments, bearing in mind the need to maintain some flexibility.

Prof. Vincenzo Caporale, President of the Biological Standards Commission, pointed out that there were currently (to May 2010) 186 Reference Laboratories with 158 experts covering 100 diseases or topics in 36 countries, but that there was insufficient networking between those laboratories.

The meeting was chaired by Prof. Caporale; Dr Alf-Eckbert Füssel was appointed Rapporteur.

The agenda for the meeting was adopted with the understanding that the present meeting should concentrate its discussion on Agenda Item 3 – Mandates and Rules for OIE Reference Laboratories and Collaborating Centres. The agenda and list of members of the *ad hoc* Group and other participants are given in Appendices I and II.

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

The Terms of Reference were adopted with one amendment; the Terms as agreed upon are given at Appendix III.

3. Mandates and Rules for OIE Reference Laboratories and Collaborating Centres

The Group considered various ways to amend existing procedural documents, such as the Guidelines for Applicants for Designation as an OIE Reference Laboratory, and the Mandate and Internal Rules for OIE Reference Laboratories so as to update the documents, clarify obligations and streamline the process for designation, operation and evaluation of activities. The proposed amendments to these documents are found at Appendix IV.

The Group decided to start working on relevant provisions for Reference Laboratories and to deal with Collaborating Centres separately at its next meeting.

The Group wished to highlight the following aspects:

1. Once recognised by the OIE, a Reference Laboratory should provide its services at the global level;

2. The laboratory should be designated only when necessary legal and budgetary provisions are in place to ensure its sustainability;

3. Designating more than one OIE Reference Laboratory for the same pathogen, disease or topic in the same country should be avoided;

4. The OIE needs to set priorities regarding the designation of OIE Reference Laboratories, taking into account the preferences and needs of the regions, in order to ensure sustainability. The preferred way to support OIE Reference Laboratories is to closely involve them in surveillance, monitoring, control and eradication activities, including those initiated by other international organisations. However, the OIE also has obligations to designate an OIE Reference Laboratory for each of the listed diseases, and 17 diseases have yet to be covered;

5. Designation as an OIE Reference Laboratory should only be upon receipt of the commitment of both the OIE Delegate (Chief Veterinary Officer) and the Director of the laboratory to fulfil the Mandate;

6. OIE could either develop a specific tool similar to the "PVS" tool for monitoring and evaluating activities of OIE Reference Laboratories or integrate laboratory aspects into the existing PVS;

7. OIE Reference Laboratories must comply with Chapter 1.1.3 Quality management in veterinary testing laboratories of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*. OIE Reference Laboratories should either be accredited or should be able to provide their quality manual, including reports of proficiency testing that they have participated in, as documented proof;

8. OIE Reference Laboratories should operate according to biosafety and biosecurity standards relevant for the pathogen, disease or topic concerned, in accordance with Chapter 1.1.2 of the *Terrestrial Manual*.

The Group felt strongly that being an OIE Reference Laboratory implies a commitment that would be in conflict with membership in laboratory networks belonging to other international organisations, and such overlapping membership should therefore be avoided; collaboration and partnerships between organisations that consist of sharing of resources and assets is however, strongly recommended.[1]

To review the mandate and internal rules for Collaborating Centres, it was proposed to schedule the next Meeting of the *ad hoc* Group from 31 August to 1 September 2010 at the OIE Headquarters in Paris, pending confirmation.

4. Other Agenda Items

The Group did not address other Items as had been agreed when adopting the Agenda.

5. Adoption of report

Due to time limitation, the Group could not adopt its report during the session. It was agreed to finalise the report by correspondence.

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…/Appendices

1 NB: the OIE Council did not agree with this view of the *ad hoc* Group (September 2010).

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON
THE SCIENTIFIC PARTNERSHIPS AMONG
OIE REFERENCE LABORATORIES AND COLLABORATING CENTRES
Paris, 6–7 May 2010

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Provisional Agenda

1. Opening, Designation of Chair and Rapporteur, Adoption of Agenda
2. Consideration of draft Terms of Reference for the meeting
3. Mandates and Rules for OIE Reference Laboratories and Collaborating Centres
   - Review and propose update, if necessary
4. Assessment of the need for and approaches to scientific partnerships among laboratories
   - Clarify objectives, expected outcomes and incentives
5. Management of scientific partnerships among Laboratories and Collaborating Centres
   - Provide written guidance on leadership, reporting, membership and good practice
6. Any other business
7. Adoption of report

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Appendix II

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

Paris, 6–7 May 2010

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Appendix III

TERMS OF REFERENCE OF THE *AD HOC* GROUP

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

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

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

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Appendix IV

REFERENCE LABORATORIES

MANDATE

The principal mandate of Reference Laboratories of the World Organisation for Animal Health (OIE) is [~~shall have as their principal mandate~~]:

- to function as world reference [~~a~~] centres of expertise on [~~and standardisation for a~~] designated pathogens and [~~, or~~] diseases [~~or topics~~];
- to use, promote and disseminate diagnostic methods validated according to OIE Standards;
- to develop reference material in accordance with OIE requirements, and implement and promote the application of OIE Standards;
- to store and distribute to national laboratories biological reference products and any other reagents used in the diagnosis and control of the designated pathogens and [~~, or~~] diseases [~~or topics~~];
- to develop and validate new procedures for diagnosis and control of the designated pathogens and [~~, or~~] diseases [~~or topics~~];
- to gather, process, analyse and disseminate epizootiological data relevant to their speciality;
- to place expert consultants at the disposal of the OIE.

