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

**Paris, 3–5 February 2009**

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The OIE Biological Standards Commission met at the OIE Headquarters from 3 to 5 February 2009. Dr Bernard Vallat, Director General of the OIE, welcomed the Members of the Commission, Professor Steven Edwards, President, Dr Beverly Schmitt, Vice-President, Dr Mehdi El Harrak, Secretary General, and Dr Santanu K. Bandhopadhyay, member of the Commission, as well as the other expert participant, Dr Peter Wright, Canada. The other member of the Commission (Dr Vladimir Drygin) was invited but could not attend the meeting.

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

### **1. OIE Reference Laboratories and Collaborating Centres**

#### **1.1. Letter from the President of the OIE re: cross-country Collaborating Centre applications, and laboratory networks**

Dr Barry O'Neil, the President of the OIE, had indicated in response to a letter from Prof. Edwards that the Administrative Commission supported, in principle, proposals for cross-country Collaborating Centre applications, provided that there were assurances that there would be good inter-institutional management procedures in place that includes one country having the mandate to be single point of contact, though that point of contact could rotate.

On the subject of the OIE adopting a procedure for officially recognising Reference Laboratory networks, Dr O'Neil wrote that this topic would be discussed by the OIE Administrative Commission, which meets later this month. Dr Gideon Brückner, Deputy Director General of the OIE, proposed that a resolution on veterinary reference laboratory networks and networking could be presented for adoption at the one-day OIE Seminar to be held in conjunction with the WAVLD<sup>1</sup> Conference in Madrid in June (see item 8.3.)

#### **1.2. New applications for Collaborating Centre and Reference Laboratory status:**

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

*OIE Collaborating Centre for Animal Welfare Science and Bioethical Analysis*

Director Animal Welfare, MAF Biosecurity New Zealand, PO Box 2526, Wellington, NEW ZEALAND  
Tel: (64-4) 894.0368; Fax: (64-4) 8190 368; Email: david.bayvel@maf.govt.nz ; bayveld@maf.govt.nz

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<sup>1</sup> WAVLD: World Association of Veterinary Laboratory Diagnosticians

This Centre will incorporate and replace the current OIE Collaborating Centre for Animal Welfare Science and Bioethical Analysis (Asia/Pacific), and will include participation from the following institutions:

- Animal Welfare Science and Bioethics Centre (AWSBC), Massey University, Palmerston North, New Zealand;
- Animal Behaviour and Welfare Research Centre, AgResearch Ruakura, Hamilton, New Zealand;
- The Animal Welfare Science Centre, University of Melbourne, Victoria, Australia;
- The Centre for Animal Welfare and Ethics, University of Queensland, St Lucia, Queensland, Australia;
- The Commonwealth Scientific and Industrial Research Organisation (CSIRO), Division of Livestock Industries, St Lucia, Queensland, Australia.

*OIE Collaborating Centre for Animal Welfare Research*

Universidad Austral de Chile, Independencia 641, Casilla 567, Valdivia, Chile  
Tel: (56-63) 221.690; Fax: (56-63) 221.766; E-mail: cgallo@uach.cl

This centre will work jointly with the Animal Welfare Group at the Faculty of Veterinary Medicine, Alberto Lasplaces 1550 - C.P.: 11.600, Montevideo, Uruguay  
Tel.: (598-2) 628.3505; Fax: (598-2) 628.0130; Email: stellamaris32@hotmail.com

The Commission agreed in principle to a proposal from Italy for a collaborating centre working at the animal/human interface. It will be important that the centre works closely with existing centres relating to zoonotic diseases, and with established networks of OIE Reference Laboratories for specific zoonoses. The proposed title "One Health" may be trademarked or otherwise protected, so the Commission suggested the following title:

*OIE Collaborating Centre for Diseases at the Animal/Human Interface*

Istituto Zooprofilattico Sperimentale delle Venezie (IZSVe), Viale dell'Università 10, 35027 Legnaro Padova, ITALY  
Tel: (+39-049) 808.43.69; E-mail: icapua@izsvenezie.it; Contact point: Dr Ilaria Capua

*OIE Collaborating Centre for Training in integrated Livestock and Wildlife Health and Management*

Department of Veterinary Tropical Diseases, Faculty of Veterinary Science, University of Pretoria, Private Bag X04, Onderstepoort 0110, SOUTH AFRICA  
Tel: (+27-12) 529.82.69; E-mail: koos.coetzer@up.ac.za; Contact point: Prof. J.A.W. Coetzer

*OIE Collaborating Centre for Food Safety*

Research Center for Food Safety, Graduate School of Agricultural and Life Sciences, University of Tokyo, Yayoi 1-1-1, Bunkyo-ku, Tokyo, 113-8657, JAPAN  
Tel/Fax: (+81-3) 5841.5389; E-mail: aahiro@mail.ecc.u-tokyo.ac.jp; Contact point: Dr Hirokazu Tsubone

*OIE Collaborating Centre for Development and Production of Vaccines, Pharmaceutical Products and Veterinary Diagnostic Systems using Biotechnology*

Centro de Ingeniería Genética y Biotecnología (Cuban Centre for Genetic Engineering and Biotechnology), P.O. Box 6162, Ave. 31 e/ 158 y 190, Playa, Havana 10600, CUBA  
Tel: (+53-7) 271.33.13; E-mail: carlos.borroto@cigb.edu.cu

*OIE Reference Laboratory for Theileriosis*

Department of Animal Health, Institute of Tropical Medicine, Nationalestraat 155, 2000 Antwerpen, BELGIUM  
Tel: (+32-3) 2476.266; Fax: (+32-3) 2476.268; E-mail: dgeysen@itg.be  
Designated Reference Expert: Dr Dirk Geysen

