



Organisation
Mondiale
de la Santé
Animale

World
Organisation
for Animal
Health

Organización
Mundial
de Sanidad
Animal

Original: English
September 2005

REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 21–23 September 2005

The OIE Biological Standards Commission met at the OIE Headquarters from 21 to 23 September 2005. Dr Bernard Vallat, Director General of the OIE, welcomed the Members of the Commission, Prof. Steven Edwards, President, Dr Beverly Schmitt, Vice-President and Dr Anatoly Golovko, Secretary General, and the other participants, Dr Adama Diallo, representing the OIE Collaborating Centre for ELISA¹ and Molecular Techniques in Animal Disease Diagnosis, IAEA², Vienna, Austria, Dr Peter Wright, President of the OIE Ad hoc Group on Nonstructural Protein Tests for Foot and Mouth Disease Diagnosis, and Dr Stephanie Ostrowski, CDC³, Atlanta, Georgia, United States of America.

Dr Vallat mentioned the need to develop additional formal criteria for designating OIE Collaborating Centres and Reference Laboratories. While technical competence is essential, he also referred to the importance of a balanced regional element. He also emphasised the need to harmonise the terms (for example disease names) used in the *Terrestrial Animal Health Code* and *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, requesting that the Commission should take a proactive role and make appropriate recommendations to the Terrestrial Animals Health Standards Commission (Code Commission) and the Ad hoc Group on Disease Notification. Dr Vallat confirmed that the OIE was willing to maintain in the *Terrestrial Manual* chapters on diseases that had been removed from the List, as the information would be of use to Member Countries. Responding to a letter from Prof. Edwards, Dr Vallat mentioned various funding grants received by the OIE that could enable young veterinarians to attend Commission meetings as observers, or to undertake longer secondments to the OIE. This is an important element of succession planning for the future success of the OIE. He also took note of the proposal to increase the number of members on the Biological Standards Commission, which would need to be considered by the Administrative Commission in the first instance at its next meeting in February 2006.

The Agenda and List of Participants are given at [Appendices I](#) and [II](#), respectively.

1. OIE Reference Laboratories and Collaborating Centres

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

OIE Collaborating Centre for Emerging and Re-emerging Zoonotic Diseases

The Commission recommended acceptance of an application for an OIE Collaborating Centre for Emerging and Re-emerging Zoonotic Diseases from the CDC, Atlanta, Georgia, United States of America, on the understanding that the Centre would work closely with USDA on animal-related issues.

1 ELISA: enzyme-linked immunosorbent assay

2 IAEA: International Atomic Energy Agency

3 CDC: Centers for Disease Control and Prevention

OIE Collaborating Centre for Zoonoses in Europe

The Commission received an application for an OIE Collaborating Centre from the Friedrich-Loeffler-Institute, Insel Riems, Germany. The Commission agreed this in principle. In accordance with the official OIE procedure, the application was referred to the OIE Regional Commission for Europe for an opinion.

Standardisation of Diagnostic Tests and Vaccines in CIS Countries

The Commission considered an application from the Control Institute of Biotechnology and Strains of Microorganisms, Kiev, Ukraine. Drs Edwards and Schudel had visited the institute in June 2005. The institute was recently refurbished and well equipped. It was noted that the institute does not carry out diagnostic tests itself, but is responsible for maintaining standard reference strains of micro-organisms and standard preparations of diagnostic reagents and vaccines. The Commission recommends that the laboratory first enter into a 'twinning' agreement with the OIE Reference Laboratory for rabies (AFFSA⁴, Nancy, France) with a view to capacity building. This could then position the institute for a full application either as a Collaborating Centre or a Reference Laboratory.

Prevention and Eradication of Screwworms

The Commission noted an application for an OIE Collaborating Centre for the Prevention and Eradication of Screwworms from the Panama–United States Commission for the Prevention and Eradication of Screwworms (COPEG), Panama. The Commission believes that the centre would more suitably fulfil the remit of an OIE Reference Laboratory and requested that the dossier be resubmitted with this in mind.

