71 SG/12/CS2 A

Original: English
September 2002

REPORT OF THE MEETING OF THE OIE STANDARDS COMMISSION

Paris, 25– 27 September 2002

———

The OIE Standards Commission met at the OIE Headquarters from 25 to 27 September 2002. Dr Marian Truszczynski welcomed Dr Alejandro Schudel, the new Head of the OIE Scientific and Technical Department. Dr Schudel stated that he looks forward to working with the Commission and indicated that Dr Bernard Vallat sends his regrets that he would be unable to attend the Commission meeting because he was participating at the 27th World Veterinary Congress in Tunis, Tunisia.

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

1. OIE Reference Laboratories

1.1. New applications for Collaborating Centre and Reference Laboratory status

The Commission recommends the following new applications for OIE Reference Laboratory status:

Anthrax

Canadian Food Inspection Agency, Lethbridge Laboratory, P.O. Box 640, Lethbridge, Alberta T1J 3Z4, Canada. Tel.: (1.403) 382.55.04; Fax: (1.403) 381.82.83; E-mail: galep@inspection.gc.ca
Designated Reference Expert: Dr S.P. Gale

Anthrax

National Veterinary Services Laboratories, Ames, Iowa, United States of America (USA). Tel.: (1.515) 663.7565; Fax: (1.515) 663.7569; E-mail: david.a.miller@aphis.usda.gov
Designated Reference Expert: Dr D.A. Miller.

Bovine spongiform encephalopathy

National Institute of Animal Health, Ibaraki, Japan. Tel.: (81.298) 38.77.57; Fax: (81.298) 38.79.07; E-mail: tyoko@affc.go.jp
Designated Reference Expert: Dr T. Yokoyama.

Antimicrobial resistance

Veterinary Laboratories Agency, VLA Weybridge, United Kindgom (UK). Tel.: (44.1932) 34.11.11; Fax: (44.1932) 34.70.46; E-mail: c.teale@vla.defra.gsi.gov.uk
Designated Reference Expert: Dr C. Teale.

The Commission determined that there is a need for OIE Reference Laboratories for heartwater, haemorrhagic septicaemia, and trypanososmosis (tsetse-transmitted) and invites nominations from OIE Delegates.

In accordance with OIE protocol, all nominations for Reference Laboratory status must be submitted from the Delegate of the country concerned. In the case of international laboratories, nominations are accepted from the Regional Coordinator of the appropriate OIE Regional Representation.

The Commission recommended that West Nile encephalitis be added to the scope of the OIE Reference Laboratory for Equine encephalomyelitis (Eastern, Western and Venezuelan).

1.2. Updating the list of Reference Laboratories

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

Foot and mouth disease and Swine vesicular disease

Dr D. Paton to replace Dr A. Donaldson at the Institute of Animal Health, Pirbright, UK.

Bluetongue and African horse sickness

Dr G.H. Gerdes to replace Dr J. Paweska at the Onderstepoort Veterinary Institute, South Africa.

African swine fever

Dr O.C. Phiri to replace Dr M. Penrith at the Onderstepoort Veterinary Institute, South Africa.

Bovine tuberculosis

Mr K. Jahans. to replace Dr N. Palmer at the Veterinary Laboratories Agency, VLA Weybridge, UK.

Enzootic bovine leukosis

Mr C. Venables to replace Mrs R. Lysons at the Veterinary Laboratories Agency, VLA Weybridge, UK.

Rabies

The Commission was notified that the rabies expert has left the OIE Reference Laboratory in South Africa; a request for a nomination for a new expert will be sent to the Reference Laboratory.

African swine fever

The Commission approved a request that the National Veterinary Services Laboratories, Foreign Animal Disease Diagnostic Laboratory (Plum Island), USA, be removed from the list of Reference Laboratories for African swine fever.

The Commission recommends that those Reference Laboratories that have not sent an annual report for the past two years should be removed from the list. A letter will be sent in such cases to confirm the situation.

1.3. Fish Diseases Commission's guidelines for applicants

The Commission made changes to its 'Guidelines for Applicants for Designation as an OIE Reference Laboratory' based on some of the changes proposed by the Fish Diseases Commission in its equivalent guidelines.

