World Organisation for Animal Health Organización Mundial de Sanidad Animal

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REPORT OF THE MEETING OF THE OIE STANDARDS COMMISSION

Paris, 31 January – 2 February 2001

The OIE Standards Commission met at the OIE Headquarters from 31 January to 2 February 2001.

Dr B. Vallat, Director General, welcomed the Standards Commission and stated that its work was vital to meeting OIE objectives. Prof. M. Truszczynski, President of the Commission, acknowledged OIE's support for the Commission's activities. Dr Vallat noted that the Work Programme for Implementing the Recommendations of the Third Strategic Plan includes a request for funds to translate the *Manual of Standards for Diagnostic Tests and Vaccines* into Spanish and French. This Programme will be presented for adoption by the Member Countries at the General Session in May 2001. Dr Vallat suggested providing accessibility to the *Manual* on the OIE Web site within 3 years. Dr J. Pearson stated that it is proposed that the OIE will make the *Manual* available for purchase on the OIE Web site except for OIE Delegates who receive free copies. There was a suggestion to make the *Manual* available on CD-ROM.

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 discussed a request by the Centre for Animal Parasitology, Canadian Food Inspection Agency, Saskatchewan, Canada, to be designated as an OIE Collaborating Centre for Parasitology. The Commission will ask for further clarification from the Canadian laboratory before making a recommendation.

The Commission reviewed a number of new applications for OIE Reference Laboratory status, and recommends the acceptance of the following:

Avian influenza and Newcastle disease

Virology Department, Istituto Zooprofilattico Sperimentale delle Venezic, Via Romea 14/A 35020, Legnaro, Padova, Italy. Tel.: (39.049) 808.43.69; Fax: (39.049) 808. 43.60; E-mail: icapua.izs@interbusiness.it

Designated Reference Expert: Dr I. Capua.

Leptospirosis

WHO¹ Collaborating Centre for Leptospirosis, Queensland Health Scientific Services, 39 Kessels Road, Coopers Plains, P.O. Box 594, Archerfield, Queensland 4108, Australia. Tel.: (61.7) 32.74.90.01, Fax: (61.7) 32.74.90.03; E-mail: m.moore@mailbox.uq.edu.au Designated Reference Expert: Dr L.D. Smythe.

Trichinellosis

Canadian Food Inspection Agency, Centre for Animal Parasitology, 116 Veterinary Road, Saskatoon, Saskatchewan S7N 2R3, Canada. Tel.: (1.306) 975.40.71, Fax: (1.306) 975.57.11; E-mail: agajadhar@em.agr.ca

Designated Reference Expert: Dr A. Gajadhar.

Bovine tuberculosis

VLA Weybridge, New Haw, Addlestone, Surrey KT15 3NB, United Kingdom. Tel.: (44.1932) 34.11.11, Fax: (44.1932) 34.70.46; E-mail: n.palmer@vla.maff.gsi.gov.uk Designated Reference Expert: Dr N.M.A. Palmer.

Tularemia

National Veterinary Institute, Department of Wildlife, Uppsala, Sweden. Tel.: (46.18) 67.42.14, Fax: (46.18) 30.91.62; E-mail: torsten.morner@sva.se Designated Reference Expert: Dr T. Mörner.

1.2. Updating the list of Reference Laboratories

The Commission approved a request by Dr H.R. Gamble, Parasite Biology and Epidemiology Laboratory, United States Department of Agriculture, Maryland, United States of America (USA) to be removed from the list of Reference Laboratories for Trichinellosis. The Commission also approved a request by the Foreign Animal Diseases Diagnostic Laboratory (Plum Island), USA to be removed from the list of Reference Laboratories for African horse sickness. The OIE has been notified of the following changes to named experts at OIE Reference Laboratories. The Commission recommends their acceptance:

African swine fever

Dr M.L. Penrith to replace Dr G. Thomson at Onderstepoort Veterinary Institute, South Africa.

Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis

The Commission will ask that Institute of Animal Science and Health, Lelystad, the Netherlands, to designate one expert for infectious bovine rhinotracheitis.

Classical swine fever

Dr J. Pasick to replace Dr A. Clavijo at the National Centre for Foreign Animal Disease, Winnipeg, Canada.

Rinderpest and Peste des petits ruminants

Dr G. Libeau to replace Dr A. Diallo at CIRAD/EMVT², Montpellier, France.

