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## REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 31 August – 2 September 2004

The OIE Biological Standards Commission met at the OIE Headquarters from 31 August to 2 September 2004. Dr Alejandro Schudel, Head, Scientific and Technical Department, speaking on behalf of 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 ELISA<sup>1</sup> and Molecular Techniques in Animal Disease Diagnosis, IAEA<sup>2</sup>, Vienna, Austria, and Dr Peter Wright, President of the OIE Ad hoc Group on Nonstructural Protein Tests for Foot and Mouth Disease Diagnosis.

Dr Schudel highlighted the importance of establishing a standard operating procedure (SOP) for the new OIE procedure for validation and certification of diagnostic assays for infectious animal diseases.

He went on to state that the Commission should be aware of the work of the other OIE Specialist Commissions so as to strengthen its collaboration with them, for example the Ad hoc Group on Antigen and Vaccine Banks for Foot and Mouth Disease organised under the auspices of the OIE Scientific Commission for Animal Diseases. Finally he stressed the vital role of the OIE network of experts and that the Commission should work to help the OIE to improve the capacities of the OIE Reference Laboratories and Collaborating Centres.

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 Research and Training in Population Animal Health Diagnosis and Surveillance Systems*

The Commission received an application for an OIE Collaborating Centre for Research and Training in Population Animal Health Diagnosis and Surveillance Systems at the International EpiLab at the Danish Institute for Food and Veterinary Research, Søborg, Denmark. The Commission recommends its acceptance.

1 ELISA: enzyme-linked immunosorbent assay

2 IAEA: International Atomic Energy Agency

*OIE Collaborating Centre for Food Safety, Diagnosis and Control of Animal Diseases in Eastern Europe, Central Asia and Transcaucasia*

The OIE Collaborating Centre for Diagnosis and Control of Animal Diseases in Eastern Europe, Central Asia and Transcaucasia, Moscow, Russia, had requested that its title be changed to OIE Collaborating Centre for Food Safety, Diagnosis and Control of Animal Diseases in Eastern Europe, Central Asia and Transcaucasia. The new activities will be incorporated into the remit of the existing Collaborating Centre. The Commission accepted this proposal.

*OIE Collaborating Centre for Diagnosis, Epidemiology and Control of Animal Diseases in Tropical Regions*

The OIE Collaborating Centre for Diagnosis and Control of Animal Diseases in Tropical Regions, CIRAD-EMVT<sup>3</sup>, Montpellier, France, had requested that its title be changed to OIE Collaborating Centre for Diagnosis, Epidemiology and Control of Animal Diseases in Tropical Regions. The new activities will be incorporated into the remit of the existing Collaborating Centre. The Commission accepted this proposal.

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

*OIE Reference Laboratory for Highly pathogenic avian influenza and Newcastle disease*

National Reference Laboratory for Highly pathogenic avian influenza and Newcastle disease, Institute of Diagnostic Virology, Federal Research Centre for Virus Diseases of Animals (BFAV), Insel Riems, Boddenblick 5a, 17493 Greifswald – Insel Riems, GERMANY.  
Tel.: (+41) 383.517.152; Fax: (+41) 383.517.151; E-mail: ortrud.werner@rie.bfav.de  
Designated Reference Expert: Dr Ortund Werner.

*OIE Reference Laboratory for Brucellosis*

National Veterinary Reference Laboratory for Brucellosis, Institute of Bacterial Infections and Zoonoses, Federal Research Centre for Virus Diseases of Animals (BFAV), Jena, Naumburger Str. 96a, 07743 Jena, GERMANY.  
Tel.: (+41) 3641.804.324; Fax: (+41) 3641.804.228; E-mail: k.sachse@jena.bfav.de  
Designated Reference Expert: Dr Konrad Sachse.

*OIE Reference Laboratory for Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis*

National Reference Laboratory for Bovine herpesvirus type 1, Institute of Diagnostic Virology, Federal Research Centre for Virus Diseases of Animals (BFAV), Insel Riems, Boddenblick 5a, 17493 Greifswald – Insel Riems, GERMANY.  
Tel.: (+41) 383.517.223; Fax: (+41) 383.517.275; E-mail: martin.beer@rie.bfav.de  
Designated Reference Expert: Dr Martin Beer.

*OIE Reference Laboratory for Bluetongue*

Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise 'G. Caporale', Via Campo Boario, 64100 Teramo, ITALY  
Tel.: (+39.0861) 33.21; Fax: (+39.0861) 33.22.51; E-mail: savini@izs.it  
Designated Reference Expert: Dr Giovanni Savini.