2. International standardisation of diagnostic tests and vaccines

2.1. OIE standardisation programmes for diagnostic tests

LIST A DISEASES

Peste des petits ruminants – Coordinator Dr G. Libeau

Dr G. Libeau reported that work continues on the preparation of a weak positive reference serum. The Commission will ask her to submit a data sheet on this serum for review at its next meeting.

Contagious bovine pleuropneumonia – Coordinator Dr A. Pini

Dr A. Pini reported that following irradiation, the titre of the candidate reference sera is reduced four-fold. The Commission believes that the titres of the irradiated sera are still useful at the lower levels, and will ask Dr Pini to submit data sheets on the irradiated sera for review at its next meeting.

LIST B DISEASES

Enzootic bovine leukosis – Co-ordinator Dr L. Renström

Dr B. Klingeborn had reported on behalf of Dr L. Renström that a meeting of EBL reference laboratories had occurred regarding the need to develop new EBL virus reference sera to replace the current E4 standard. Dr Klingeborn also stated that work on a new standard protocol for the PCR[1] method of EBL diagnosis will start immediately. The Commission would reiterate that international reference standards should not be used as working standards, and that laboratories need both types of standards.

Equine influenza – Coordinator Dr J. Mumford

The Commission noted the data submitted for equine influenza reference sera and reaffirmed its acceptance as OIE International Reference Serum.

3. List of prescribed and alternative tests

3.1. Comments on January Report

One Member Country had opposed the removal of the BBAT[2] from the list of prescribed tests for porcine brucellosis to the list of alternative tests. The Commission decided to leave the BBAT as an alternative test based on the recommendation of the Ad hoc Group on brucellosis (see point 4). By definition, an alternative test can be used for trade purposes by bilateral agreement. Alternative test status does not preclude the BBAT from being used for surveillance purposes.

3.2. ELISA[3] for caprine arthritis/encephalitis & maedi-visna (to replace AGID[4])

The Commission had received validation data for an ELISA for caprine arthritis/encephalitis and Maedi-visna, with the request that it replace the AGID as the prescribed test for international trade. The Commission will seek the advice of experts before making a recommendation.

---

1 PCR: Polymerase chain reaction
2 BBAT: Buffered *Brucella* antigen test
3 ELISA: enzyme-linked immunosorbent assay
4 AGID: agar gel immunodiffusion

3.3. ELISA for rabies serology

The Commission evaluated the data submitted on the rabies ELISA with the view to determining its potential for designation as a prescribed test for international trade. The Commission noted that the request for supplement data and analyses on the rabies ELISA had been submitted. Based on this additional information, the Commission feels that further discussion with experts is required with respect to intra-assay variability and the correlation of antibody titres between the ELISA and FAVN[5] tests.

3.4. Nonstructural protein tests for foot and mouth disease

An Ad hoc Group on Nonstructural Protein Tests for Foot and Mouth Disease (FMD) diagnosis will meet at the OIE headquarters from 2 to 4 October 2002. The Commission will discuss the Group's report at its next meeting.

3.5. Validation of tests for bovine spongiform encephalopathy (BSE)

In 1998, the Commission for the European Union (EU) initiated an evaluation of four diagnostic immunoassays for PrP^{sc} in brain tissue, following a public call for submissions of tests for the trial. Identical aliquots of brain material were distributed to participating laboratories.

Positives samples were from confirmed clinical cases of bovine spongiform encephalopathy (BSE), and negative samples were from a BSE-free population. Three of the methods (one immunoblot and two ELISAs) correctly identified all the positive and negative samples[6]. These tests have been adopted for large-scale surveillance in the EU where >8.5 million cattle had been tested in 2001 for BSE of which 2153 were positive. This included both active and passive surveillance programmes. Further details are available in the published report[7].

More recently a further evaluation has been carried out of five immunoassays developed since the previous study[8]. Estimates were made of sensitivity, specificity and detection limits for each test. In addition, consideration was given to sample selection and the effects of sample handling and treatment on the test results. All the methods gave high values for diagnostic sensitivity and specificity. However, the study emphasised the critical importance of sample treatment, which had differing effects depending on the test method used. This has serious implications for the preparation by Reference Laboratories of standard reference materials for these assays.