Reference Laboratories of the OIE shall:

- respect the intellectual property rights on samples received and not use those results, without consent, for purposes other than determining the principal characteristics of the pathogen necessary for the country of origin to carry out an epidemiological inquiry and to decide about its control strategy;
- establish and maintain a network with other OIE Reference Laboratories designated for the same pathogen and disease and organise regular inter-laboratory proficiency testing to ensure comparability of results;
- in the case of results that are confirmed positive for any OIE listed disease, immediately inform the OIE Delegate of the Member from which the samples originated as well as the OIE Headquarters;

If requested, OIE Reference Laboratories should [~~They may also contribute to~~]:

- provide [~~provision of~~] scientific and technical training for personnel from OIE Members;
- recommend the prescribed and alternative tests or vaccines;
- provide [~~provision of~~] diagnostic testing facilities, and scientific and technical advice on disease control measures to Members:

[~~In the case of results that are confirmed positive for diseases that are reportable to OIE, the Reference Laboratory should immediately inform the OIE Delegate of the Member from which the samples originated as well as the OIE Headquarters;~~]

- organise [~~organisation of and~~] or participate in scientific meetings on behalf of the OIE;

- coordinate [~~coordination of~~] scientific and technical studies in collaboration with other laboratories or organisations;

- organise inter-laboratory proficiency testing with laboratories other than OIE Reference Laboratories for the same pathogen and disease to ensure equivalence of results;

- publish [~~publication~~] and disseminate [~~dissemination of~~] any information in their sphere of competence that may be useful to OIE Members.

REFERENCE LABORATORIES

INTERNAL RULES

Article 1

Applications for the title of Reference Laboratory of the OIE shall be submitted to the Director General by the Delegate of the Member to which the laboratory belongs [~~or by the corresponding Regional Commission~~].

Article 2

Applications received shall be presented by the Director General, after consultation with the Biological Standards Commission or the Aquatic Animal Health Standards Commission, as appropriate, to the Council at its annual meetings. Applications shall be selected solely on the basis of scientific and technical competence of the candidate establishment, in particular its commitment to its sustainable operation as an 'OIE Reference Laboratory' and the excellence of the proposed specialist.

Article 3

Applications endorsed by the Council shall be presented to the World Assembly of Delegates of the OIE for approval.

Article 4

The Director General shall notify the OIE Delegate of the Member in which the approved laboratory is situated and the Head of the approved laboratory upon the designation as an 'OIE Reference Laboratory'.

Article 5

This notification shall confer on the laboratory the right to use the title 'OIE Reference Laboratory' and the OIE emblem on all documents issued by the laboratory in its official capacity [~~and the right of the designated specialist within the laboratory to use the title of OIE Expert~~].

Article 5bis

The Head of the laboratory shall be responsible for the overall implementation of the Mandate.

Article 6

The specialist proposed by the laboratory may, after the approval by the Biological Standards Commission or the Aquatic Animal Health Standards Commission, as appropriate, use the title of "OIE Expert".

Article 6bis

The OIE Expert is responsible for the implementation of the technical aspects of the Mandate and is subject to the [~~OIE Experts exercise their function within the~~] "rules applicable to OIE Experts".

Article 7

The rights conferred by Article 5 [~~upon a laboratory~~] and by Article 6 [~~an expert~~] require full compliance with the Mandate of an OIE Reference Laboratory. [~~within the limits of facilities available, and~~] The Laboratory shall provide [~~provision of~~] a brief report of activities as an OIE Reference Laboratory, according to the template established by the OIE Headquarters, at the end of each calendar year [~~of their mandate~~]. A copy of this report will be made available [~~distributed~~] to all OIE Members.

Article 7bis

The OIE Reference Laboratory shall maintain a system of quality assurance, biosafety and biosecurity relevant for the pathogen and the disease concerned.

Article 8

The designation shall be withdrawn if the Laboratory fails to comply with the provisions of the Mandate and the present rules. In such case [~~valid for four years, at the end of which~~] the Director General of the OIE, after consulting the Biological Standards Commission or the Aquatic Animal Health Standards Commission, as appropriate, [~~may~~] proposes the withdrawal to the Assembly[~~that it be renewed by either party~~].

The Laboratory may revoke the designation at any time.

Article 9

Any major change within the Laboratory or in relation to budgetary and legal provisions applicable to it that may impair its competence (particularly the departure of a designated expert) shall be reported immediately to the Director General of the OIE.

GUIDELINES FOR APPLICANTS FOR DESIGNATION AS OIE REFERENCE LABORATORY

1. Name of expert (an [~~a brief~~] informal curriculum vitae and documented proof of international recognition for his/her expertise, e.g. publications in peer-reviewed journals, awards, membership in high-profile academic boards, should be included).

2. Name and address of laboratory (telephone and fax numbers, e-mail address, Web site).

3. Name of the Head of laboratory (Responsible Official) [~~Director~~].

3a. Relevant legal and budgetary provisions in place that provide assurance on the sustainability and functioning of the laboratory.

4. Experience in diagnostic testing for the disease according to the OIE Standards (approximate number of tests performed annually for each technique).

5. Additional expertise in diagnostic techniques [~~the disease~~] (agent characterisation techniques, molecular techniques, monoclonal antibody techniques, etc.), epidemiology and control of the disease.

6. Experience in standardisation and validation of diagnostic tests.

7. Reagent production capability (provide details of current stock of reagents for the disease).

8. Capability for timely international shipment and receipt of samples in accordance with the requirements for postage and packaging of biological materials described in [~~Chapter 1.1.1. of~~] the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals,* [~~Sixth Edition, 2008~~] and the OIE *Terrestrial Animal Health Code* or the OIE *Aquatic Animal Health Code.*

8a. Guarantees to ensure that staff respect the confidential nature of certain subjects, results or communications

9. Current and completed research and methods development projects on the disease, including a list of relevant publications.

10. Training and consultation experience for the disease in the last two years (courses provided, number of people trained, examples of international consultation).

11. Contribution to the preparation or reviewing of reference documents (chapters for the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, OIE *Manual of Diagnostic Tests for Aquatic Animals*, disease cards, etc.).