Regarding Reference Laboratory applications, the Commission emphasised that applicants should demonstrate their international profile and activity, as well as technical competence, in order to qualify as OIE Reference Laboratory. It recommends acceptance of the following new applications for OIE Reference Laboratory status:

OIE Reference Laboratory for Avian influenza

Canadian Food Inspection Agency, National Centre for Foreign Animal Disease, Winnipeg, CANADA.

Tel.: (+1-204) 789-2013; Fax: (+1-204) 789-2038; E-mail: jpasick@inspection.gc.ca

Designated Reference Expert: Dr John Pasick.

OIE Reference Laboratory for Rabies

Rabies and Wildlife Zoonoses Group, Virology Department, Veterinary Laboratories Agency (VLA⁵), Weybridge, New Haw, Addlestone, Surrey KT15 3NB, UNITED KINGDOM

Tel.: (+44-1932) 35.78.40; Fax: (+44-1932) 35.72.39; E-mail: t.fooks@vla.defra.gsi.gov.uk

Designated Reference Expert: Dr Anthony Fooks.

OIE Reference Laboratory for Bovine spongiform encephalopathy

Canadian Food Inspection Agency, National Centre for Foreign Animal Disease, Winnipeg, CANADA

Tel.: (+1-204) 789-2021; Fax: (+1-204) 789-2038; E-mail: czubs@inspection.gc.ca

Designated Reference Expert: Dr Stefanie Czub.

OIE Reference Laboratory for Trypanosoma evansi (Surra)

Institute of Tropical Medicine Antwerp, Department of Parasitology, Nationalestraat 155, B-2000 Antwerpen, BELGIUM

Tel.: (+32-3) 247.65.34; Fax: (+32-3) 247.63.73; E-mail: fclaes@itg.be

Designated Reference Expert: Dr Filip Claes.

4 AFSSA : Agence française de sécurité sanitaire des aliments

5 VLA: Veterinary Laboratories Agency

OIE Reference Laboratory for Avian tuberculosis

Although this disease has now been removed from the OIE list, the Commission considers there is a value in designating a Reference Laboratory because of the importance of comparative bacteriology with other *Mycobacterium* species. The Commission therefore recommends acceptance as Reference Laboratory for:

Veterinary Research Institute, Hudcova, Brno, CZECH REPUBLIC
Tel.: (+420-5) 33.33.16.01; Fax: (420.5) 33.33.12.29; E-mail: pavlik@vri.cz
Designated Reference Expert: Dr Ivo Pavlik.

1.2. Updating the list of Reference Laboratories

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

Bluetongue

Dr Peter Daniels to replace Dr Bryan Eaton at the Australian Animal Health Laboratory, Geelong, AUSTRALIA.

Contagious equine metritis

Dr Hendrik-Jan Roest to replace the late Dr Elbarte Kamp at the Central Institute for Animal Disease Control (CIDC) Lelystad, NETHERLANDS.

Equine viral arteritis

Dr Takashi Kondo to replace Dr Yoshio Fukunaga at the Epizootic Research Station, Equine Research Institute, The Japan Racing Association, Tochigi, JAPAN.

Salmonellosis

Dr C. Anne Muckle to replace Dr Cornelius Poppe at the Laboratory for Foodborne Zoonoses, Guelph, Ontario, CANADA.

1.3. Template for annual reports

The Aquatic Animals Health Standards Commission had proposed various changes to the template for annual reports from Reference Laboratories. The Commission will take this forward in correspondence during coming months.

1.4. Guidelines for applications for Collaborating Centre status

The Commission discussed the criteria that should be applied to new applicants for Collaborating Centre status. The difference between the mandate of Collaborating Centres and that of Reference Laboratories has been taken into account. There should be a sectoral focus, along with a discrete scientific discipline that is not disease-specific. As currently, applications are considered by both the appropriate Regional Commission (to confirm the need) and the Biological Standards Commission (to advise on technical competence), a regional focus should be considered.