The Commission also determined that there is a need for OIE Reference Laboratories for Japanese encephalitis, avian infectious bronchitis and leishmaniosis and invites proposals for new reference laboratories for these diseases from OIE Delegates.

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3 CIRAD-EMVT : Centre de coopération internationale en recherche agronomique pour le développement - Département d'élevage et de médecine vétérinaire

## 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:

### *Classical swine fever*

Dr Shunji Yamada to replace Dr A.Fukusho at the National Institute of Animal Health, Toyko, Japan.

### *Rabies*

Dr Claude T. Sebeta to replace Dr Antoinette Liebenberg at the Onderstepoort Veterinary Institute, South Africa.

### *Paratuberculosis and Bovine tuberculosis*

Dr Maria Laura Boschioli to replace Marie-Françoise Thorel at AFSSA<sup>4</sup> Alfort, France.

### *Rinderpest and Peste des petits ruminants (PPR)*

The Commission has decided to temporarily suspend the designation of the OIE Reference Laboratory for Rinderpest and Peste des petits ruminants (PPR) at the Kenya Agricultural Research Institute from the OIE List, and would encourage the ‘twinning’ of this laboratory with another laboratory capable of supporting its relevant scientific needs.

## 1.3. Letter to OIE Reference Laboratories/Collaborating Centres

The Commission noted a letter that had been sent from the Director General of the OIE to the OIE network of Reference Laboratories and Collaborating Centres. The letter stressed the important role of OIE Reference Laboratories and Collaborating Centres in supporting OIE Member Countries. It also mentioned the change to the Mandate of OIE Reference Laboratories that had been adopted by resolution during the General Session in May of this year. The new mandate now requires OIE Reference Laboratories to inform the OIE Central Bureau of results that confirm the presence of disease for diseases that are reportable to the OIE. Such information will be sent by the OIE Central Bureau to the OIE Delegate of the country concerned before any publication. This change will increase accuracy, transparency and speed of animal disease reporting and the visibility of OIE Reference Laboratories to reflect their leadership in the world. The Commission recommends that the OIE Animal Health Information Department develop a procedure for the experts to follow when sending these results to the OIE Central Bureau.

The letter of the Director General again indicated that the OIE is keen to identify laboratories within developing countries that are well placed to provide services within their region and to strengthen their operations by encouraging twinning of such laboratories with those from other regions or countries. Finally, the letter explained that in order to involve the OIE network of experts more and more in the elaboration of OIE policies, the OIE plans to organise an international conference for all the experts from OIE Reference Laboratories and Collaborating Centres.

## 1.4. Report on Chinese laboratories

Dr James Pearson, OIE Consultant, reported on a mission to the People’s Republic of China that he and three other OIE experts had undertaken. The mission assessed the suitability of national reference veterinary laboratories, proposed by the Chinese veterinary authorities, to meet the OIE Reference Laboratory requirements and obligations to be designated by the OIE as Reference Laboratories; to provide advice to the Chinese veterinary authorities on how to become OIE Reference Laboratories; to provide an overview of the OIE programmes; to assess the quality of the avian influenza vaccines produced in laboratories in the People’s Republic of China; and to provide advice to the Chinese veterinary authorities on the above. The report has been endorsed without any change by the Chinese Authorities and published on the OIE Website.

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4 AFSSA : Agence française de sécurité sanitaire des aliments

## 2. International standardisation of diagnostic tests and vaccines

### 2.1. Progress on OIE standardisation programmes for diagnostic tests

#### LIST A DISEASES

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

The OIE Reference Laboratory for FMD in Pirbright, UK, had sent datasheets for new reference sera for FMD serology to complement the existing adopted reference sera. Commission decided to refer the matter to the Ad hoc Group on Nonstructural Protein Tests for Foot and Mouth Disease Diagnosis.

*Highly pathogenic avian influenza (HPAI) – Coordinator: Dr B. Panigrahy, National Veterinary Services Laboratories, Ames, United States of America*

The OIE Reference Laboratories for HPAI are continuing to work on a programme for harmonisation of serology procedures for HPAI diagnosis.

#### LIST B DISEASES

*Caprine arthritis/encephalitis and maedi-visna – Coordinator: Dr C Vitu, AFSSA Sophia Antipolis, France*

The OIE Reference Laboratory had reported that the project was in progress to prepare standard sera for maedi-visna and caprine arthritis/encephalitis.

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

Prof. Zablotsky informed the Commission of the protocol being used to develop standard sera for dourine. The Commission thanked Prof. Zablotsky for his work on this project and looks forwards to receiving the results.

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

Dr Mumford asked the Laboratories Commission for clarification on the requirements for preparing standard sera for equine herpesvirus (EHV). The Commission would reply in writing.