Appendix IV

Original: English
May 2010

REPORT OF THE SECOND MEETING OF THE OIE *AD HOC* GROUP ON DISEASES OF CAMELIDS

Paris, 3–5 May 2010

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1. Opening and purpose of the meeting

The second meeting of the OIE *ad hoc* Group on Diseases of Camelids was held in Paris from 3 to 5 May 2010. Dr Kazuaki Miyagishima, Deputy Director General of the OIE and Head of the Scientific and Technical Department, welcomed the participants. He emphasised the strategic importance for the OIE and its Biological Standards Commission to address diseases of camelids, and mentioned that, for this second meeting, the Group would have to continue its work on important issues such as determining priority diseases, setting up a network of laboratories for diseases of camelids and enhancing, where relevant, the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*) by including specific requirements for camelids.

2. Designation of chairperson and rapporteur

The meeting was chaired by Dr Mehdi El Harrak, and Dr Bernard Faye acted as rapporteur.

3. Adoption of the Agenda and Terms of Reference

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

4. Updating of the list of diseases of interest for Camelids drafted during the first meeting of the *ad hoc* Group

During the Second ISOCARD[1] Conference held in Djerba, Tunisia, in March 2009, the list proposed by the *ad hoc* Group during its first meeting in July 2008 had been presented by Dr El Harrak. Proposals were made by some participants of the Group to complete this list. Since the first meeting, a lot of new data had also been collected. This second meeting provided an opportunity to update the list of diseases of interest for camelids.

The updated list of diseases is presented in Appendix IV. The major discussion and changes are summarised below:

The diseases were still presented in a list divided into three categories: Viral diseases, Bacterial diseases and Parasitic and Fungal diseases (this last category initially included Parasitic diseases only). For each category, the diseases were listed by family of camelids (dromedary camels, bactrian camels and New World camelids) and classified into three groups for each of these families with Group I: Known to produce significant diseases, Group II: diseases for which camelids are potential pathogen carriers, and Group III: Minor diseases.

1 International Society of Camelid Research and Development

The Group agreed that multifactorial diseases (e.g. neonatal diarrhoea, respiratory disease complex, mastitis and sudden mortality syndrome) could be included in the list. However, as these diseases were caused by different aetiological bacteria (e.g. *Escherichia coli*, *Streptococcus* sp., *Staphylococcus aureus*), viral (e.g. rotavirus, coronavirus) or fungal (e.g. *Candida* sp.) agents and as the recommendations to diagnose or control these diseases were not specific to camelids, they were finally not added to the list. The Group agreed that for these diseases, a holistic approach (ecopathology) should be adopted including risk factors and different aetiologies.

For the three categories and each family of camelids, diseases were added, deleted or moved from one group to another, and information was updated when relevant.

For the category "Viral diseases", the Group recalled that it had removed foot and mouth disease (FMD) from dromedary camels and New World camelids as they were not susceptible while bactrian camels were susceptible to FMD. However this finding would need to be further investigated with regard to the serotypes involved and the role of camelids as potential carriers. Further research would therefore be necessary, especially on diagnostic techniques (NSP tests[2] and c-ELISA[3]) and for the identification of virus receptors. The Group recommended that if tests were carried out on suspected samples, two different NSP tests be used to avoid as far as possible false positives. Influenza A infections were added to Group I of viral diseases for bactrian camels based on a scientific publication (Yamnikova *et al*. [1993]. A reassortant H1N1 influenza A virus caused fatal epizootics among camels in Mongolia. *Virology*., **197(2)**, 558-563).

For the category "Bacterial diseases", the Group agreed that Brucellosis appeared to be one of the most important bacterial diseases of camelids (caused mainly by *Brucella abortus* for bactrian camels contrary to dromedary camels and New World camelids where *B. melitensis* is predominant). Dermatophilosis was added to Group I of bacterial diseases for dromedary camels.

For the category "Parasitic and Fungal diseases", gastrointestinal parasitoses were added to Group I for dromedary and bactrian camels as these diseases, caused by several different parasites (*Trichostrongylus*, *Haemonchus*, *Taenia* etc.) have a significant economic impact. For the same reason, ring worm was added to Group I of parasitic and fungal diseases for the dromedary and bactrian camels and to Group III for the New World camelids. Coccidioidomycosis (emerging fungal disease) was added to Group III for New World camelids.

5. Update on the current disease situation with regards to camelids worldwide, diseases of priority for validation of diagnostic assays and the need for research in diseases of camelids

A round table was organised to provide the OIE with a list of the main diseases of camelids according to the different regions of the world. The regions described were the Middle East (with the exclusion of the Gulf countries) (Dr Bengoumi), North and West Africa (Dr El Harrak), Eastern Africa (Dr Khalafalla), the Gulf countries (Dr Wernery) and South Asia for dromedary camels (Dr Gahlot); Central Asia for bactrian camels mainly (Dr Faye); and South America for small camelids (Dr De Lamo).

Viral diseases:

North and West Africa, and the Middle East: camelpox, Rift Valley fever (RVF), bluetongue (BT) and peste des petits ruminants (PPR).

Eastern Africa: camelpox, PPR-like, contagious ecthyma and papillomatosis.

Gulf countries: camelpox, ecthyma, BT, bovine viral diarrhea (BVD) and rabies.

South Asia: camelpox, rabies, infectious bovine rhinotracheitis (IBR) and PPR.

Central Asia: camelpox, rabies, FMD in bactrian camels and influenza.

South America: BVD, Equine Rhinopneumonitis (EHV 1 and 4), BT and rotavirus.

2 Nonstructural protein tests
3 Competitive enzyme-linked immunosorbent assay

Bacterial diseases:

North and West Africa, and the Middle East: brucellosis caused by *B. melitensis*, *caseous lymphadenitis*, salmonellosis and colibacillosis.

Eastern Africa: brucellosis, enterotoxemia, dermatophilosis and *caseous lymphadenitis*.

Gulf countries: clostridiosis, enterotoxemia, brucellosis, paratuberculosis, lymphadenitis, tuberculosis (TB), salmonellosis and colibacillosis.

South Asia: brucellosis, *caseous lymphadenitis*, tuberculosis, haemorrhagic septicaemia (pasteurellosis), enterotoxemia, salmonellosis, Q fever, paratuberculosis, leptospirosis and rickettsia diseases.