¹ World Health Organization

² Centre de coopération internationale en recherche agronomique pour le développement, Département d'élevage et de médicine vétérinaire (International Cooperation Centre for Agronomic Research and Development - Department of Tropical Livestock and Veterinary Medicine)

1.3. Annual reports of Reference Laboratories and Collaborating Centres

Reports had been received from 110/117 Reference Laboratories and 6/8 Collaborating Centres. The Commission commented once again on the impressive range of activities by the Reference Laboratories and Collaborating Centres towards the objectives of the OIE, and the continuing support provided by individual experts to the work of the Standards Commission. A small number of annual reports for 2000 have not been received so far and a reminder letter will be sent to those concerned.

The full set of reports will be supplied to Member Countries and to all the Reference Laboratories and Collaborating Centres. The international activities relevant to the work of the OIE are summarised below³:

	International activities	Percentage of Laboratories/Collaborating Centres carrying out these activities		
		Reference Laboratories	Collaborating Centres	
a)	Diagnostic testing	98%	17%	
b)	Production/testing/distribution of diagnostic reagents	89%	33%	
c)	Research	82%	17%	
(d)	International harmonisation/standardisation of methods	45%	83%	
e)	Preparation and supply of international reference standards	47%	17%	
f)	Collection, analysis and dissemination of epizootiological data	35%	17%	
g)	Provision of consultant expertise	46%	50%	
h)	Provision of scientific and technical training	53%	83%	
i)	Organisation of international scientific meetings	16%	100%	
j)	Participation in international collaborative studies	61%	100%	
k)	Publications	77%	83%	

1.4. Reference Laboratories conducting validated tests in wildlife

The Commission reviewed the Table of OIE Reference Laboratories using veterinary diagnostic tests to diagnose diseases in wild animal species (see Appendix III of the Standards Commission report, November 2000 report) and noted some changes that had been submitted since November. The Table will be forwarded to the OIE Working Group on Wildlife Diseases for comment.

2. International standardisation of diagnostic tests and vaccines

2.1. OIE standardisation programmes for diagnostic tests

LIST A DISEASES

Foot and mouth disease - Coordinator Dr A.I. Donaldson

The Commission reviewed the submitted data sheets regarding proposed foot and mouth disease (FMD) reference sera and agreed they should now be formally designated as OIE International Standard Sera for FMD serology.

³ Reports from aquatic animal diseases laboratories are not included in this analysis

Contagious bovine pleuropneumonia - Coordinator Dr A. Diallo and J.L. Martel

The Commission determined that there is still a need for further validation of the proposed weak positive reference sera for contagious bovine pleuropneumonia (CBPP). The FAO/IAEA⁴ Centre for ELISA⁵ and Molecular Techniques in Animal Disease Diagnosis will test and distribute the weak positive sera to other laboratories for further evaluation and comparison. The Commission will contact Dr F.G. Santini, OIE Reference Expert for CBPP at the OIE Reference Laboratory in Teramo, Italy, with regards to the preparation of candidate reference sera for use in any of the serological tests for CBPP.

Classical swine fever – Coordinator Dr S. Edwards

Dr S. Edwards reported that the reference sera have been prepared and are in the process of being freeze-dried.

LIST B DISEASES

Rabies serology - Coordinator Dr F. Cliquet

The Commission will contact Dr Cliquet to inquire on the progress being made with producing negative reference sera.

Enzootic bovine leukosis – Coordinator Dr L. Renström

No progress report had been received. The Commission will send a reminder to Dr Renström on the request for weak positive sera and to inquire whether there will be further work done on validation of PCR⁶ for enzootic bovine leukosis.

Equine influenza – Coordinator Dr J. Mumford

Dr Mumford reported that she is working with the European Pharmacopoeia on a procedure to make available the Reference Sera that have been prepared. It is hoped that this will be resolved and the sera will be available before the next meeting of the Standards Commission.

Equine rhinopneumonitis – Coordinator Dr J. Mumford

Dr Mumford, reported that no progress has been made on the preparation of the Reference Sera but she still considers that the sera are needed and hopes to prepare them this year. The Commission will inquire about potential collaboration with NIBSC⁷ in regards to the storage and distribution of OIE international standards.