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

Dr Nielsen had asked for clarification of the process of standardisation. The Commission stated that standard sera should be evaluated using the reference test as described in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)*. Sera could then be distributed to other laboratories for calibrating their own tests.

A report had been received from the European Pharmacopoeia (EP) on the reporting phase of a study to establish three EP biological reference preparations for equine influenza horse antiserum. The Commission drew attention to the fact that these have already been adopted by the OIE an international reference sera.

## 3. List of prescribed and alternative tests

### 3.1. FPA<sup>5</sup> for determination of antibody to smooth *Brucella* spp. in sheep and goats

The Commission had received reports from experts but would seek further information before an opinion could be reached on this test.

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5 FPA: Fluorescence polarisation assay

### **3.2. Prescribed tests for brucellosis serology**

The Commission noted the Conclusions and Recommendations of the MZCP<sup>6</sup> International Training Course on Animal Brucellosis Laboratory Diagnosis, held in Damascus, Syria, 13–17 June 2004.

## **4. Preparation of a manual on veterinary laboratory biosecurity standards**

Dr Peter Mani from the IVBAG<sup>7</sup> attended this agenda item. In January 2004, the Commission received a proposal from the IVBAG to prepare a manual on veterinary biosecurity standards under the aegis of the OIE and the FAO<sup>8</sup>, and had approved the concept. An Ad hoc Group will be formed under the Chairmanship of Dr Beverly Schmitt, Vice-President of the Laboratories Commission. The FAO will be invited to participate. The Terms of Reference for this Group will be to: develop an international standard for the design, construction and operation of veterinary laboratories and animal facilities dealing with biological agents (and toxins); to take account of existing standards and guidelines for both animal pathogen containment and human biosafety; and to report to the OIE Biological Standards Commission. It is hoped to have the first draft of this guideline handbook by May 2005. The Ad hoc Group will also provide input on the update of Chapter I.1.6 of the *Terrestrial Manual* on human safety in the veterinary microbiology laboratory.

## **5. 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 congratulated the Consultant Editor and Scientific Editor of the fifth edition of the *Terrestrial Manual* for their work. Few comments on this edition had been received as yet. A questionnaire will be sent out to all OIE Delegates and Reference Laboratories requesting their views. It is suggested that the binding be reconsidered before the sixth edition.

Changes to the list of prescribed tests adopted by the International Committee in May 2004 had already been introduced into the web version of the *Terrestrial Manual*. The Commission discussed chapters that were a high priority for revision. A timetable for production of the sixth edition will be discussed at the January 2005 meeting. The Consultant Editor will need to attend that agenda item.

## **6. Specific procedures for OIE to validate and approve diagnostic tests**

### **6.1. Review of the standard operating procedure (SOP) for the OIE procedure for validation and certification of diagnostic assays for infectious animal diseases**

Dr Patrick Dehaumont, OIE Expert from the OIE Collaborating Centre for Veterinary Medicinal Products, Fougères, France, attended this agenda item. Dr Dehaumont had prepared a draft SOP for the administration of applications by the OIE. The Commission approved the SOP.

The Commission agreed to ask an expert to draft an electronic form, which will be posted on the web, to aid applicants submitting diagnostic tests for consideration. This electronic form will be peer reviewed by the Commission members with the Collaborating Centre in Vienna. The Commission would like the specific procedures to validate and approve diagnostic tests to receive immediate attention.

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6 MZCP: Mediterranean Zoonoses Control Programme of the World Health Organization

7 IVBAG: International Veterinary Biosafety Advisory Group

8 FAO: Food and Agriculture Organization of the United Nations

## 7. Liaison with other Commissions and Groups

- **SCIENTIFIC COMMISSION FOR ANIMAL DISEASES**

### 7.1. Report of the meeting of the Ad hoc Group on Antigen and Vaccine Banks for Foot and Mouth Disease

The Commission noted the draft report of the Ad hoc Group meeting.

- **TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION**

### 7.2. Antimicrobial resistance

During the General Session in May, a new appendix for the *Terrestrial Animal Health Code*, Appendix 3.9.4 Risk analysis for antimicrobial resistance was adopted by the International Committee. The Code Commission had requested the Laboratories Commission to reconvene the Ad hoc Group on Antimicrobial Resistance to take account of Member Country comments on this Appendix with a view to proposing any changes necessary in this Appendix.

The Biological Standards Commission noted the Conclusions from the Joint FAO/OIE/WHO 2nd Workshop on Non-human Antimicrobial Usage and Antimicrobial Resistance: Management Options, Oslo, Norway, 15–18 March 2004. The implementation of the conclusions will be addressed by the OIE Ad hoc Group on Antimicrobial Resistance.