1.5. First International Conference of OIE Reference Laboratories and Collaborating Centres, Brazil, November 2006

The Commission discussed the agenda for the First International Conference of OIE Reference Laboratories and Collaborating Centres, which will be held in Florianópolis, Santa Catarina, Brazil, in November 2006. It will develop a list of topics at its meeting in January 2006, and is open to suggestions from Member Countries, Reference Laboratories and Collaborating Centres.

1.6. Reference Laboratory obligations

Following a review of some correspondence with a number of the OIE Reference Laboratories, the Commission re-iterated the importance of OIE Reference Laboratories fulfilling their responsibilities in accordance with their Mandate.

2. International standardisation of diagnostic tests and vaccines

2.1. Progress on OIE standardisation programmes for diagnostic tests

Foot and mouth disease (FMD) serology – Coordinator: Dr D. Paton Institute for Animal Health, Pirbright, United Kingdom

The OIE Reference Laboratory for FMD in Pirbright, UK, has been asked to update the datasheets for reference sera for FMD serology in the light of correspondence among the Reference Laboratories.

Contagious bovine pleuropneumonia - Dr A. Pini, Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise 'G. Caporale', Teramo, Italy

The Commission requested clarification of the application of the existing OIE Reference Sera for different classes of serological assay, as the current data sheets may be misleading.

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

Dr Nielsen had proposed distributing a kit containing a coated plate, all the reagents and a protocol for an indirect ELISA and a competitive ELISA. The Commission approved this approach. The Commission requested Dr Nielsen to send the kit to the other OIE Reference Laboratories so that the sera can be evaluated and a decision on whether to designate them as OIE-approved sera could be made.

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

Mrs Stack reported that she was having difficulties obtaining a supply of sera from known infected animals. The Commission recognised the difficulty, but encouraged her to continue seeking a source, with the support of the Central Bureau, in view of the importance of international standardisation of diagnostic tests for this disease.

Caprine arthritis/encephalitis and maedi-visna – Coordinator: Dr K. Klewer, Institute Pourquier, France

Dr Klewer had provided a project update on the evaluation of candidate standard sera for maedi-visna. This work was going well. Work has not yet started on sera for caprine arthritis/encephalitis and there is a query whether there are commercial products available.

Enzootic bovine leukosis – Coordinator: Dr L. Renström, National Veterinary Institute, Uppsala, Sweden

The OIE Reference Laboratories in Sweden, Germany and the UK are working together on the development of a new standard serum. The serum is currently being validated. No progress had been made on the project to establish a standard protocol for a PCR⁶ test.

Dourine – Coordinator: Prof. V.T. Zablotsky, All-Russian Research Institute for Experimental Veterinary Medicine (VIEV), Moscow, Russia

The VLA in the UK had evaluated the candidate reference sera prepared by Prof. Zablotsky. Although the negative sera were causing some difficulty, the positives looked promising and Prof. Zablotsky would be asked to send the sera to other testing laboratories for further evaluation.

Equine rhinopneumonitis – Coordinator Dr J. Mumford, Animal Health Trust, Newmarket, United Kingdom

Dr Mumford informed the Commission that she is no longer working on the preparation of standard sera for equine herpesvirus-1, so the Commission decided to remove this project from its active list.

6 PCR: Polymerase chain reaction

2.2. A review of tests available for diagnosis of tuberculosis in non-bovine species

The Commission discussed a document that it had requested from Dr Debbie Cousins of the OIE Reference Laboratory for bovine tuberculosis in Australia entitled 'A review of tests available for diagnosis of tuberculosis in non-bovine species'. The document is of very high quality and the Commission is extremely grateful to Dr Cousins for the work she put into gathering and analysing the valuable information it contains. Dr Ostrowski agreed to seek further information on testing in non-human primates. The Commission has suggested that Dr Cousins' report be published in the OIE *Scientific and Technical Review*. The recommendations in the report were endorsed and are shown in Appendix III.