Central Asia: TB, brucellosis and salmonellosis.

South America: enterotoxemia, colibacillosis, brucellosis and TB.

Parasitic and Fungal diseases:

North and West Africa, and Middle East: trypanosomosis, mange, gastrointestinal parasites and tick infestations.

Eastern Africa: mange, trypanosomosis, ring worm (dermatophytosis) and gastrointestinal parasites.

Gulf countries: mange, ring worm (dermatophytosis), coccidiosis and gastrointestinal parasites.

South Asia: mange, ticks, trypanosomosis and gastrointestinal parasites.

Central Asia: gastrointestinal parasites, mange, cephalopinosis and fleas.

South America: sarcocystosis, echinococosis, coccidiosis and mange.

All these diseases required more research and the Group discussed research priorities (infection trials, diagnostic tests, vaccine development, drug resistance etc.) according to the importance of some of these diseases (economic impact, public health, high morbidity and/or mortality, trade constraints) at the global level. After discussion, ten diseases were retained: emerging diseases (PPR, BT, RVF), contagious ecthyma, BVD (in small camelids), brucellosis, enterotoxemia, TB (bactrian and small camelids), mange and tick infestations.

Research to be carried out for these diseases was detailed in the columns “recommendations for diagnosis” and “recommendations for prevention” of the list developed for the diseases of interest for camelids (Appendix IV).

6. Consideration on the setting up of an OIE laboratory network on diseases of camelids linked with already existing networks on this topic

The Group agreed on the need to set up a network of laboratories for diseases of camelids with the main objective of exchanging information and validating diagnostic tests that were currently used for the significant diseases in other species for the different species of camelids. The Group suggested that Dr El Harrak act as the coordinator of this laboratory network. Three types of laboratories would be included: OIE Reference Laboratories for the diseases of interest, associated research laboratories (e.g. Biopharma in Morocco, Central Veterinary Research Laboratory in Dubaï and *Brucella* Vaccine Centre in Saudi Arabia) and laboratories in camel-rearing countries that were first in line to collect data and samples in the field. The countries to be involved would be, but not limited to, Argentina, Chad, Chile, China (People’s Rep. of), Djibouti, Ethiopia, India, Iran, Kazakhstan, Kenya, Mauritania, Mongolia, Pakistan, Peru, Saudi Arabia, Sudan, Syria, Tunisia, Turkmenistan, the USA and Yemen. Contacts would be made with the OIE Delegates during the General Session by Dr El Harrak.

The Group would encourage twining projects between OIE Reference Laboratories and National Laboratories from camelid-rearing countries with the potential to support the other National Laboratories in their region.

The Group suggested that the OIE encourage the representatives of camel-rearing countries (OIE Delegates) to facilitate the shipment of samples from their national laboratories to OIE Reference Laboratories for validation of diagnostic assays, surveillance programmes or when outbreaks occur. However it noted the high costs of such shipments and wondered if specific and sustainable funds (international organisations, donors etc.) could be made available to support such shipment as had been done recently for example with the shipment of avian influenza samples.

7. Review of the disease-specific chapters of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* for the diseases of interest for Camelids

The Group reviewed the list of the disease-specific chapters in the *Terrestrial Manual* to identify the chapters that address diseases of concern for camelids with the aim of verifying if the chapters would need to include specific requirements for diagnostic assays or vaccine production for camelids.

Noting that brucellosis (*B. abortus* and *B. melitensis*), PPR, TB and BVD were listed as bovidae diseases, as ovidae/capridae diseases or under both, the Group proposed that these four chapters be reviewed for potential inclusion of specific requirements for camelids. The chapters selected and the names of the participants of the Group responsible for this review are detailed below. The Group would provide the results of this review by mid-June to the OIE Headquarters and the Biological Standards Commission.

Dr Bengoumi: brucellosis; Dr De Lamo: BVD; Dr El Harrak: BT and West Nile fever; Dr Faye: trypanosomosis and mange; Dr Gahlot: TB and mange; Dr Khalafalla: PPR; and Dr Wernery: coccidiosis, trypanosomosis, FMD and Rift Valley fever.

8. Other matters

The Group agreed that a review article on FMD in camelids be proposed for publication by OIE (e.g. in a plurithematic issue of the OIE *Scientific and Technical Review*).

A virtual forum might be implemented in the future for the participants of this Group (Dr Wernery as leader on this project) allowing them to exchange relevant scientific information. A similar forum might be implemented for the laboratory network described above (Dr El Harrak as a leader of this project).

The Group had been requested by the OIE *ad hoc* Group on Brucellosis to review the report of its last meeting. The Group agreed on the need to draft a chapter on Brucellosis for camelids in the *Terrestrial Animal Health Code*, but also noted the need to do the same for the *Terrestrial Manual*. The Group suggested that Dr Bengoumi, on behalf of the Group, would participate in the forthcoming meeting of the *ad hoc* Group on Brucellosis that would be held in July 2010. It also suggested the names of experts who could be interested in attending this meeting. The Group would make comments and prepare a common position on Brucellosis in Camelids to be presented by Dr Bengoumi to the forthcoming meeting of the *ad hoc* Group on brucellosis.

The Group proposed having a third meeting of the Group in due time to review the results of the important research programmes mentioned in this report being carried out in the coming months.

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…/Appendices

Appendix I

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

Paris, 3–5 May 2010

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Agenda

1. Opening and purpose of the meeting;
2. Designation of rapporteur;
3. Adoption of the Agenda and Terms of Reference;
4. Updating of the List of diseases of interests for Camelids drafted during the first meeting of the *ad hoc* Group;
5. Update on the current disease situation with regards to camelids worldwide, diseases of priority for validation of diagnostic assays and the need for research in diseases of camelids;
6. Consideration on the setting up of an OIE laboratory network on diseases of camelids linked with already existing networks on this topic;
7. Review of the disease-specific chapters of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial* Animals for the diseases of interest for Camelids;
8. Other matters;
9. Finalisation and adoption of the draft report.