*OIE Reference Laboratory for Camel pox*

Central Veterinary Research Laboratory, P.O. Box 597, Dubai, UNITED ARAB EMIRATES.  
Tel.: (+971-4) 337.5165; Fax: (+971-4) 336.8638; E-mail: cvrl@cvrl.ae  
Designated Reference Expert: Prof. Ulrich Wernery

*OIE Reference Laboratory for Brucellosis*

Zoonosis Laboratory, Bacteriology & Parasitology Division, National Veterinary Research & Quarantine Service (NVRQS), Ministry of Food, Agriculture, Forestry, and Fisheries (MIFAFF), 480 Anyang 6-dong, Manan-gu, Anyang-si, Kyunggi-do, KOREA (REP. OF)  
Tel: (+82-31) 467.1765; Fax: (+82-31) 467.1778; E-mail: jungsc@nvrqs.go.kr  
Designated Reference Expert: Dr Suk-chan Jung

*OIE Reference Laboratory for Avian influenza*

High Security Animal Disease Laboratory, Indian Veterinary Research Institute, Indian Council of Agricultural Research, Anand Nagar, Bhopal – 462021, Madhya Pradesh, INDIA  
Tel.: (+91-7552) 75.92.04/75.46.75; Fax: (+91-7552) 75.88.42; E-mail: scd\_11@yahoo.co.in  
Designated Reference Expert: Dr S.C. Dubey

*OIE Reference Laboratory for Rift Valley fever and Crimean-Congo fever*

Unité de génétique moléculaire des Bunyavirus, Département de Virologie, Institut Pasteur, 25 rue du Dr Roux 75724 Paris cedex 15, FRANCE  
Tel.: (+33-1) 40.61.31.34; Fax: (+33-1) 40.61.32.56; E-mail:  
Designated Reference Expert: Dr Michèle Bouloy

*OIE Reference Laboratory for Bovine spongiform encephalopathy and Scrapie*

Laboratorio Nacional de Referencia (LNR) para Encefalopatías Espongiformes Transmisibles (EET) animales, Institutos de Patobiología y Virología, Centro de Investigaciones en Ciencias Veterinarias y Agronómicas (CICV), Instituto Nacional de Tecnología Agropecuaria (INTA), Casilla de Correo 77, 1708 Morón Pcia., Buenos Aires, ARGENTINA  
Tel/Fax: (+54-11) 4621-1289/1712/1447/ 1676; Fax: (+54-11) 4621-1743;  
E-mail: jviera@cnia.inta.gov.ar ; gpinto@cnia.inta.gov.ar  
Designated Reference Expert: Dr Francisco Javier Blanco Viera

*OIE Reference Laboratory for Equine influenza*

Irish Equine Centre, Johnstown, Naas, Co. Kildare, IRELAND  
Tel.: (+353-45) 86.62.66; Fax: (+353-45) 86.62.73; E-mail: acullinane@equine-centre.ie  
Designated Reference Expert: Prof. Ann Cullinane

### 1.3. 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:

*Paratuberculosis and bovine tuberculosis*

Dr Bernardo Alonso to replace Dr Amelia Bernardelli at the Servicio Nacional de Sanidad y Calidad, Agroalimentaria (SENASA), Argentina.

*Anthrax*

Dr Betty Golesteyn-Thomas to replace Dr Pam Gale at the Canadian Food Inspection Agency Laboratory in Lethbridge, Canada.

*Foot and mouth disease*

Dr Rahana Mohan Dwarka to replace Dr Wilna Vosloo at the Onderstepoort Veterinary Institute, South Africa.

*Foot and mouth disease and Swine vesicular disease*

Dr Jef Hammond to replace Dr David Paton at the Institute for Animal Health, Pirbright, United Kingdom.

*Avian mycoplasmosis (Mycoplasma gallisepticum, M. synoviae)*

Dr Naola Ferguson-Noel to replace Dr Stanley Kleven at the University of Georgia, College of Veterinary Medicine, Georgia, United States of America.

The Commission acknowledged a request from the Delegate of Canada that the OIE Reference Laboratory for Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis in Alberta and Saskatchewan be removed from the list. It also acknowledged a request from the expert and the Director of the National Veterinary Institute (SVA), Uppsala, Sweden that the OIE Reference Laboratory for contagious caprine pleuropneumonia be removed from the list.

#### 1.4. Request to appoint more than one expert at OIE Reference Laboratories

The Commission reiterated its position that, to avoid confusion, a single expert be designated as the contact point at OIE Reference Laboratories, recognising that this designated expert may consult other experts.

#### 1.5. Review of Reference Laboratory and Collaborating Centre twinning applications

Keith Hamilton, coordinator at the OIE Reference Laboratory and Collaborating Centre Twinning initiative, reported progress with the programme. Eleven projects have been approved to date. Two full applications were approved in principle for twinning projects:

Rabies: Friedrich-Loeffler-Institute – Federal Research Institute for Animal Health, Germany and the Etlik Central Veterinary Control and Research Institute, Rabies Diagnosis Laboratory, Turkey. Having reviewed the application, the Commission emphasised that the purchase of reagents must be limited to the improvement of capability and not for routine diagnosis. The Commission endorsed the project.

Avian influenza and Newcastle disease: CSIRO Australian Animal Health Laboratory (AAHL), Geelong, Australia and the Malaysian Veterinary Research Institute (VRI) Ipoh Perak, Malaysia. The Commission noted that the proposed budget is very high, and suggested that applications such as this for two closely related diseases might be 10-15% higher than for a single disease, but not double the budget.