3. List of prescribed and alternative tests

3.1. Liquid-phase ELISA for FMD

A number of Member Countries had commented that the solid-phase ELISA for FMD serology is not available in all countries or for all serotypes, and had asked that the liquid-phase ELISA be reinstated as a prescribed test for trade. Following consultation with FMD Reference Laboratory experts, the Commission acceded to this request and will make a recommendation to the International Committee.

3.2. FPA⁷ for determination of antibody to smooth *Brucella* spp. in sheep and goats

The Commission had sought the opinion of a number of experts and received a consensus view that there are not yet sufficient data to accept the FPA as a prescribed test for trade in small ruminants. The validation data is sufficient to support its adoption as an 'alternative' test.

3.3. Real-time PCR for detection of IBR⁸ virus in extended bovine semen

Biosecurity New Zealand had sent a preliminary validation dossier in support of an application to designate its real-time PCR test for detection of IBR virus in extended bovine semen as a prescribed test for trade. The Commission felt the work was encouraging and will seek expert peer review once the completed dossier has been received.

3.4. Rift Valley fever

In view of the newly adopted chapter on Rift Valley fever in the *Terrestrial Code*, there was now a need to designate a prescribed test (see Article 2.2.14.12). Dr Diallo informed the Commission about a meeting organised by the IAEA, which will be held shortly in Senegal, on Rift Valley fever. He agreed to provide the conclusions of this meeting on Rift Valley fever diagnostic tests.

4. Ad hoc and Working Groups

4.1 Report of the Third Meeting of the Ad hoc Group on Antigen and Vaccine Banks for Foot and Mouth Disease

4.1.1. OIE/FAO Network of FMD Reference Laboratories

The Commission endorsed the concept of an OIE/FAO Network of FMD Reference Laboratories.

4.1.2. Text for the *Terrestrial Manual* on vaccine matching tests

The Commission noted the text on vaccine matching for FMD that the Ad hoc Group had drafted. This will be forwarded to the authors of the FMD chapter.

⁷ FPA: Fluorescence polarisation assay

⁸ IBR: Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (bovine herpesvirus 1)

4.2 Ad hoc Group on biosafety/biosecurity

Dr Schmitt updated the Commission on the activities of the Ad hoc Group. Work on drafting a 'Veterinary Biosafety Facility Construction Handbook' is in progress, with a target launch date of November 2006. Once the content is finished it is proposed the handbook should be published by the OIE.

The Group had also begun to update the *Terrestrial Manual* chapter on human safety in the veterinary laboratory. This chapter currently has an appendix that corresponds to the chapter from the *Terrestrial Code* covering international transfer and laboratory containment of animal pathogens. After consulting the Terrestrial Animal Health Standards Commission, it was agreed that information on international transfer of animal pathogens would remain in the *Terrestrial Code* chapter, but the more technical details regarding laboratory containment should be moved to the *Terrestrial Manual* with a cross reference from the *Terrestrial Code*. The Biological Standards Commission agreed to draft a suitably modified text for the *Terrestrial Code* and requested the Ad hoc Group to incorporate the existing Appendix into the body of the chapter in the *Terrestrial Manual*.

4.2.1. WHO⁹ vaccine production

The WHO had requested comments on a draft document concerning development of WHO biosafety guidelines for human pandemic influenza vaccine production. The Commission considered this document comprised a good assessment of the risks, including those arising from the use of reassortant strains for vaccine production. It advised that the proposed containment described as "BSL¹⁰-3 enhanced" did in fact meet the requirements of OIE Containment Level 4 (specifically in regard to HEPA filtration and waste treatment) and was suitable for pathogenic strains. It was noted that there is ongoing confusion between Biosafety Levels 1 to 4, which are designed both to protect staff and to prevent escape of pathogens, and Containment Levels 1 to 4, which are focused on prevention of pathogen escapes.