The Commission noted these useful results and would take them into account immediately in the revision of the text for the *Manual of Standards for Diagnostic Tests and Vaccines* (the *Manual*). It was emphasised that the studies only related to comparisons of clinically affected animals with known negatives, and therefore could not be used to assess predictive values of the tests when used on preclinical animals.

3.6. Indirect ELISA for rinderpest

The Commission acknowledges the receipt of a dossier entitled 'Validation of an enzyme-linked immunosorbent assay for the detection of antibodies against rinderpest virus in cattle' and congratulates the authors for all of the work that they have done on this important disease. The data presented were reviewed and the Commission agrees that the indirect ELISA may prove beneficial as a screening test for the surveillance of rinderpest based on the preliminary evidence provided. The Commission feels that certain aspects of the analytical and diagnostic validation need to be clarified and/or expanded with respect to the comparative performance of the indirect ELISA, competitive ELISA and the virus neutralisation test, especially in the detection of antibody responses to rinderpest virus lineages I and II. The Commission looks forward to receiving this additional information.

---

5 Fluorescent antibody virus neutralisation

6 Evaluation of tests for diagnosis of TSE in bovines, European Commission, July 1999.

7 Report on the monitoring and testing of bovine animals for the presence of bovine spongiform encephalopathy (BSE) in 2001, European Commission, June 2002.

8 Evaluation of five rapid tests for the diagnosis of transmissible spongiform encephalopathy in bovines (2^{nd} study), European Commission, March 2002.

4. Report of the meeting of the Ad hoc Group on Brucellosis

The Ad hoc Group on Brucellosis met with the Commission and presented the report of the Group's meeting. The purpose of the meeting was to harmonise the three individual *Manual* chapters on brucellosis caused by smooth *Brucella* sp. (namely the chapters on bovine, caprine/ovine, and porcine brucellosis). The Group decided that as these three chapters are sufficiently similar with respect to methods for agent identification and for serological/immunological detection, and certain aspects of vaccine production, descriptions common to all three should be consolidated into one representative chapter – Bovine brucellosis. The chapters on Porcine and Caprine and ovine brucellosis would thus be shortened, with common methods cross referenced to the Bovine brucellosis chapter; these two chapters would therefore only contain information and descriptions unique to their respective diseases. Each chapter would identify prescribed and alternative tests for international trade and, where appropriate, discuss the suitability of available tests for control and surveillance programmes. Once these chapters have been redrafted and approved by the OIE Reference Experts, they will be sent again to Member Countries for comment.

For the future, the Ad hoc Group suggested that the Commission consider having just one chapter on disease caused by smooth *Brucella* sp. The Commission recognises that consolidation of the brucellosis chapters would have an impact on the *International Animal Health Code* (the *Code*). The Commission may consider combining these chapters for the sixth edition of the *Manual* to be published in 2008. In the meantime, the International Animal Health Code Commission would be informed of this proposition.

The three OIE Reference Experts who were Members of the Ad hoc Group agreed to collaborate on the development of standard reference sera for use in porcine, ovine and caprine tests in order to calibrate new assays between laboratories.

The Ad hoc Group asks that the OIE Reference Experts be consulted about any proposed change to the list of prescribed and alternatives tests for brucellosis. The Group also proposed that it continue to meet during the publication cycles of new editions of the *Manual* as the Members found meeting face to face to be very useful.

5. Questionnaire on bovine tuberculosis

The Commission has received replies to its questionnaire on tuberculin and will assess the data.

6. OIE *Manual of Standards of Diagnostic Tests and Vaccines*

For this section of the agenda the Commission was joined by the new consultant editor, Dr J.E. Pearson. Progress on the preparation of chapters for the next edition of the *Manual* was reviewed. Three mailings have been distributed for Member Country comments and many helpful comments have been received. The Commission provided detailed advice to the editor on specific technical issues in individual chapters.

The Commission reviewed the list of chapters that have not yet been received. All chapters need to be received as soon as possible to permit their review by experts in OIE Member Countries by the OIE General Session in May 2003 (the remaining chapters will be sent for comment in two batches: one due to be sent out in January 2003 and the second in March 2003).