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Appendix II

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

Paris, 3–5 May 2010

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List of participants

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Appendix III

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

Paris, 3–5 May 2010

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Terms of Reference

- Update the list of diseases of camelids proposed by the ad hoc Group during its first meeting, taking into account any recent publications and the ISOCARD (International Society of Camelid Research and Development) Conference held in Djerba, Tunisia, in March 2009;

- Determine the diseases of priority for validation of diagnostic assays and the need for research in this area;

- Review the disease-specific chapters of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* for the diseases that concern Camelids in view of adding, if necessary, specific requirements for diagnostic assays and vaccine production, and propose an outline for these revisions and a timetable to draft them;

- Provide an update on the current disease situation with regards to camelids worldwide;

- Consider setting up an OIE laboratory network on diseases of camelids linked with already existing networks on this topic.

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Appendix IV

INFECTIOUS DISEASES OF INTEREST FOR CAMELIDS

As updated at the second meeting of the OIE *ad hoc* Group on Diseases of Camelids (May 2010)

A) Viral diseases in camelids

Group I = Known to produce significant diseases
Group II = Diseases for which camelids are potential pathogen carriers
Group III = Minor 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, TEM, virus isolation, IHC and PCR	ELISA VNT*	An ELISA kit has been developed but still needs to be validated	Vaccination
Contagious ecthyma	TEM, IHC and PCR	None	Virus isolation is necessary	Investigation on vaccine development
Papillomat-osis	TEM, PCR and IHC	None		Autogenous Vaccination
Rabies	OIE *Terrestrial Manual* 2008, Chapter 2.1.13, FAT and IHC	VNT* Investigation on serological tests		Vaccination with cattle dose. However the vaccination protocol needs to be investigated
RVF	OIE *Terrestrial Manual* 2008, Chapter 2.1.14, Culture, AGID, PCR and Histopathology	c-ELISA VNT*	1. Validation of an ELISA on more samples would be necessary 2. Investigation on susceptibility and duration of viraemia	Investigation on vaccination
Group II				
AHS	OIE *Terrestrial Manual* 2008, Chapter 2.5.1., Virus isolation, PCR, ELISA and VN	None	1. Investigation of susceptibility for virulent strains and serotypes 2. Investigation of duration of viraemia 3. Development of an ELISA	
BT	OIE *Terrestrial Manual* 2008, Chapter 2.1.3, Virus isolation, immunological methods and PCR	c-ELISA	Investigation of susceptibility for virulent strains and serotypes, and carrier states	1. Investigation for vaccination. 2. Application of the trade measures used for bovines

BVD	OIE *Terrestrial Manual* 2008, Chapter 2.4.8, Virus isolation, PCR, IHC and ELISA	c-ELISA VNT*	1. Validation of serological tests in milk 2. Virus isolation needed 3. Investigation on susceptibility	
PPR	OIE *Terrestrial Manual* 2008, Chapter 2.7.11, Virus isolation, AGID and PCR	None	1. c-ELISA should be validated 2. Investigation on susceptibility for virulent strains	
Group III				
CCHF	Virus isolation** and PCR	None	1. Validation of ruminant c-ELISA 2. Serological survey	
Herpesvirus Infections	OIE *Terrestrial Manual* 2008, Chapter 2.5.9 (EHV), Chapter 2.4.13 (IBR), PCR, virus isolation and Immunofluorescence	VNT*	1. Validation of serological tests 2. Investigation on susceptibility for EHV 4 and BHV 1	Investigation on vaccination using horse protocol
West Nile Fever	OIE *Terrestrial Manual* 2008, Chapter 2.1.20, PCR and virus isolation	c-ELISA	Investigation on susceptibility for the two strains	

*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, TEM, virus isolation, IHC and PCR	ELISA VNT*	An ELISA method has been developed but still needs to be validated	Vaccination. A protocol need to be investigated
Contagious ecthyma	TEM and IHC	None	Virus isolation	Investigation on vaccine development
FMD	OIE *Terrestrial Manual* 2008, Chapter 2.1.5., PCR and virus isolation	NSP c-ELISA	1. Double check with NSP ELISA 2. More investigations needed	Vaccination. A protocol need to be investigated
Influenza A infections	Virus isolation, PCR and ELISA	HI	Investigations on the susceptibility for the different serotypes need to be done	Investigation on vaccination using horse protocol

Rabies	OIE *Terrestrial Manual* 2008, Chapter 2.1.13, FAT and IHC	VNT* Investigation on serological tests		Vaccination with cattle dose. However the vaccination protocol need to be investigated
Group II				
BVD	OIE *Terrestrial Manual* 2008, Chapter 2.4.8, Virus isolation, PCR, IHC and ELISA	VNT*	1. Validation of serological tests 2. Investigation on susceptibility	
Group III				
BT	OIE *Terrestrial Manual* 2008, Chapter 2.1.3, Virus isolation, immunological methods and PCR	c-ELISA	Investigation of susceptibility for virulent strains and serotypes, and carrier states	1. Investigation for vaccination 2. Application of the trade measures used for bovines
CCHF	Virus isolation** PCR	None	1. Validation of ruminant c-ELISA 2. Serological survey	
Herpesvirus Infections	OIE *Terrestrial Manual* 2008, Chapter 2.5.9 (EHV), Chapter 2.4.13 (IBR), PCR, virus isolation and Immunofluorescence	VNT*	1. Validation of serological tests 2. Investigation on susceptibility for EHV 1, EHV 4 and BHV 1	Investigation on vaccination using horse protocol

New World camelids

Diseases	**Identification of the agent**	**Serological tests**	**Recommendations for diagnostic**	**Recommendations for prevention**
Group I				
BVD	OIE *Terrestrial Manual* 2008, Chapter 2.4.8, Virus isolation, PCR, IHC and ELISA	c-ELISA VNT*	Validation of serological tests	Investigation on vaccination using bovine protocol
BT	OIE *Terrestrial Manual* 2008, Chapter 2.1.3, Virus isolation, immunological methods and PCR	c-ELISA	Investigation of susceptibility for virulent strains and serotypes	1. Vaccination using sheep protocol 2. Application of the trade measures used for bovines
Herpesvirus Infections	OIE *Terrestrial Manual* 2008, Chapter 2.5.9 (EHV), Chapter 2.4.13 (IBR), PCR, virus isolation and Immunofluorescence	VNT*	1. Validation of serological tests necessary 2. Investigation on susceptibility for EHV 1 and BHV 1	Investigation on vaccination