The Commission also considered that where a vaccine strain (including reassortants) had been shown to be of low pathogenicity for poultry, using the tests described in the *Terrestrial Manual*, then the proposed "BSL-2 enhanced" would provide adequate containment. Further tests such as ferret inoculation would then be required to assess the pathogenicity for humans.

4.3. Proposed Expert Group on TSE¹¹ tests

A proposal had been received from the OIE Reference Laboratory in VLA Weybridge, UK, to convene an OIE Ad hoc Group of experts to evaluate laboratory test approval procedures for diagnostic tests for TSEs. The Commission endorsed this and suggested to the OIE Director General the names of experts who could participate in this Group.

4.4 OIE Ad hoc Group on Biotechnology

The Commission approved the proposed Terms of Reference and provisional list of participants for this Group.

5. Review of the OIE guidelines

5.1 Guidelines on inactivation of adventitious agents

Following reports from a number of Reference Laboratories, the Commission recognised that the current recommendation to use gamma irradiation for reference sera was not suitable for all applications due to apparent denaturation of the antibody activity. There is a number of alternative (chemical) approaches. Dr Diallo will prepare a report on this topic to be reviewed by the Commission at its meeting in January 2006.

9 WHO: World Health Organization

10 BSL: Biosafety level

11 TSE: transmissible spongiform encephalopathies

5.2 Update of OIE Quality Standard (for veterinary laboratories)

Dr Wright will compare the OIE Quality Standard against the newly updated ISO/IEC¹² 17025:2005, *General requirements for the competence of testing and calibration laboratories* and advise the Commission at its next meeting on what areas of the OIE Quality Standard need to be modified, if relevant.

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

For this agenda item, the Commission was joined by the Consultant Editor, Dr James Pearson. The Commission reviewed the status of the sixth edition of the *Terrestrial Manual*. The first batch of draft chapters would be sent to Member Countries this autumn for comment. It is hoped to circulate the chapters identified at the previous meeting as needing urgent revision by January 2006. If necessary the Commission can deal with Member Country comments by correspondence.

The Commission reviewed the list of diseases adopted at the General Session in May 2005. For diseases that had been removed from the list but for which there are *Terrestrial Manual* chapters, it was decided to retain those chapters. For diseases newly added to the list, potential chapter authors were identified, except in the case of Crimea–Congo haemorrhagic fever where further advice will be sought from Member Countries. Advice is also being sought from Member Countries on whether there is a need for material on tests for non-human primates.

7. OIE Registry of Validated and Certified Diagnostic Assays

An application had been received for inclusion of a diagnostic test for BSE on the OIE Registry of Validated and Certified Diagnostic Assays. The Commission identified potential expert reviewers. Other applications are claimed to be in preparation.

8. Liaison with other Commissions and Groups

- SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

8.1. Report of the meeting of the OIE Ad hoc Group on BSE¹³ Diagnostic Methods – the Need for Standardisation

The Commission noted the report of this expert group and emphasised its continuing interest in this very important topic. It will continue to work with the OIE Reference Laboratories on standardisation of tests for BSE.

- TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

8.2. Rabies recombinant vaccines for international trade

Following a recommendation from the OIE Conference on Rabies in Europe, held in June 2005 in Kiev, Ukraine, the Commission stated that parenteral vaccination of domestic animals using recombinant vaccines expressing the rabies virus glycoprotein in a live virus vector such as canary pox, should not be considered as live rabies virus vaccines. The *Terrestrial Manual* chapter will be modified to reflect this view, and a suitable text will be provided to the Code Commission for the *Terrestrial Code* chapter.

- AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

8.3. Clarification of disease reporting by Reference Laboratories for endemic diseases

Since the General Session in May 2004, OIE Reference Laboratories must inform the OIE Central Bureau directly of confirmed positive diagnostic results for diseases that are reportable to the OIE (after consultation with the OIE Delegate of the country from which the sample originated). In

12 ISO/IEC: International Organization for Standardization/International Electrotechnical Commission

13 BSE: bovine spongiform encephalopathy

response to a query from the Aquatic Animal Health Standards Commission, the Commission recommends that this reporting requirement should not apply to diseases that are endemic to the country of origin of the sample, in order to avoid imposing over-burdensome reporting requirements on Reference Laboratories.

9. Any other business

9.1. Update on IABs¹⁴ Conferences (Ames and Ploufragan)

The Commission noted the report sent by Dr Schmitt on the Conference on Marker vaccines and differential diagnostic tests in disease control and eradication, which was held in Ames, Iowa, USA, from 4 to 6 April 2005.

The Commission noted the final programme for the Conference entitled New Diagnostic Technology: Applications in Animal Health and Biologics Controls, which will be held in Saint Malo, France, from 3 to 5 October 2005.

9.2. Update on WAVLD¹⁵ meeting in Montevideo, Uruguay

The Commission discussed the preliminary programme for the 7th OIE Seminar on Biotechnology, on the theme of “Application of Biotechnology to Zoonotic Disease Diagnosis” to be held on 17 November 2005 during the WAVLD meeting in Montevideo, Uruguay.

9.3. Biological Weapons Convention

The Commission noted the report sent by Dr James E. Pearson following his representation of OIE at the Biological Weapons Convention in Geneva, Switzerland, June 2005.

9.4. Synthetic peptide FMD vaccine

The Commission had received information from a commercial company on the development of a synthetic peptide vaccine for FMD, and had sought expert advice. The consensus view of the experts is that it is too soon to develop specific guidelines for peptide vaccines.

9.5. Convention on Biological Diversity

Dr Alejandro Schudel informed the Commission about the meeting of the Convention on Biological Diversity, held in Montreal, Canada, September 2005.

9.6. DTI Foresight User Challenge Workshop, April 2005

The Commission noted the continuing inputs by OIE to this UK Government-sponsored initiative. Prof. Edwards represents OIE on the high level stakeholder group, Dr Dewan Sibartie had attended a meeting in Uganda concerning future needs and opportunities in Africa, while various specialists had attended a series of user challenge workshops in the UK.

9.7. Fowl pox recombinant avian influenza vaccine

The Commission had received further information from a commercial company on its fowlpox virus vectored recombinant avian influenza vaccine. The report provided additional evidence that maternal antibody did not interfere with vaccinal immunity when the vaccine is administered to day-old chicks. On the advice of the experts consulted, the Commission decided that this issue is adequately addressed in the *Terrestrial Manual* chapter.

14 IICAB/IABs: Institute for International Cooperation in Animal Biologics/International Association for Biologics

15 WAVLD: World Association of Veterinary Laboratory Diagnosticians

9.8. Symposium on Genomics and animal health

The Commission supported OIE's decision to co-sponsor a USDA/IABs symposium on genomics and animal health.

9.9. Assessment of classical swine fever diagnostics and vaccine performance

The Commission reviewed a document that it had requested from Prof. Volker Moennig of the OIE Reference Laboratory for classical swine fever in Germany entitled 'Assessment of Classical Swine Fever Diagnostics and Vaccine Performance'. Prof. Moennig had prepared an excellent and comprehensive review and the Commission is extremely grateful to him. It will be supplied to the author of the chapter to assist in updating for the next edition of the *Terrestrial Manual*. The Commission has also suggested that the document could be published in the OIE *Scientific and Technical Review*.

9.10. Materials transfer agreement

After examining a number of materials transfer agreements (MTAs) from different institutions, and noting the work done in this area by the OFFLU network, the Commission decided not to develop a generic OIE MTA. Individual institutions should continue to define their own MTA requirements.