Prof. Edwards reported considerable interest following his presentation on twinning to the regional meeting of the national veterinary services laboratories in the Americas (see agenda item 8.3.1). The Commission noted the annual report of the twinning project between IZSVe Italy and Federal Centre for Animal Health (FGI ARRIAH), Russia.

#### 1.6. Annual Reference Laboratory and Collaborating Centre reports for 2008 for terrestrial animal diseases

The CD-ROM of the all the Annual Reference Laboratory and Collaborating Centre reports for 2007 is now available and Delegates, Experts and Regional Representatives should receive it shortly.

Reports had been received from 141/147 Reference Laboratories and 24/28 Collaborating Centres for terrestrial animal diseases or topics. The Commission expressed its ongoing appreciation of the enthusiastic support and expert advice given to OIE by the Reference Laboratories and Collaborating Centres. The full set of reports for 2008 will be supplied to Member Countries and to all the Reference Laboratories and Collaborating Centres on a CD-ROM. The international activities relevant to the work of the OIE are summarised in the table:

<b>Reference Laboratories</b>	
<b>General activities</b>	<b>Percentage of Laboratories carrying out these activities</b>
1 Test(s) in use/or available for the specified disease	100%
2 Production and distribution of diagnostic reagents	86%
<b>Specific OIE activities</b>	
3 International harmonisation/standardisation of methods	68%
4 Preparation and supply of international reference standards	59%
5 Research and development of new procedures	88%
6 Collection, analysis and dissemination of epizootiological data	68%
7 Provision of consultant expertise	66%
8 Provision of scientific and technical training	66%
9 Provision of diagnostic testing facilities	52%
10 Organisation of international scientific meetings	37%
11 Participation in international scientific collaborative studies	66%
12 Presentations and publications	83%

## Collaborating Centres

General activities	Percentage of Collaborating Centres carrying out these activities
1 Activities as a centre of research, expertise, standardisation and dissemination of techniques	92%
2 Proposal or development of any procedure that will facilitate harmonisation of international regulations applicable to the surveillance and control of animal diseases, food safety or animal welfare	71%
3 Placement of expert consultants at the disposal of the OIE	75%
<b>Specific OIE activities</b>	
4 Provision of scientific and technical training within to personnel from OIE Member Countries and Territories	79%
5 Organisation of scientific meetings on behalf of the OIE	46%
6 Coordination of scientific and technical studies in collaboration with other laboratories or organisations	79%
7 Publication and dissemination of any information that may be useful to OIE Member Countries and Territories	92%

## 2. International standardisation of diagnostic tests and vaccines

### 2.1. OIE standardisation programmes for diagnostic tests

*Highly pathogenic avian influenza (HPAI) – Coordinator: Dr Paul Selleck, Australian Animal Health Laboratory (AAHL), Geelong, Victoria, Australia*

Dr Selleck had reported that a candidate reference serum for the avian influenza AGID<sup>2</sup> test had been prepared and he will soon send it to the other Reference Laboratories for evaluation.

The Commission noted that reagents for other serological tests such as haemagglutination and haemagglutination inhibition tests are also necessary and that this is one of the OFFLU<sup>3</sup> initiatives.

*Caprine and ovine brucellosis – Coordinator Mrs Judy Stack, VLA Weybridge, UK*

The Commission would request that Mrs Stack provide a final set of data and data sheets for the candidate sera so that they can be proposed for adoption by the International Committee.

*Dourine – Coordinator Dr Noboru Inoue, National Research Center for Protozoan Diseases, Obihiro University of Agriculture and Veterinary Medicine, Japan*

Dr Inoue confirmed that there is no clear definition of what defines an isolate of *Trypanosoma equiperdum* as distinct from other strains, there are no internationally validated standard sera for dourine testing, and no recognised standard strain that is representative of currently circulating isolates. Given the lack of clarity over what constitutes the disease agent, the Commission would ask the *ad hoc* Group on Diagnostic Tests for Trypanosomoses (see item 4.4) for its opinion on the continued listing of dourine.

### 2.2. Tests for porcine reproductive and respiratory syndrome

The Commission noted a comment from the *ad hoc* Group on porcine reproductive and respiratory syndrome that tests for the currently listed for this disease are not considered robustly validated. The expert would be asked to take this issue forward.

<sup>2</sup> AGID: agar gel immunodiffusion

<sup>3</sup> OFFLU: OIE/FAO Network on Avian Influenza

### **2.3. International Evaluation Panel for use as Reference Standard for Assays that Detect Antibodies against Non-Structural Proteins of Foot and Mouth Disease Virus in Cattle**

Dr Ingrid Bergmann had provided draft Guidelines for the use of the serum bovine panel she had developed. The Commission asked the OIE to respond with suggested changes to the guidelines.

### **2.4. Guidance document on how to apply the available diagnostic tests to the management of paratuberculosis**

The OIE expert on paratuberculosis had agreed to prepare a draft guidance document on how to apply the available diagnostic tests to the management of this disease. He reported that the work is in progress. The Commission was keen to see a first draft as soon as possible.

## **3. List of prescribed and alternative tests**

### **3.1. Indirect and competitive enzyme-linked immunosorbent assays as prescribed tests for caprine and ovine brucellosis**

A request had been received from the *ad hoc* Group on Brucellosis to designate the indirect and the competitive enzyme-linked immunosorbent assays (ELISAs) as prescribed tests for trade for caprine and ovine brucellosis. The *ad hoc* Group had also indicated in its revisions to the brucellosis chapters from the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* that it would like to designate the fluorescence polarisation assay (FPA) as a prescribed test for trade for caprine and ovine brucellosis, and to designate the buffered *Brucella* antigen test (BBAT), the complement fixation test (CFT) and the FPA as prescribed tests for trade for porcine brucellosis.