The Commission noted that some users of the *Manual* were confused to find certain OIE List B diseases included in Part 3 of the *Manual* (Other Diseases of Importance in International Trade) and not in Part 2 (OIE Listed Diseases). It is therefore proposed to move those chapters currently in Part 3 that cover List B diseases but that may not have an equivalent chapter in the *Code*, into Part 2 as the next chapter in the appropriate section (for example the multiple species or bovine disease section). Chapters that address a disease affecting many species, such as salmonellosis, will remain in Part 3 but a cross reference to this chapter will be included in Part 2 for those *Salmonella* species that are mentioned in the *Code*.

The Commission was asked to consider publishing the fifth edition of the *Manual* in three volumes for reasons of size and economics. It agreed to this proposal and suggested that introductory and List A chapters be included in one volume and the remaining chapters be divided between the last two volumes. A description of what is included in each volume should be listed on the spines of the volumes.

The fourth edition of the *Manual* should not be translated into French and Spanish at this late stage due to the impending publication of the fifth edition. The Commission supports the translation of the upcoming fifth edition chapters of the *Manual* into French and Spanish as soon as the chapters are completed.

7. Standards Commission Guidelines

7.1. Preparation of booklet on guidelines

The title of the booklet will be 'OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases'. The foreword to the booklet and the proposed glossary were approved. The booklet will also include a list of references under the title 'Further Reading'. The booklet will be ready to be sold in the next few months. The Commission supported approaching ILAC[9] regarding their potential endorsement of the OIE Standard for Management and Technical Requirements for Laboratories Conducting Tests for Infectious Diseases.

7.2. Guidelines on validation, quality control, and reference materials for PCR assays

Dr Sándor Belak, from the National Veterinary Institute, Uppsala, Sweden, joined the Commission to discuss the new *Manual* chapter entitled Validation and quality control of the polymerase chain reaction methods used for diagnosis of infectious diseases. The Commission thanked Dr Belak for his efforts in drafting this new chapter. A discussion followed on what is considered to be an appropriate method for validating PCR assays and whether the guidelines described in the chapter on Principles of validation of diagnostic assays for infectious diseases can be applied. Dr Belak supports the use of PCR instead of virus isolation for many agents, particularly for samples from which it is difficult to isolate virus, such as semen. He also believes that more and more commercial PCR kits are becoming available for veterinary diagnostics.

The Commission and Dr Belak reviewed the draft text addressing specific issues and proposing changes. Once the draft text is complete, it will be sent to Member Countries for comment.

7.3. Guidelines on antimicrobial resistance

The Commission reviewed the draft guidelines on antimicrobial resistance that had been prepared by the Ad hoc Group on Antimicrobial Resistance. The Commission agreed that these guidelines should be reviewed by OIE experts in this field, the new OIE Reference laboratory for antimicrobial resistance and the OIE Collaborating Centre for Veterinary Medicinal Products. Comments will be reviewed and discussed at the next Standards Commission meeting.

8. Liaison with other Commissions

Ê CODE COMMISSION

8.1. Proposal to remove atrophic rhinitis of swine from List B – follow-up from January meeting

The Commission reviewed the input from experts on atrophic rhinitis and determined to leave the chapter in the *Manual*. This will be reviewed once the new criteria for categorisation and notification of diseases are established.

9 International Laboratory Accreditation Conference

8.2. Bluetongue surveillance guidelines

The Commission will forward the proposed bluetongue surveillance guidelines to the OIE Reference Laboratories for bluetongue.

8.3. Definition of avian influenza/Newcastle disease

The Commission discussed the possibility that a proposal to change the definition of reportable strains of avian influenza would be submitted. It was noted that an Ad hoc Group would convene in late October to discuss this issue among others. The Commission will discuss the Ad hoc Group's report at its January 2003 meeting.

9. Any other business

9.1. Terms of Reference for Standards Commission

The Commission recommends that the proposed new name be changed to 'Scientific Standards Commission'. It also would like to recognise the invaluable help it receives from the other participants at its meetings. Without the assistance of these participants, the Commission would find it impossible to complete its work load.

9.2. Letter on BSE testing

The Commission will consult with experts regarding a comparative evaluation of the immunoblot and immunohistochemistry techniques for BSE diagnosis.

9.3. Joint OIE/WAVLD[10] Symposium in Thailand 2003

The OIE Biotechnology Symposium will focus on vaccines and companion diagnostics for avian influenza, classical swine fever and FMD. Dr Schudel will seek regional experts from the Far East to give presentations at Symposium, and encourage the participation of experts from developing countries at this symposium.