9.11. Mission report of a visit to National FMD Reference Laboratory, Lanzhou, China

The Commission noted the report sent by Dr David Paton on his visit to the National FMD Reference Laboratory in Lanzhou, the People's Republic of China.

9.12. Veterinary Vaccines Forum, Prague, June 2005

The Commission noted the report sent by Dr David Mackay on the Veterinary Vaccines Forum, which was held in Prague, Czech Republic, from 2 to 3 June 2005. Dr Mackay's paper from this meeting on the EU Regulatory Framework for Veterinary Vaccines was received with gratitude.

9.13. Report of the First International Meeting on the Design and Analysis of Evaluation Studies

The Commission noted the report sent by Dr Matthias Greiner on the First International Meeting on the Design and Analysis of Evaluation Studies, which was held in Nairn, Inverness, Scotland, from 28 to 30 March 2005. Of particular interest was the Group's offer to evaluate validation study designs for potential submissions to the OIE Registry. The Commission expressed its gratitude to the Group for reviewing the validation template and welcomed the Group's recommendations, which would be considered.

9.14. Dates of next Biological Standards Commission meeting

The next meeting of the Biological Standards Commission will be held from 25 to 27 January 2006.

.../appendices

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 21–23 September 2005

Agenda

1. OIE Reference Laboratories and Collaborating Centres
 2. International Standardisation of Diagnostic Tests and Vaccines
 3. List of Prescribed and Alternative Tests
 4. Ad hoc and Working Groups
 5. Review of the OIE Guidelines
 6. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
 7. OIE Register of Diagnostic Tests
 8. Liaison with Other Commissions
 9. Any Other Business
-

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION
Paris, 21–23 September 2005

List of participants

MEMBERS

Prof. Steven Edwards (*President*)
 VLA Weybridge
 New Haw, Addlestone
 Surrey KT15 3NB
 UNITED KINGDOM
 Tel.: (44-1932) 34.11.11
 Fax: (44-1932) 34.70.46
 Email: s.edwards@vla.defra.gsi.gov.uk

Dr Beverly Schmitt
(Vice-President)
 National Veterinary Services
 Laboratories, Diagnostic Virology
 Laboratory, P.O. Box 844, Ames,
 IA 50010
 UNITED STATES OF AMERICA
 Tel.: (1-515) 663.75.51
 Fax: (1-515) 663.73.48
 Email:
 beverly.j.schmitt@aphis.usda.gov

Dr Anatoly Golovko
(Secretary General)
 State Science Control Institute of
 Biotechnology and strains of
 Microorganisms, 30 Donezkaya St.,
 Kiev 03151
 UKRAINE
 Tel.: (380-44) 243.83.31
 Fax: (380-44) 243.70.65
 Email: golovko@biocontrol.kiev.ua

OTHER PARTICIPANT

Dr Peter Wright
 Canadian Food Inspection Agency, National Centre for
 Foreign Animal Disease, 1015 Arlington Street
 Winnipeg, Manitoba R3E 3M4
 CANADA
 Tel.: (1-204) 789.20.09
 Fax: (1-204) 789.20.38
 Email: pwright@inspection.gc.ca

OTHER PARTICIPANT

Dr Stephanie Ostrowski
 External Activities Program and WHO Collaborating
 Centre for Biosafety & Training, CDC-Office of Health
 and Safety, Centers for Disease Control and Prevention
 1600 Clifton Rd, Atlanta, GA 30333
 UNITED STATES OF AMERICA
 Email: sro1@cdc.gov

OIE CENTRAL BUREAU

Dr Bernard Vallat
 Director General
 OIE 12 rue de Prony
 75017 Paris, FRANCE
 Tel.: (33-1) 44.15.18.88
 Fax: (33-1) 42.67.09.87
 Email: oie@oie.int

Dr Alejandro Schudel
 Head, Scientific and Technical Dept
 Email: a.schudel@oie.int