All proposals for designations of prescribed tests must be accompanied with all the required validation data in accordance with the OIE validation template. The Commission accepted the recommendations of the *ad hoc* Group subject to confirmation of the validation data.

### **3.2. Prescribed test for rabbit haemorrhagic disease**

In several places in the chapter on rabbit haemorrhagic disease from the OIE *Terrestrial Animal Health Code* “serological tests” are required prior to international movement of rabbits (see paragraphs 13.2.7, 13.2.8, 13.2.10 of the chapter) on the “herd” of origin rather than necessarily the animals themselves. The Biological Standards Commission wrote to the OIE authors (Drs Lorenzo Capucci and Antonio Lavazza) of this disease chapter to request their advice on which test might be designated as prescribed, i.e. suitable for testing prior to international trade in animals, and what validation data exist to support the recommendation. Drs Capucci and Lavazza sent a report summarising the available diagnostic tests and their sensitivity and specificity. Based on their advice, the Commission recommends that the ELISA be adopted as an alternative test for trade for rabbit haemorrhagic disease, but that no test is yet sufficiently validated for designation as prescribed.

### **3.3. Alternative test for bluetongue**

Following the advice of Dr Peter Daniels, OIE expert and author of the *Terrestrial Manual* chapter on Bluetongue, the Commission agreed to remove the AGID from the list of prescribed tests for this disease and to add it to the list of alternative tests.

## **4. Expert, *ad hoc* and Working Groups**

### **4.1. Report of the Meeting of the *ad hoc* Group on Vaccines Related to New and Emerging Technologies**

The report of the meeting held from 18 to 20 November 2008 was accepted and is included as [Appendix III](#) of this report, for Member comment.

The Group revised the template for Part C of the disease-specific chapters in the *Terrestrial Manual* (on vaccines and diagnostic biologicals). It also proposed dividing the current introductory chapter on

biotechnology into two chapters: one on diagnostics and one on vaccines. The Commission agreed to this proposal and pointed out that the chapter on diagnostics would just be a review of the current biotechnology chapter whereas the one on vaccines would be a new chapter.

The Group had identified that the vaccine section of the following chapters needs to be updated as there has been biotechnological progress: foot and mouth disease, Newcastle disease, classical swine fever, and Hendra and Nipah virus diseases. The Group would be asked to co-ordinate this work before passing the texts back to the Commission for approval.

#### **4.2. Report of the Meeting of the Expert Surveillance Panel on Equine influenza Vaccine Composition**

The Commission reviewed and endorsed the 2009 report of the Expert Surveillance Panel on Equine influenza Vaccine Composition, which can be found at [Appendix IV](#). The main points are that the panel does not recommend inclusion of an H7N7 virus in current vaccines; and no longer supports the need for inclusion of a Eurasian lineage H3N8 virus represented by A/equine/Newmarket/2/93. The key recommendations will also be published in the OIE *Bulletin*.

#### **4.3. Report of the Meeting of the *ad hoc* Group on Validation of Diagnostic Assays**

The report of the meeting held from 2 to 4 February 2009 and the draft *Terrestrial Manual* chapter on Principles and methods of validation of diagnostic assays for infectious diseases were accepted. The report is included as [Appendix V](#) of this report, for Member comment. The draft chapter was sent to OIE Members for comment (Ref. GKB/SL 35.796, 25 February 2009).

The main work of the *ad hoc* Group was to combine the two introductory chapters on validation from the *Terrestrial Manual* into one single redrafted chapter. The Group will now develop a number of appendices that will eventually be added to this chapter; these will cover: development and optimisation of antibody detection assays; development and optimisation of antigen detection assays by immunological means; development and optimisation of nucleic acid detection tests; measurement of uncertainty; statistical approaches to validation; equivalency; and selection and use of reference panels. The Group will also develop a number of guidelines to support the dossier used for the OIE Procedure for validation and certification of diagnostic assays.

#### **4.4. Terms of Reference for *ad hoc* Group on Diagnostic Tests for Trypanosomes**

The Commission suggested the following Terms of Reference for this *ad hoc* Group:

- to define the species of the parasite(s) and diagnostic criteria for parasite identification;
- to describe the current global situation regarding dourine and surra;
- to recommend diagnostic tests; and to revise the chapters in the *Terrestrial Manual*.

The Group would also be asked its views on keeping dourine on the OIE list.

#### **4.5. *Ad hoc* Group on Camelidae Diseases**

Dr Mamadou Lamine Dia from Mauritania had sent comments on the report of the first meeting of this *ad hoc* Group. The Commission pointed out that the tables in the *ad hoc* group report did not classify diseases of Camelidae according to their economic importance. The Commission agreed with Dr Dia that there is need for a competitive ELISA for diagnosis.

After the Isocard Conference in Tunisia, some members of the *ad hoc* Group will meet a second time to discuss the outcome of the Conference and future developments in the area of camelid diagnostics. They will advise the OIE whether the full group should be reconvened.

#### **4.6. Terms of Reference for an *ad hoc* Group on Diagnostic Tests in Relation to New and Emerging Technologies**

This Group will be given as its Terms of Reference to update the current chapter on biotechnology taking account of the newly updated validation chapter (see item 4.3 above).

#### **4.7. Training on Transport of Diagnostic Specimens and IATA<sup>4</sup> Guidelines**

Dr François Diaz informed the Commission about a World Health Organization (WHO) initiative consisting of organising regional training workshops on biosafety and laboratory biosecurity, with a special session on how to package diagnostic specimens for shipment. For the two workshops organised in Africa, the OIE was invited to give a presentation on the OIE standards on this topic. Dr Diaz mentioned that a closer relationship between WHO and OIE was proposed for the organisation of future workshops. The Commission supported this initiative, which could be of interest to veterinary laboratory staff of OIE Member Countries and Territories.