Group II				
Contagious ecthyma	TEM and IHC	None	Virus isolation	Investigation on vaccine development
Group III				
Camelpox	OIE *Terrestrial Manual* 2008, Chapter 2.9.2, TEM, virus isolation, IHC and PCR	ELISA VNT*	An ELISA kit has been developed but still needs to be validated	
Equine encephalomye litis	OIE *Terrestrial Manual* 2008, Chapter 2.5.5. and Chapter 2.5.14., PCR and virus isolation	None	1. Investigation on susceptibility 2. Validation of available serological tests	
Rabies	OIE *Terrestrial Manual* 2008, Chapter 2.1.13, FAT and IHC	VNT*		Vaccination protocol need to be investigated
West Nile fever & other Flaviviruses	OIE *Terrestrial Manual* 2008, Chapter 2.1.20, PCR and virus isolation	c-ELISA VNT*	Investigation on susceptibility	

b) Bacterial diseases in camelids

Group I = Known to produce significant diseases
Group II = Diseases for which camelids are potential pathogen carriers
Group III = Minor diseases

Dromedary camels

Diseases	**Identification of the agent**	**Serological tests**	**Recommendations for diagnostic**	**Recommendations for prevention**
Group I				
Anthrax	OIE *Terrestrial Manual* 2008 Chapter 2.1.1., Immunofluorescence, PCR, culture and identification of *Bacillus anthracis*	None	None	1. Vaccination in endemic area 2. Need for vaccine field trial
Brucellosis (*B. melitensis*)	OIE *Terrestrial Manual* 2008, Chapter 2.4.3., Staining methods, culture and PCR	CF, RBT, SAT, c-ELISA	CF, RBT, SAT and c-ELISA need to be validated	1. Vaccination 2. Vaccination protocols need to be investigated
Clostridia infections	Isolation and typing of bacteria and detection of toxins	ELISA and PCR tests available for toxinotyping (perfringens).	Investigation on multiplex PCR	Investigation on vaccination

Colibacillosis	OIE *Terrestrial Manual* 2008, Chapter 2.9.11., Culture, immunological method and PCR	None	1. Identification of the most pathogenic biovars 2. Development of serological tests necessary	Development of vaccines
Dermatophilosis (*Dermatophilus congolensis)*	OIE *Terrestrial Manual* 2008, Chapter 2.4.10., Culture, immunological methods and PCR	None	Identification of the most pathogenic strains	Development of vaccines
Haemorrhagic septicaemia (*Pasteurella multocida* or *Mannheimia hemolytica*)	OIE *Terrestrial Manual* 2008, Chapter 2.4.12., Culture and PCR	None	Controversial data on susceptibility and aetiology which need therefore also to be investigated	Protocol for vaccination needs to be investigated
Johne's disease	OIE *Terrestrial Manual* 2008, Chapter 2.1.11., Culture and PCR	None	Validation of serological tests	Eradication of seropositive animals after validation of the tests
Pyogenic diseases (*Caseous lymphadenitis*)	Isolation and typing of bacteria	None	Development of serological test for *Corynebacterium pseudotuberculosis* and *Staphylococcus aureus*	Development of vaccines
Salmonellosis	OIE *Terrestrial Manual* 2008, Chapter 2.9.9., Culture and PCR	None	1. Identification of the most prevalent biovars and investigation on susceptibility 2. Development of serological tests	Development of vaccines
Group II				
Leptospirosis	OIE *Terrestrial Manual* 2008, Chapter 2.1.9., PCR	MAT	1. Identification of the most prevalent biovars 2. Investigation on susceptibility	Development of vaccines
Q fever	OIE *Terrestrial Manual* 2008, Chapter 2.1.12., Staining, isolation of the agent and PCR	CF	1. Investigation on susceptibility 2. Validation of serological tests	Development of vaccines
Tuberculosis	OIE *Terrestrial Manual* 2008, Chapter 2.4.7., Direct identification, culture and PCR	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
Group III				
Chlamydiosis	Isolation and identification of the agent	c-ELISA	Validation of serological tests	
Glanders (*Melioidosis*)	OIE *Terrestrial Manual* 2008, Chapter 2.5.11., Culture and PCR	CF	Validation of serological tests	Eradication of seropositive animals
Plague (*Yersiniosis*)	Isolation of bacteria	None	Development of serological test	Eradication of infected animals

Bactrian camels

Diseases	Identification of the agent	Serological tests	Recommendations for diagnostic	Recommendations for prevention
Group I				
Anthrax	OIE *Terrestrial Manual* 2008 Chapter 2.1.1., Immunofluorescence, PCR, culture and identification of *Bacillus anthracis*	None	None	1. Vaccination in endemic area 2. Need for vaccine field trial
Brucellosis (*B. abortus* and *B. melitensis*)	OIE *Terrestrial Manual* 2008, Chapter 2.4.3., Staining methods, culture and PCR	CF, RBT, SAT, c-ELISA	CF, RBT, SAT and c-ELISA need to be validated for *B. abortus* and *B. melitensis.* Tests also need to be validated.	1. Vaccination according to the species (*B. abortus* or *B. melitensis*) 2 Vaccination protocols need to be investigated
Clostridia infections	Isolation and typing of bacteria and detection of toxins	ELISA and PCR tests available for toxinotyping (perfringens).	Investigation on multiplex PCR	Investigation on vaccination
Colibacillosis	OIE *Terrestrial Manual* 2008, Chapter 2.9.11., Culture and PCR	None	1. Identification of the most pathogenic biovars 2. Development of serological tests necessary	Development of vaccines
Johne's disease	OIE *Terrestrial Manual* 2008, Chapter 2.1.11., Culture and PCR	None	Validation of serological tests	Eradication of seropositive animals after validation of the tests
Plague (*Yersiniosis*)	Isolation of bacteria	None	Development of serological test	1. Eradication of infected animals 2 Control of vectors
Pyogenic diseases (*Caseous lymphadenitis*)	Isolation and typing of bacteria	None	Development of serological test for *Corynebacterium pseudotuberculosis* and *Staphylococcus aureus*	Development of vaccines
Salmonellosis	OIE *Terrestrial Manual* 2008, Chapter 2.9.9., Culture and PCR	None	1. Identification of the most prevalent biovars and investigation on susceptibility 2. Development of serological tests	Development of vaccines
Tuberculosis	OIE *Terrestrial Manual* 2008, Chapter 2.4.7., Direct identification, culture and PCR	RT test	1. Investigation should be conducted with serological test 2. Investigation on skin test	Eradication of positive animals after validation of the tests