9.4. Update on the European Union Committee on Diagnostic techniques for FMD, classical swine fever and avian influenza

Dr Steve Edwards attended the meeting of the EU Committee on Diagnostic Techniques for FMD, classical swine fever and avian influenza. He gave an account to the EU Committee of the OIE position on test validation. Dr Edwards will attend further meetings in the next 2 months and will report back to the Standards Commission.

9.5. FAO/IAEA[11] Consultants Meeting on 'OIE Validation and Certification of Diagnostic Assays for Infectious Animal Diseases'

Dr Adama Diallo presented concerns regarding clarification of OIE test validation standards and applicability of tests for different purposes. In view of these concerns, FAO/IAEA Joint Division decided to convene a consultants meeting entitled 'OIE Validation and Certification of Diagnostic Assays for Infectious Animal Diseases', in Vienna, Austria. The Commission will discuss the outcome of the consultation at its next meeting.

9.6. Dates of next Standards Commission meetings

The next meeting of the Standards Commission will be held from 14 to 17 January 2003.

_____

.../Appendices

10 WAVLD: World Association of Veterinary Laboratory Diagnosticians
11 FAO/IAEA: Food and Agriculture Organization of the United Nations/International Atomic Energy Agency

Appendix I

MEETING OF THE OIE STANDARDS COMMISSION

Paris, 25–27 September 2002

Agenda

1. OIE Reference Laboratories
2. International standardisation of diagnostic tests and vaccines
3. List of prescribed and alternative tests
4. Report of the meeting of the Ad hoc Group on Brucellosis
5. Questionnaire on bovine tuberculosis
6. OIE *Manual of Standards for Diagnostic Tests and Vaccines*
7. Standards Commission guidelines
8. Liaison with the other Commissions
9. Any other business

MEETING OF THE OIE STANDARDS COMMISSION
Paris, 25 - 27 September 2002

_____

List of participants

MEMBERS

Prof. Marian Truszczynski *(President)*
National Veterinary Research Institute
57 Partyzantow St., 24-100 Pulawy
POLAND
Tel.: (48-81) 886.32.70
Telex: 642401
Fax: (48-81) 887.71.00.
Email: mtruszcz@esterka.piwet.pulawy.pl

Dr Steve Edwards
(Vice-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
(Secretary General)
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

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

OIE COLLABORATING CENTRE

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) 2600.26049
Fax: (43-1) 2600.28222
Email: a.diallo@iaea.org

OIE CENTRAL BUREAU

Dr Alejandro Schudel
Head, Scientific and Technical Dept
12 rue de Prony
75017 Paris
FRANCE
Tel.: (33-1) 44.15.18.88
Fax: (33-1) 42.67.09.87
Email: a.schudel@oie.int

Dr Dewan Sibartie
Deputy Head, Scientific & Technical Dept
d.sibartie@oie.int

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

GUEST PARTICIPANTS

Dr Bruno Garin-Bastuji
Unité Zoonoses Bactériennes, Agence Française de
Sécurité Sanitaire des Aliments (AFSSA), BP 67,
94703 Maisons-Alfort Cedex
FRANCE
Tel.: (33-1) 49.77.13.00
Fax: (33-1) 49.77.13.44
Email: b.garin@afssa.fr

Dr Klaus Nielsen
Canadian Food Inspection Agency, Animal
Diseases Research Institute, P.O. Box 11300,
Station H, Nepean, Ontario K2H 8P9
CANADA
Tel: (1-613) 228.66.98
Fax: (1-613) 228.66.67
Email: nielsenk@inspection.gc.ca

Dr Alastair P. MacMillan
VLA Weybridge, New Haw, Addlestone, Surrey
KT15 3NB, UNITED KINGDOM
Tel: (44-1932) 34.11.11
Fax: (44-1932) 34.70.46
Email:a.p.macmillan@vla.defra.gsi.gov.uk

Prof. Sándor Belak
Department of Virology, The National Veterinary
Institute, Biomedical Centre, Box 585, SE-751 23
Uppsala, SWEDEN
Tel.: (46-18) 67.41.35
Fax: (46-18) 471.45.20
Email: sandor.belak@bmc.uu.se

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