### **5. OIE Register of diagnostic tests**

#### **5.1. Opinion of the BSC on a final report from the experts and review of other applications**

Dr Diaz updated the Commission on the application form sent in December regarding the ELISA kit from Biorad for detection of bovine spongiform encephalopathy, scrapie and chronic wasting disease. The Commission recommended the kit for adoption providing that the text on the insert is amended to take account of the experts' comments.

He also reported that he was in contact with a kit manufacturer for a future application, and updated the Commission on the status of a submitted dossier for an FMD kit that is currently being assessed by a panel of experts.

#### **5.2. Presentation for adoption of an updated version of the Standard Operating Procedure**

Dr Diaz presented an update to the SOP regarding use of the OIE logo. The Commission agreed to this improvement.

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

#### **6.1 Analysis of the user questionnaire on the 6th edition of the *Terrestrial Manual* (2008)**

For this agenda item, the Commission was joined by the Consultant Editor, Dr James Pearson.

Over 50 replies had been received to the user questionnaire on the sixth edition of the *Terrestrial Manual*. The Commission expressed its thanks to Delegates and other experts for this very informative feedback. Comments on disease-specific chapters would be given to the corresponding authors when they are asked to update their chapters.

#### **6.2. Chapters for proposal in May 2009**

The Commission reviewed the chapters that had been identified for update this year and proposed some amendments. These chapters will shortly be circulated to Members for comment and will be proposed for adoption this May.

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<sup>4</sup> IATA: International Air Transport Association



### 6.3. Identifying chapters for update in 2010

The following chapters were identified for revision this year:

- 1 Hendra and Nipah virus diseases,
- 2 Newcastle disease,
- 3 Foot and mouth disease,
- 4 Classical swine fever  
(these four diseases had been identified by the *ad hoc* Group on Vaccines Related to New and Emerging Technologies [item 4.1.]; the vaccine section needs to be revised in the light of biotechnology development),
- 5 Crimean–Congo haemorrhagic fever (to be added to Chapter 2.9.1. – Bunyaviral diseases of animals [excluding Rift Valley fever])
- 6 Porcine reproductive and respiratory syndrome,
- 7 Bovine spongiform encephalopathy,
- 8 Rabies,
- 9 African horse sickness,
- 10 Aujeszky's disease
- 11 Rabies
- 12 Vesicular stomatitis
- 13 Japanese encephalitis
- 14 Q fever
- 15 Leishmaniosis
- 16 Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- 17 Bovine babesiosis
- 18 Lumpy skin disease
- 19 Contagious bovine pleuropneumonia
- 20 Sheep pox and goat pox
- 21 Equine influenza
- 22 Equine rhinopneumonitis
- 23 Atrophic rhinitis of swine
- 24 Marek's disease
- 25 Avian chlamydiosis
- 26 Fowl typhoid and Pullorum disease
- 27 Duck virus hepatitis
- 28 Rabbit haemorrhagic disease
- 29 Salmonellosis
- 30 Mange
- 31 Swine influenza.

## 7. Liaison with other Commissions and Groups

### 7.1. Terrestrial Animal Health Standards Commission

The Code Commission had received a number of Member Country comments on proposed chapters for the *Terrestrial Code*. The Biological Standards Commission provided advice on some of the issues; for other more technical comments, the Commission sought the advice of the relevant experts.

On the issue of the use of the ELISA on bulk milk samples as a surveillance tool for bluetongue, the Commission, having sought the advice of the OIE experts, accepts the test as a surveillance tool for bluetongue. A sentence to this effect will be inserted into the *Terrestrial Manual* chapter.

The Biological Standards Commission considered a proposal to develop a *Terrestrial Manual* chapter on porcine circovirus, but as it is not yet a listed disease, this Commission does not currently have the resources at present to develop such a text.

The Code Commission had received a large number of comments on the issue of Salmonellosis. The *Terrestrial Manual* chapter on salmonellosis has been identified for immediate update and proposal for adoption in May 2010 (see item 6.3).

## 8. Any other business

### 8.1. Update on OFFLU

Dr Keith Hamilton updated the Commission on the significant progress that has been made by the OFFLU network.

OFFLU continues to strive for global representation in its activities, new Reference Laboratories for avian influenza will be encouraged to take an active role in the activities of the network. OFFLU is planning to hold an OFFLU day at the 7th International Symposium on Avian Influenza, Athens, Georgia, USA on 8th April 2009.

OFFLU continues to recommend that laboratory experts deposit avian influenza viral genetic sequences in publicly available databases and will be publishing information about such databases on its website.

OFFLU has developed stronger links with WHO and collaborates on several technical issues; OFFLU representatives have attended several WHO meetings and likewise WHO representatives are included in OFFLU meetings.

The OFFLU technical activities add purpose to the OFFLU network; there are currently eight of them. Several have relevance to the activities of the Biological Standards Commission, including; an activity to develop guidance on minimum biosafety requirements for handling avian influenza viruses; development of a standard H5 antiserum; development of an RNA standard; harmonisation of proficiency testing; data on commercially available avian influenza test kits and avian influenza vaccine quality assurance.

### 8.2. Partnership on Biosafety and Laboratory Biosecurity between Human and Animal Health Stakeholders

The Commission was informed of an initiative to begin biosafety and laboratory biosecurity dialogue between the human and animal sectors so as to identify specific needs and develop a plan to address them. The WHO, FAO and OIE will collaborate on this project. The Commission fully endorsed this initiative.