Group II				
Leptospirosis	OIE *Terrestrial Manual* 2008, Chapter 2.1.9., PCR	MAT	1. Identification of the most prevalent biovars 2. Investigation on susceptibility	Development of vaccines
Q fever	OIE *Terrestrial Manual* 2008, Chapter 2.1.12., Staining, isolation of the agent and PCR	CF	1. Investigation on susceptibility 2. Validation of serological tests	Development of vaccines
Group III				
Glanders (Melioidosis)	OIE *Terrestrial Manual* 2008, Chapter 2.5.11,	CF	Validation of serological tests	Eradication of seropositive animals
Chlamydiosis	Isolation and identification of the agent	c-ELISA	Validation of serological tests	
Haemorrhagic septicaemia (*Pasteurella multocida* or *Mannheimia hemolytica*)	OIE *Terrestrial Manual* 2008, Chapter 2.4.12., Culture and PCR	None	Investigation on susceptibility	

New World camelids

Diseases	Identification of the agent	Serological tests	Recommendations for diagnostic	Recommendations for prevention
Group I				
Anthrax	OIE *Terrestrial Manual* 2008 Chapter 2.1.1., Immunofluorescence, PCR, culture and identification of *Bacillus anthracis*	None	None	1. Vaccination in endemic area 2. Need for vaccine field trial
Brucellosis (*B. melitensis*)	OIE *Terrestrial Manual* 2008, Chapter 2.4.3., Staining methods, culture and PCR	CF, RBT, SAT, c-ELISA	CF, RBT, SAT and c-ELISA need to be validated	1. Vaccination 2. Vaccination protocols need to be investigated
Colibacillosis	OIE *Terrestrial Manual* 2008, Chapter 2.9.11., Culture and PCR	None	1. Identification of the most pathogenic biovars 2. Development of serological tests necessary	Development of vaccines
Enterotoxaemia	Isolation and typing of bacteria	ELISA and PCR tests available for toxins identification	Investigation on multiplex PCR	Protocol for vaccination needs to be investigated with available toxoid bacteria vaccines
Leptospirosis	OIE *Terrestrial Manual* 2008, Chapter 2.1.9., PCR	MAT	Identification of the most prevalent biovars and investigation on susceptibility	Development of vaccines
Salmonellosis	OIE *Terrestrial Manual* 2008, Chapter 2.9.9., Culture, immunological methods and PCR	None	1. Development of serological tests 2. Identification of the most prevalent biovars	Development of vaccines

Tuberculosis	OIE *Terrestrial Manual* 2008, Chapter 2.4.7., Direct identification, culture and PCR	RT test	Tuberculin testing does not work. Serological tests should be developed	Eradication of positive animals after validation of the tests
Group II				
Johne's disease	OIE *Terrestrial Manual* 2008, Chapter 2.1.11., Culture and PCR	None	Validation of serological tests	Eradication of seropositive animals after validation of the tests
Pyogenic diseases (internal abscesses)	Isolation and typing of bacteria	None	Development of serological test for *Corynebacterium* and *Staphylococcus*	Development of vaccines
Q fever	OIE *Terrestrial Manual* 2008, Chapter 2.1.12., Staining, isolation of the agent and PCR	CF	1. Investigation on susceptibility 2. Validation of serological tests	Development of vaccines
Group III				
Actinobacillosis	Isolation and identification of the agent	None	Validation of serological tests	
Pasteurellosis (Haemorrhagic septicaemia)	OIE *Terrestrial Manual* 2008, Chapter 2.4.12., Culture and PCR	None	Investigation on susceptibility	

c) Parasitic and Fungal diseases in camelids

Group I = Known to produce significant diseases
Group III = Minor diseases

Dromedary camels

Diseases	Identification of the agent	Serological tests	Recommendations for diagnostic	Recommendations for prevention
Group I				
Cephalopina infestation	Direct agent identification	None	Identification of the parasite	Research for new treatment
Coccidiosis	Direct agent identification: *Eimeria, Isospora* and *Cryptosporidium* in young camels	None	1. Identification of the parasite 2. Development of PCR would be useful	Research for new treatment and development of vaccines
Gastro intestinal parasitosis	Direct agent identification: *Trichostrongylosis, Haemonchus, Taenia, etc*	None	Identification of the parasite	Investigation on treatment protocol and drugs resistance
Hydatidosis Echinococcosis	OIE *Terrestrial Manual* 2008, Chapter 2.1.4, Direct agent identification, Coproantigen tests and PCR	ELISA	ELISA can be used with anti-camel conjugates	1. Treatment of the dogs 2. Development of vaccine