OIE COLLABORATING CENTRES

Dr Adama Diallo
 FAO/IAEA Centre for ELISA and Molecular Techniques
 in Animal Disease Diagnosis International Atomic Energy
 Agency Wagramerstrasse 5, P.O. Box 100, A-1400 Vienna
 AUSTRIA
 Tel.: (43-1) 2600.28355
 Fax: (43-1) 2600.28222
 Email: a.diallo@iaea.org

CONSULTANT MANUAL EDITOR

Dr James E. Pearson
 4016 Phoenix
 Ames, Iowa 50014
 UNITED STATES OF AMERICA
 Email: jpearson34@aol.com

Dr Christianne Bruschke
 Chargé de Mission, Scientific & Technical Dept
 c.bruschke@oie.int

Ms Sara Linnane
 Scientific Editor, Scientific and Technical Dept
 Email: s.linnane@oie.int

Mr François Diaz
 Secretariat for Validation, Certification and Registry of
 Diagnostic Assays, Scientific & Technical Dept
 Email: f.diaz@oie.int

A REVIEW OF TESTS AVAILABLE FOR DIAGNOSIS OF TUBERCULOSIS IN NON-BOVINE SPECIES

Prepared by Debby Cousins and Nishel Florisson

*Australian Reference Laboratory for Bovine Tuberculosis (OIE Laboratory for Tuberculosis),
Department of Agriculture, 3 Baron Hay Court, South Perth, Western Australia, 6151
dcousins@agric.wa.gov.au; (+61-8) 93.68.34.51; (+61-8) 94.74.18.81*

Background to the Paper

An OIE Ad hoc Group on Tuberculosis met in November 2004 and reviewed the chapter on bovine TB in the OIE *Terrestrial Animal Health Code*. The conclusions of the Group were that although the chapter is naturally focused on TB in cattle, there was a need to identify biological tests for pigs and other animals, given the unsuitability or lack of validation of the tuberculin test in non-bovine species.

In addition, it was determined that the Biological Standards Commission:

- i) Should request that the OIE Reference Laboratories provide, in the first instance, a view on what information is available regarding validation of diagnostic tests for tuberculosis in non-bovine species.
- ii) Would appreciate advice on what further priority work needs to be done to improve the availability of appropriate tests for such species.

Following initial e-mail on this topic to all OIE Reference Laboratories for Tuberculosis, the Commission invited Dr Cousins of the Australian Laboratory, to lead a review collating all available information, incorporating inputs from the other OIE Reference Laboratories and other sources, and determining where the gaps lie in the data and making recommendations on where benefits might accrue from future investments.

The full paper as presented to the Biological Standards Commission provides detailed scientific information together with recommendations for further action.

Recommendations

That in order to collate validation data on the diagnosis of tuberculosis in species other than bovine, the OIE

- i) Develop a template suitable for submitters to allow collection of key information to allow integrated data analysis of tests used for diagnosis of tuberculosis;
- ii) Encourage veterinarians and researchers to submit data from test evaluation studies using the developed template so that over time the data can be accumulated;
- iii) Make the information available to interested parties as appropriate for the purpose of further study and test validation.

© **World Organisation for Animal Health (OIE), 2005**

This document has been prepared by specialists convened by the OIE. Pending adoption by the International Committee of the OIE, the views expressed herein can only be construed as those of these specialists.

All OIE (World Organisation for Animal Health) publications are protected by international copyright law. Extracts may be copied, reproduced, translated, adapted or published in journals, documents, books, electronic media and any other medium destined for the public, for information, educational or commercial purposes, provided prior written permission has been granted by the OIE.

The designations and denominations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the OIE concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers and boundaries.

The views expressed in signed articles are solely the responsibility of the authors. The mention of specific companies or products of manufacturers, whether or not these have been patented, does not imply that these have been endorsed or recommended by the OIE in preference to others of a similar nature that are not mentioned.