### 8.3. Meetings, Conferences and Workshops

*Past:*

#### 8.3.1. Conclusions of the First Meeting of the National Laboratories of the Veterinary Services of the Americas, Panama 8–10 December 2008

The Commission noted the conclusions of the Panama meeting, including the proposal to develop a regional network of national veterinary services laboratories. OIE Reference Laboratories in the region should be a part of this. A letter would be sent to the Delegates requesting information on proficiency test services providers.

#### 8.3.2. Epizone

Dr Elisabeth Erlacher-Vindel updated the Commission on the Epizone meeting in which she had participated. Epizone is an EU project on emerging diseases (European network of excellence) that has been funded for 5 years. Dr Erlacher-Vindel suggested that the OIE might become more involved in the future in several issues developed by Epizone.

#### 8.3.3. OIE Workshop on Vaccine Quality and GLP (Good Laboratory Practice) in ASEAN<sup>5</sup> countries, 13–16 January 2009

Dr Diaz updated the Commission on a workshop held in Bandung, Indonesia, in which he had participated. The purpose of this workshop was to provide the national competent authorities of ASEAN countries with updated information on vaccine production and vaccine quality with

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<sup>5</sup> Association of South East Asian Nations, established on 8 August 1976 in Bangkok, Thailand with the signing of the Bangkok Declaration. The association consists of Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam. The purpose of ASEAN is to ensure peace, prosperity and freedom for the region.

reference to the OIE *Terrestrial Manual*, including Good Manufacturing Practices (GMP) and GLP, and to support regional harmonisation of technical requirements in this area.

8.3.4. Second OIE International Workshop on Equine Viral Arteritis: 13–15 October 2008, Kentucky, USA

The Commission noted the report of the Kentucky meeting. It recommended that a summary of the conclusions and recommendations be published in the OIE *Bulletin*.

*Future:*

8.3.5. One-day OIE Symposium on Veterinary Laboratory Networks and Networking, to be held during the 14th WAVLD Symposium (on 19 June 2009)

The Commission finalised the draft programme and a proposed list of speakers for the OIE Symposium on Veterinary Laboratory Networks and Networking to be held in conjunction with the next WAVLD Symposium in Madrid, Spain, 18–20 June 2009. These speakers would be contacted shortly.

8.3.6. Second Conference for OIE Reference Laboratories and Collaborating Centres

The Biological Standards Commission believes that there should be a Second Conference for OIE Reference Laboratories and Collaborating Centres, and that the OIE should seek potential sponsors for this event. The tentative dates are 21–23 June 2010.

8.3.7. Regional Conference on Porcine Reproductive and Respiratory Syndrome, planned to be organised by the OIE Regional Representative for Asia/Pacific

The Commission noted this proposal from the OIE Regional Representative for Asia/Pacific.

*For information:*

8.3.8. Biotechnology: Nanotechnology. Joint FAO/WHO Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications, 1–5 June 2009.

The OIE has invited Dr Anne MacKenzie to participate as OIE observer at the above-named meeting.

#### **8.4. Global rinderpest status**

The Commission took note of the ongoing dialogue at a high level between OIE and FAO regarding the progression towards global eradication of rinderpest. The Commission stands ready to advise on the subject of virus stocks, where they are currently held and what should be the long-term strategy. The Commission noted that the strategy should cover both virulent virus and live vaccine stocks, although the former is obviously of greater concern. OIE Reference Laboratories would be strong candidates as virus repositories, but this would require wide political agreement. The President of the Commission confirmed that a resolution reflecting the views of the Commission on this issue will be presented for adoption during the 77<sup>th</sup> OIE general Session in May 2009.

#### **8.5. VICH<sup>\*</sup>: discussion documents with the aim of preparing a VICH Concept Paper on harmonisation of the batch safety test**

The Commission reiterated its agreement to incorporate any relevant standards developed and adopted by VICH into the OIE *Terrestrial Manual*.

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\* VICH: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

#### **8.6. Prequalifying of veterinary vaccines before release**

A recommendation had been received from the OIE/FAO/WHO Tripartite Group to initiate discussions on the potential for prequalifying veterinary vaccines before release onto the market. The Biological Standards Commission strongly advises OIE not to pursue such an initiative; as the profit margin for veterinary vaccines is very slight, such a requirement would have a detrimental impact on the number of veterinary vaccines marketed.

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

During the General Session in May of this year, the International Committee will elect a new Biological Standards Commission, comprising six members. As it is not known who will be on the Commission, dates cannot yet be set for the autumn meeting, but it is hoped that it will be possible to organise it either the week beginning 14 September or the week beginning 28 September 2009.

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.../Appendices

**MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION**

**Paris, 3–5 February 2009**

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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. Expert, *ad hoc* and Working Groups
  5. OIE Register of diagnostic tests
  6. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
  7. Liaison with other Commissions
  8. Any Other Business
-



**MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION**  
**Paris, 3–5 February 2009**

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**REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON VACCINES  
IN RELATION TO NEW AND EMERGING TECHNOLOGIES  
Paris, 18–20 November 2008**

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A meeting of the OIE *ad hoc* Group on Vaccines in Relation to New and Emerging Technologies was held at the OIE Headquarters in Paris from 18 to 20 November 2008. The meeting was chaired by Dr David Mackay. Dr Cyril Gay accepted to act as rapporteur. The Agenda and List of Participants are given at [Appendices I and II](#), respectively.

## **1. Introduction**

The *ad hoc* Group on Vaccines in Relation to New and Emerging Technologies was welcomed by Dr Gideon Brückner, Deputy Director General, OIE, on behalf of Dr Bernard Vallat, Director General of the OIE.