Mange (*Sarcoptes scabiei*)	OIE *Terrestrial Manual* 2008, Chapter 2.9.8, Direct agent identification	c-ELISA	Identification of the parasite for differential diagnosis from other skin diseases (Psoroptes, Ring Worm, etc.)	1. Quarantine and efficient drug for treatment 2. Development of vaccine
Ring Worm (Dermatophytosis)	Direct agent identification	None	Agent identification	Vaccines available (initially for bovines) but protocol for the vaccination need to be validated
Tick infestations	Direct agent identification	None	Identification of the parasite	Development of treatment protocols and vaccine
Trypanosomosis	OIE *Terrestrial Manual* 2008, Chapter 2.4.8, PCR	CATT and Indirect ELISA (Neither ELISA is commercially available)	1. Indirect ELISA can be used with anti-camel conjugates 2. PCR	1. Systematic control for trade 2. Treatment of positive animal 3. Need of investigation on the resistance to drugs
Group III				
Myasis other than Cephalopina	Direct agent identification	None	Identification of the parasite	Avermectines
Neosporosis	Direct agent identification	ELISA	1. Investigation on susceptibility 2. Serological assay by ELISA. Development of PCR would be useful	Development of vaccine
Toxoplasmosis	OIE *Terrestrial Manual* 2008, Chapter 2.9.10, Isolation, tissue sections, PCR, Oocyst detection	SAT ELISA	Investigation on susceptibility	

Bactrian camels

Diseases	**Identification of the agent**	**Serological tests**	**Recommendations for diagnostic**	**Recommendations for prevention**
Group I				
Cephalopina infestation	Direct agent identification	None	Identification of the parasite	Research for new treatment
Coccidiosis	Direct agent identification: *Eimeria, Isospora* and *Cryptosporidium* in young camels	None	1. Identification of the parasite 2. Development of PCR would be useful	Research for new treatment and development of vaccines
Gastro intestinal parasitosis	Direct agent identification: *Trichostrongylosis, Haemonchus, Taenia, etc*	None	Identification of the parasite	Investigation on treatment protocol and drugs resistance

Hydatidosis Echinococcosis	OIE *Terrestrial Manual* 2008, Chapter 2.1.4, Direct agent identification, Coproantigen tests and PCR	ELISA	ELISA can be used with anti-camel conjugates	1. Treatment of the dogs 2. Development of vaccine
Mange (*Sarcoptes scabiei*)	OIE *Terrestrial Manual* 2008, Chapter 2.9.8, Direct agent identification	c-ELISA	Identification of the parasite for differential diagnosis from other skin diseases (Psoroptes, Ring Worm, etc.)	1. Quarantine and efficient drug for treatment 2. Development of vaccine
Ring Worm (Dermatophytosis)	Direct agent identification	None	Agent identification	Vaccines available (initially for bovines) but protocol for the vaccination need to be validated
Ticks infestation	Direct agent identification	None	Identification of the parasite	Development of treatment protocols and vaccine
Trypanosomosis	OIE *Terrestrial Manual* 2008, Chapter 2.4.8, PCR	CATT and Indirect ELISA (Neither ELISA is commercially available)	1. Indirect ELISA can be used with anti-camel conjugates 2. PCR	1. Systematic control for trade 2. Treatment of positive animal 3. Need of investigation on the resistance to drugs
Group III				
Myasis other than Cephalopina	Direct agent identification	None	Identification of the parasite	Avermectines
Neosporosis		ELISA	Serological assay by ELISA. Development of PCR would be useful	Investigation on susceptibility
Toxoplasmosis	OIE *Terrestrial Manual* 2008, Chapter 2.9.10, Isolation, tissue sections, PCR, Oocyst detection	SAT ELISA	Investigation on susceptibility	

New World camelids

Diseases	**Identification of the agent**	**Serological tests**	**Recommendations for diagnostic**	**Recommendations for prevention**
Group I				
Coccidiosis	Direct agent identification: *Eimeria, Isospora* and *Cryptosporidium* in young animals	None	1. Identification of the parasite 2. Development of PCR would be useful	Research for new treatment and development of vaccines
Hydatidosis Echinococcosis	OIE *Terrestrial Manual* 2008, Chapter 2.1.4, Direct agent identification, Coproantigen tests and PCR	ELISA	ELISA can be used with specific conjugates	Treatment of the dogs. Development of vaccine

Mange (*Sarcoptes scabiei*)	OIE *Terrestrial Manual* 2008, Chapter 2.9.8, Direct agent identification	c-ELISA	Identification of the parasite for differential diagnosis from other skin diseases (psoroptes, Ring Worm, etc.)	Quarantine and good drug for treatment Development of vaccine
Neosporosis	PCR IF	ELISA	Investigation on susceptibility	Evaluation of available vaccine
Sarcocystosis	Agent identification	ELISA	An ELISA needs to be validated	Development of vaccine
Trematodosis	Indirect agent identification	ELISA only for *Fasciola hepatica*	Identification of the large and small trematodes in post mortem	Treatments. Protocol needs to be validated
Group III				
Coccidioidomycosis	Direct agent identification (post mortem)	CF and AGID		Treatments available
Ring Worm (Dermatophytosis)	Direct agent identification	None	Agent identification	Vaccines available (initially for bovines) but protocol for the vaccination need to be validated

List of Abbreviations:

Ab-ELISA:	Antibody enzyme-linked immunosorbent assay
AHS:	African horse sickness
BHV:	Bovine herpesvirus
BT:	Bluetongue
BVD:	Bovine viral diarrhoea
CATT:	Card-agglutination trypanosoma test
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
CVRL:	Central Veterinary Research Laboratory (Dubai, UAE)
EHV:	Equine herpesvirus
FAT	Fluorescent antibody test
FMD:	Foot and mouth disease
HI:	Heamaglutination inhibition
IBR/IPR:	Infectious bovine rhinotrachitis/Infectious pustular vulvovaginitis
IHC:	Immunohistochemistry
MAT:	Microscopic agglutination test
NSP ELISA:	Nonstructural protein enzyme-linked immunosorbent assay
OIE:	World Organisation for Animal Health
OIE *Terrestrial Manual*:	OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
PCR:	Polymerase chain reaction
PPR:	Peste des petits ruminants
RBT:	Rose-Bengal test
RVF:	Rift Valley fever
SAT:	Sero-agglutination test
TEM:	Transmission electron microscopy
VNT:	Virus neutralisation test