The Commission will ask the reference laboratories about the number of requests for reference sera and state in its annual report that OIE international reference sera are available and their use is encouraged

2.2. International comparison of dourine complement fixation test antigens

Dr L. Touratier presented the results of the international comparison of dourine CFT⁸ antigens. This comparison was undertaken in an attempt to assess the differences in CFT test results among international laboratories that may be due to antigen variation due to use of different strains of *T. equiperdum*. It was determined that although there were different strains used in the CFT, the antigens tested produced remarkably similar results on the ring test. There was further discussion concerning the fact that there have been no *T. equiperdum* isolations made in the past 19 years. Due to the lack of standardisation and validation of the CFT antigen in many countries, the Commission supports the identification of a characterised, standard strain of *T. equiperdum* for use in the CFT. The Commission also supported the study planned by Dr F. Claes, Institute of Tropical Medicine, Antwerp, Belgium to compare *T. equiperdum* strains.

Food and Agriculture Organization of the United Nations/International Atomic Energy Agency

⁵ Enzyme-linked immunosorbent assay

⁶ Polymerase chain reaction

⁷ National Institute for Biological Standards and Control

⁸ Complement fixation test

Dr Touratier stated there was a need for a surra reference laboratory and recommended a laboratory in Japan. The Commission suggested the recommended laboratory could apply again for reference laboratory status.

2.3. Bovine tuberculosis

In order to determine the need for further activity in the area of international harmonisation of diagnostic tests for bovine tuberculosis, the Commission will send a letter to all OIE Delegates requesting information on the diagnostic procedures in use for bovine tuberculosis with emphasis on source and standardisation of tuberculin for the skin test.

3. List of prescribed and alternative tests

The Commission reviewed the current list of prescribed and alternative tests for international trade. It was noted that reference laboratories for paratuberculosis supported the Commission's decision to remove the CFT from list of 'alternative' tests for this disease; however, the test will still be included in the *Manual*. No other changes were made to the list of tests.

4. OIE Manual of Standards of Diagnostic Tests and Vaccines

4.1. Finalising the fourth edition of the *Manual*

Dr B. Garin-Bastuji, on behalf of all the OIE Reference Laboratories for brucellosis in Europe, discussed various aspects of the chapter on bovine brucellosis for the fourth edition of the *Manual*. The Commission appreciated Dr Garin-Bastuji's comments and recommendations. The Commission will recommend that the OIE brucellosis experts use international meetings as opportunity to discuss changes in the chapters for the next edition of the *Manual*. The Commission stated that it is important that experts from other parts of the world be included in this discussion.

The Commission reviewed the list of *Manual* chapters that are awaiting final approval. They also considered reviewer comments on the glossary. Copies of the fourth edition of the *Manual* should be available in March 2001. The Commission determined that a user questionnaire will be loosely inserted in the *Manual* so as to be available to anyone who receives the book. It was recommended that this user questionnaire also be available on the OIE Web site. The Commission would strongly encourage the production of a CD-ROM version of the *Manual*, available with each hard copy. The Commission recommends removing the third edition from the OIE Web site once the fourth edition is published.

4.2. Planning the fifth edition of the *Manual*

The Commission discussed plans for the fifth edition of the *Manual*. It was determined to bring the production schedule forward by 6 months in order to have adequate time to complete the chapter review processes before publication in 2004. The Commission expressed a concern about the low percentage of Member Countries that respond with comments on the draft chapters and strongly encourages Member Countries to provide input and to include pertinent laboratories in the review process. New authors will be sought for a number of chapters, both to replace those who are no longer available and to provide fresh inputs in some cases. The deadline for contributors' acceptance for updating chapters will be July 2001 and the Commission will review the list of contributors at the September 2001 meeting. The letter of invitation sent to chapter contributors will clarify that their role as contributors will be acknowledged, but that the OIE, based on Member Country input, has the final responsibility for the content of the chapters. Emphasis on the aim of the *Manual*, including standardisation of diagnostic procedures for diseases of zoonotic and public health importance, will be stressed. Long descriptions of diseases should be avoided as this information is available elsewhere.

Based on the OIE's strategic plan, the Commission proposes to include new chapters on zoonotic diseases in the fifth edition of the *Manual*. The following chapters will be added: an introductory chapter on antimicrobial resistance, campylobacteriosis, toxoplasmosis, arboviral equine diseases (Eastern, Western and Venezuelan equine encephalomyelitis, Japanese encephalitis and West Nile fever), bunyaviral diseases of animals, enterotoxogenic *Escherichia coli*, cryptosporidiosis, swine influenza and large paramyxoviruses (Nipah and Hendra). In addition, contributors will be asked to include text on differential diagnoses.