Dr Brückner mentioned that two *ad hoc* Groups had been set up to review new and emerging technologies: one on vaccines and the other on diagnostics. He identified the task of the Group on vaccines for the current meeting: The Group is to propose for revision/new structure relevant chapters (both horizontal and disease-specific chapters) in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* related to progress in vaccine technologies. The Group should also identify aspects of food safety that might be related to the use of recombinant vaccines. However, as food safety falls under the mandate of the Codex *Alimentarius* Commission, the Group is only to consider animal health and the safety of animal products originating from animals vaccinated with recombinant vaccines.

Dr Elisabeth Erlacher-Vindel (Deputy Head, OIE Scientific and Technical Department) presented a review of OIE Standards, Specialist Commissions, Committees, and the OIE *Codes* and *Manuals*.

## **2. Proposals for revision/new structure of relevant chapters (both horizontal and disease-specific chapters) in the *Terrestrial Manual***

The Group discussed and agreed that the overarching criteria for selecting chapters to be revised should be new vaccine technologies that are either licensed or in the pipeline; i.e. vaccine technologies that have moved beyond scientific publication in peer-reviewed journals to the development stage and have a high probability of being licensed in the near future. Specific criteria for determining the need to revise a chapter include 1) regulatory improvements and 2) technical improvements relative to safety, efficacy, purity and potency. Using EU guidelines for terminology, purity and potency will be termed “quality” standards. Safety will refer to safety to animals, potential risks to the consumer; i.e. risk to humans and to the environment.

The Group felt that this approach described above was the best approach in light of the wide range of activities in the field of veterinary vaccinology with a great emphasis on the use of new technologies that will enable the development of vaccines specifically designed for control and eradication (e.g. prevention of transmission, marker vaccines for differentiating infected from vaccinated animals as well as the required co-development of validated companion diagnostic test kits) rather than just the prevention of clinical signs to lower the economic impact of disease in intensive animal production settings.

Regarding the actual revisions of specific chapters of the *Terrestrial Manual* in relation to progress in vaccine technologies, the Group recommends the revision of the section on “Requirements for vaccines and diagnostic biologicals” for some disease-specific chapters. The future revisions of the chapters might be assigned to individual Group members in cooperation with the authors of the respective chapter.

The OIE also requested that the Group review the organisational structure of the *Terrestrial Manual* chapters. Accordingly, the Group reviewed the section on “Requirements for vaccines and diagnostic biologicals” for disease-specific chapters and proposed that it be amended as shown in the outline in Appendix III. The aim of the revision is to give more focus to vaccines and their intended use (i.e. for production versus for disease control and eradication), and to provide a format that is more in line with international regulatory requirements. The Group also proposes a framework for vaccines that are based on biotechnology techniques.

### **3. Identification and prioritisation of chapters that need to be updated because of progress in vaccine technologies and proposed timetable**

#### **a) Horizontal chapters**

##### Chapter 1.1.7. Biotechnology in the diagnosis of infectious diseases and vaccine development.

The Group recommends that the chapter on Biotechnology be divided into two chapters:

- 1) Application of biotechnology to the development of diagnostics
- 2) Application of biotechnology to the development of vaccines

The second proposed chapter, on vaccine development (currently Section D), should require significant revisions as it does not represent the scope of new technologies that are currently being applied to the discovery and development of new and improved vaccines. The current chapter is disjointed and lacks focus. The Group recommends that the following specific vaccine topics and technologies be addressed in the context of the needs, applications, and use of vaccines for the control of diseases:

- Reverse genetics
- Chimeric viruses
- Recombinant vector technologies
- DNA vaccines
- Subunit vaccines
- Molecular adjuvants
- Virus-like particles
- Vaccine delivery

The Group recommends that these topics form the basis for the vaccine chapter, together with an introduction that explains how new technologies can be used to design vaccines for an intended purpose, e.g. prevention of transmission, marker vaccines to implement DIVA (differentiating infected from vaccinated animals) strategies, mass vaccination, oral vaccination of wildlife, improved cross-protection, stimulation of innate immunity to improve onset or duration of protection, etc. With regard to DIVA strategies, the Group recommends that the companion (DIVA) diagnostics be addressed as a separate section in the diagnostic chapter. The section should emphasise the importance of linking the development of such diagnostics to the corresponding DIVA vaccines.

The following revision should also be incorporated:

- Remove nanotechnology as a separate section and incorporate content under vaccine delivery.

##### Chapter 1.1.8. Principles of veterinary vaccine production

The Group recommends improvements to the following sections of the current chapter:

- The chapter should be restructured to reflect a logical systematic process as proposed for the disease specific chapters (see Appendix III).
- The sections in this chapter should be updated and revised in line with VICH<sup>1</sup> guidelines where they exist.
- Quality assurance
  - o This section should be expanded to include principles of good manufacturing practice; e.g. auditing suppliers of raw materials, building quality into manufacturing procedures.
- Licensing of products derived from biotechnology
  - o Appendix 1.1.8.2 needs to be expanded to include additional information on the risk assessment process and needs to be properly referenced in the chapter. Much work has been done in this area and processes that have been successfully used are available in the public domain. The risk assessment should include both products derived from biotechnology and novel conventional attenuated products. In addition, this section should include appropriate references to reflect measures that have been used successfully.
  - o Compile Appendix 1.1.8.1., Appendix 1.1.8.2. and Appendix 1.1.9.1. into one new chapter
  - o The Group recommends moving the section entitled “vaccinovigilance” in Appendix 1.1.8.2 to chapter 1.1.8. This section should also be extended to provide the key concepts and objectives of vaccinovigilance, including mechanisms for its implementation.