## 8. Any other business

### 8.1. Transport of pathogens

Dr James Pearson, OIE Expert Consultant, reported on the meeting of the United Nations Sub-Committee of Experts on the Transport of Dangerous Goods (UNSCETDG), held in July 2004 in Geneva, Switzerland. The OIE request to amend the list of infectious substances that are prohibited from being shipped as UN 3373 (Diagnostic specimens) had been approved. The timetable for implementation of this and other changes was discussed. The Commission asked Dr Pearson to propose to the UNSCETDG at their December 2004 meeting that an exemption for serum from healthy animals be incorporated into the regulations. Dr Pearson would attend this meeting on behalf of the OIE.

### 8.2. Letter re: Cartagena Protocol on Biosafety

The Commission recommended that the OIE send a representative to this meeting and suggested that the Collaborating Centre in Ames be approached for a nominee.

### 8.3. Conferences

The Commission continued to review its involvement in a number of international conferences organised in collaboration with IICAB/IABs<sup>9</sup>, AFSSA/IABs and WAVLD<sup>10</sup>, as well as the OIE/WHO<sup>11</sup>/European Union/AFSSA Conference on Rabies in Europe, and the proposed International Conference for OIE Reference Laboratories and Collaborating Centres (see point 1.3. above).

The preliminary programme was agreed for the OIE Biotechnology Seminar at the WAVLD conference in Montevideo, Uruguay.

### 8.4. Letter on evaluation of proficiency testing

The OIE Reference Laboratory for brucellosis and contagious bovine pleuropneumonia in Teramo, Italy, had contacted the OIE concerning the organisation of international proficiency testing for these diseases. The Commission welcomed this proposal and the OIE Central Bureau will contact the laboratory directly.

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

10 WAVLD: World Association of Veterinary Laboratory Diagnosticians

11 WHO: World Health Organization

#### **8.5. Disease cards**

Mr Richard Reinap II, OIE intern, joined the meeting for this agenda item. He gave a report update on progress in updating the OIE disease cards. The Committee congratulated Mr Reinap and Dr Lupo, the previous intern, on their excellent work. All the existing cards have been updated and 29 new cards had been drafted. Once approved by all the relevant OIE Reference Laboratories, the cards would be placed on the OIE web site. It was decided that in the future the disease cards would be updated by the contributors to the *Terrestrial Manual* at the same time as they update the *Terrestrial Manual* chapters.

#### **8.6. IAEA's consultation on early warning devices and tools**

The Commission was informed that there would be a joint FAO/IAEA Consultants meeting on early warning devices and tools from 29 November to 3 December 2004 in Vienna, Austria and suggested that the President of the Commission, or a colleague nominated by him, would attend this meeting.

#### **8.7. Avian influenza bioengineered vaccine**

The FAO had requested the OIE to undertake an expedited review and produce recommendations on the use of bioengineered vaccines for avian influenza. The OIE Central Bureau will contact experts as a matter of urgency.

#### **8.8. International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)**

Dr Patrick Dehaumont explained the role of the OIE in VICH. VICH focuses on harmonising registration requirements for veterinary medicinal products in the EU, USA and Japan. Countries not involved in VICH are kept informed of its progress through the OIE. Fundamental to the existence of VICH is the Steering Committee that is empowered to drive the harmonisation process. IFAH (International Federation for Animal Health) coordinates the positions of the three regional industry federations. IFAH and the OIE signed an official agreement in order to improve the exchange of information between the two organisations. The Steering Committee created a Task Force chaired by the OIE and composed of one representative from each member region and from the observers. The ongoing work of this task force will help the Steering Committee to evaluate needs and resources and to draw up proposals for remodelling the future VICH, including new ways of working.

The OIE, as an associated member, pays particular attention to all of these activities and does its utmost to help to contribute to the process of harmonisation of registration of veterinary medicines at the world-wide level in order to strengthen the protection of public and animal health and to help to harmonise international practices. The Biological Standards Commission agreed that it is important for the Commission and the OIE Member Countries to be informed of the activities of VICH.

#### **8.9. Dates of next Biological Standards Commission meeting**

The next meeting of the Biological Standards Commission will be held from 26 to 28 January 2005.

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**MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION**

**Paris, 31 August – 2 September 2004**

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**Agenda**

1. OIE Reference Laboratories and Collaborating Centres
2. International Standardisation of Diagnostic Tests and Vaccines
3. List of Prescribed and Alternative Tests
4. Preparation for a manual on veterinary laboratory biosecurity standards
5. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
6. Specific procedures for OIE to validate and approve diagnostic tests
7. Liaison with the other Commissions
8. Any other business



**MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION**  
**Paris, 31 August – 2 September 2004**

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