The Commission recommends that Dr G.A.C. Cullen continue as consultant editor of the Manual.

5. Preparation of booklet on guidelines

Drs R. Jacobson and P. Wright are continuing their work on rewriting the assay validation paper from the *OIE Scientific and Technical Review* (1998), **17** (2), 469–526, to make the format compatible with the other documents for the booklet of guidelines.

6. Liaison with the Code Commission

6.1. Paratuberculosis

The Commission asked the Reference Experts on paratuberculosis for their opinions on various testing procedures in order to get a consensus view on diagnostic specificity and sensitivity of the individual tests, and how each test is best applied for screening individual animals and herds.

The following is a summary of the input from the OIE Reference Laboratories on the sensitivity and specificity of the tests available. All the tests are quite specific – over 90% with some ELISAs reported to be 98%. However, the sensitivity of all the serological procedures is low – reports of 50–75% sensitivity. There have been isolated reports of false-positive results with some ELISA methods. It was agreed that the ELISA is the best serological test available and can be used as a herd screening test and to detect heavy shedders of the organism. Intradermal testing has poor sensitivity and specificity. Culture is very specific but requires long incubation. PCR has poor sensitivity if used directly on faecal samples, but is useful in identification of cultures.

6.2. Validity of tests for bovine spongiform encephalopathy

The Commission decided that the draft chapter of the *Manual* on bovine spongiform encephalopathy is a reasonable statement of the current position. The OIE will contact the reference laboratories about standardisation of tissue preparation methods for PrP immunoassays.

6.3. Removal of atrophic rhinitis of swine

The Standards Commission recommends that the Code Commission removes atrophic rhinitis of swine from List B diseases. The Commission will remove the chapter on this disease from the *Manual*.

7. Standardisation and Harmonisation of Laboratory methodologies used for the Detection and Quantification of Antimicrobial Resistance

Dr B. Röstel of the OIE Collaborating Centre for Veterinary Medicinal Products, Fougères, France, presented the guidance document on the standardisation and harmonisation of laboratory methodologies used for the detection and quantification of antimicrobial resistance that has been adopted by the OIE Ad hoc Group on Antimicrobial Resistance. The Ad hoc Group made the following recommendations:

- that a chapter on principles of the detection and quantification of antimicrobial resistance be added to the *Manual*
- that OIE regional reference laboratories for the detection and quantification of antimicrobial resistance be established
- that antimicrobial susceptibility testing methods be standardised and susceptibility data be harmonised
- the desire for laboratories to become accredited and participate in external proficiency programmes
- that bacterial reference/quality control strains be established along with interpretative criteria for commonly encountered bacteria such as *Salmonella* and *Campylobacter*.

Dr Röstel stated that a paper on laboratory techniques for antimicrobial testing is in development by Ad Hoc Group members. The Commission recommends that a chapter on antimicrobial resistance be added to the fifth edition of the *Manual* and will consider the addition of standardised laboratory techniques for inclusion in the *Manual*. The Commission will consider the suggestion of the Ad hoc Group to establish reference laboratories and is open to suitable nominations.

8. Any other business

- **8.1.** The Commission has asked the Central Bureau to set up a Web site for the Standards Commission by May. This site will include the Commission's Mission Statement (<u>Appendix III</u>), reports of the Commission meetings, disease and diagnostic testing information, standard reference sera information and links to other OIE Web sites.
- **8.2.** Dr P. Boireau addressed the Commission regarding continued availability of the OIE Biotechnology database. The Commission supported the OIE Working Group on Biotechnology's proposal to send a questionnaire to the OIE Reference Laboratories, Collaborating Centres and other laboratories that have participated in the past to get input on what the future of the database should be
- **8.3.** Planning for the OIE/WAVLD Symposium on Biotechnology is now completed. The title is Standardisation of diagnostic tests that rely on gene amplification systems. The programme and the speakers are shown in Appendix IV.
- **8.4.** Dr Pearson attended the First Meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety, held in Montpellier, France, 11–15 December 2000. The Protocol has been adopted and will put restrictions on international movement of genetically modified agents including vaccines.
- **8.5**. The OIE will be co-sponsoring a meeting on FMD following the OIE General Session in 2002 and the Standards Commission has been asked to assist in planning the program. This meeting will cover all aspects of the disease and diagnostics.
- **8.6.** The FMD and Other Epizootics Commission has proposed that the wording in the FMD Chapter of the *Code* be changed from 'disease' to the FMD 'infection' with attached definition of infection. The Commission supports this definition criteria.
- **8.7.** The OIE Collaborating Centre in Ames, Iowa is planning a meeting on the 'Efficacy and Availability of Vaccines for OIE List A and Emerging Diseases', that will be held 16–18 September 2002 in Ames Iowa. A representative from the Standards Commission will be invited to participate on the organising committee.
- **8.8.** The FMD Commission proposed that the OIE support the organisation of the Third International Conference on Orbiviruses; with emphasis on bluetongue. This disease has taken on new significance due to outbreaks of bluetongue in Europe and North Africa. The FMD Commission also suggested that a conference on mosquito-transmitted emerging arboviruses should be held with emphasis on the diseases of Rift Valley and West Nile Fever.
- **8.9.** Recommendations for strains of virus to be used in equine influenza vaccines:

Dr Mumford, OIE equine influenza expert, New Market, UK, reported that there has been no significant antigenic change in strains of virus that have been isolated in the last 2 years. She recommended that a notice be published in the OIE *Bulletin* that restates the recommendation published in the OIE *Bulletin* in July/August 1998.

10. Date of next Standards Commission meeting: 24–26 September 2001.	
/	Appendices



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MEETING OF THE OIE STANDARDS COMMISSION

Paris, 31 January - 2 February 2001

Agenda

- 1. OIE Reference Laboratories
- 2. International standardisation of diagnostic tests and vaccines
- 3. List of prescribed and alternative tests
- 4. OIE Manual of Standards for Diagnostic Tests and Vaccines
- 5. Preparation of booklet on guidelines
- 6. Liaison with the Code Commission
- 7. Standardisation and Harmonisation of Laboratory methodologies used for the Detection and Quantification of Antimicrobial Resistance
- 8. Any other business



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MEETING OF THE OIE STANDARDS COMMISSION Paris, 31 January – 2 February 2001

List of participants

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Organización Mundial de Sanidad Animal

MISSION STATEMENT FOR THE STANDARDS COMMISSION

The mission of the OIE Standards Commission is to develop international standards for veterinary laboratory diagnosis and vaccines.

Subtext:

The Commission will achieve this by:

- a) Revision of the *OIE Manual of Standards for Diagnostic Tests and Vaccines* on a 4 year cycle, to incorporate the latest scientific information and methodology;
- b) Encouraging the OIE Reference Laboratories to develop standard reference materials and methods for diagnostic tests and vaccines;
- c) Provision of advice to the OIE on scientific and technical aspects of disease diagnosis and control;
- d) Communication of data on standards, on new and emerging diseases and infectious animal diseases including those of public health significance.



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JOINT OIE/WAVLD9 BIOTECHNOLOGY SEMINAR

Parma, Italy, 4 July 2001

Standardisation of diagnostic tests that rely on gene amplification systems

Programme

10:30-10:40	Introductory remarks John Gorham, Pullman, Washington, USA
10:40-11:00	The role of the OIE in setting standards for gene amplification techniques <i>James E. Pearson, OIE, Paris, France</i>
11:00-11:40	Standardisation of molecular diagnosis of animal diseases Sandor Belak, Uppsala, Sweden
11:40-12:20	Application of the polymerase chain reaction to the diagnosis of trypanomosis Marc Desquesnes, Bobo Dioulasso, Burkina Faso
12:20-13:20	LUNCH
13:20–14:00	Standardisation and quality control of diagnostic reverse-transcription polymerase chain reaction assays: Detection and identification of single nucleotide polymorphisms in poultry pathogens using new fluorescence hybridisation based technology <i>Daral Jackwood, Columbus, Ohio, USA</i>
14:00-14:40	Emergency disease diagnosis using nucleic acid detection systems: The challenges of technology change, quality assurance and diversity of tests <i>David Boyle, Geelong, Victoria, Australia</i>
14:40-15:00	The use of polymerase chain reaction for the diagnosis of aquatic animal diseases Donald V. Lightner, Tuscon, Arizona, USA
15:00-15:40	The use of new gene amplification techniques to measure scrapie resistance in sheep <i>Kath A. Webster, VLA Weybridge, United Kingdom</i>
15:40–16:00	Final questions; summary and conclusions of the meeting Sandor Belak and other seminar speakers

⁹ World Association of Veterinary Laboratory Diagnosticians



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