#### Chapter 1.1.9. Tests for sterility and freedom from contamination of biological materials

The only anticipated impact of new technologies on the issue of sterility is the need to include testing for adventitious agents related to the expression system. This should be included in Chapter 1.1.8. in the section on testing requirements for seed materials.

#### Chapter 1.1.10. Guidelines for international standards for vaccine banks

This chapter needs to include, in the selection and storage sections, text on companion diagnostic kits for DIVA vaccines. Governments need to take into consideration that the acquisition of such tools should be considered in concert.

The Group also recommends deleting the last paragraph on DIVA diagnostics in the section on regulatory standards as it does not provide additional information.

#### Chapter 1.1.11. The role of official bodies in the international regulation of veterinary biologicals.

This chapter should be revised to include differences in the regulatory approaches for biotechnology products.

### **b) Disease-specific chapters**

Specific chapters to be revised were selected based on evidence from the scientific literature on licensing of new technologies or new technologies that are in the pipeline and attainable, including consultations with experts where appropriate.

### **c) Proposed timetable**

The Group identified chapters to be revised and proposed a timetable for those revisions.

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1 VICH: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

#### 4. Identification of aspects of food safety that might be related to the use of recombinant vaccines

The OIE *Terrestrial Manual* sets minimum standards for biologicals for use in living animals destined for international trade. Aspects covered include safety of target and non-target animals, the vaccine handler, the consumer, and the environment. As part of this assessment, the competent regulatory authorities consider the safety of food commodities derived from vaccinated animals. Included as part of the authorisation procedure are risk management measures to manage identified risks, e.g. by setting an appropriate withdrawal period. The Group observed that there are several appendices in the *Terrestrial Manual* related to the risk assessment of veterinary biological products (Appendix 1.1.8.1., Appendix 1.1.8.2. and Appendix 1.1.9.1.) and recommends that they all be brought together into one chapter entitled: "Risk assessment considerations for veterinary biologicals". Within this chapter, specific consideration could be given to risk assessment of vaccines containing or consisting of live genetically modified organisms (GMO), including novel delivery systems. The Group recognises that a generic risk assessment for all products of biotechnology is not possible; risk assessments should be carried out on a case-by-case basis.

To consider thoroughly the food safety aspects of recombinant vaccines, the Group proposes to extend the current number of participants of scientific information provides for additional expertise. This Group should not seek to create new guidelines but should create a framework for risk assessment based on existing guidelines from the different regions of the world.

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.../Appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON VACCINES  
IN RELATION TO NEW AND EMERGING TECHNOLOGIES  
Paris, 18 - 20 November 2008**

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**Agenda**

1. Opening and purpose of the meeting
2. Designation of chairperson and rapporteur
3. Adoption of the agenda
4. Review and adoption of the draft terms of reference
5. Proposals for revision/new structure of relevant chapters (both horizontal and disease-specific chapters) in the *Terrestrial Manual*
6. Identification and prioritization of chapters that need to be updated because of progress in vaccine technologies and proposed timetable
7. Identification of aspects of food safety that might be related to the use of recombinant vaccines
8. Finalisation of the draft report for submission to the OIE Biological Standards Commission

**MEETING OF THE OIE AD HOC GROUP ON VACCINES  
IN RELATION TO NEW AND EMERGING TECHNOLOGIES**

**Paris, 18 - 20 November 2008**

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Appendix III

**Proposal of new outline for the section “Requirements for vaccines and diagnostic biologicals”  
of the disease-specific chapters**

1. Background
    - a) Rationale and intended use of the product
  2. Outline of production and minimum requirements for conventional vaccines
    - a) Characteristics of the seed
      - i) Biological characteristics
      - ii) Quality criteria (sterility, purity, freedom from extraneous agents)
    - b) Method of manufacture
      - i) Procedure
      - ii) Requirements for substrates and media
      - iii) In process controls
      - iv) Final product batch tests
        - Sterility/purity
        - Safety
        - Batch potency
    - c) Requirements for authorization
      - i) Safety requirements
        - Target and non-target animal safety
        - Reversion-to-virulence for attenuated/live vaccines
        - Environmental consideration
      - ii) Efficacy requirements
        - For animal production
        - For control and eradication
      - iii) Stability
  3. Vaccines based on biotechnology
    - a) Vaccines available and their advantages
    - b) Special requirements for biotechnological vaccines, if any
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## **EXPERT SURVEILLANCE PANEL ON EQUINE INFLUENZA VACCINE COMPOSITION**

**National Institute for Medical Research, Mill Hill, London, United Kingdom, 20 January 2009**

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### **Conclusions and Recommendations**

#### **Influenza activity January 2008–January 2008**

During 2008, outbreaks of the H3N8 subtype were reported from Brazil, China (People's Rep. of) and Mongolia, Columbia, Czech Republic, Egypt, France, Germany, India, Ireland, Japan, Kuwait, Russia, Sweden, the UK, and the USA. Australia was declared free of influenza in 2008 after an intensive eradication programme.

#### **Source of viruses characterised during 2008**

Viruses available for characterisation during 2008 were isolated in the Czech Republic, Germany, Ireland, Japan, Switzerland, the UK, and the USA. Information on field observation, vaccine status and genetic and antigenic characterisation from several laboratories was considered.

#### **Field data**

Influenza infection was confirmed in both vaccinated and unvaccinated horses. Most vaccines available contained out of date viruses but insufficient information was available to conclude whether infection occurred in the face of high levels of vaccinal antibody.

#### **Characterisation of viruses isolated during 2008**

Sixteen viruses isolated in 2008 were characterised antigenically by haemagglutination inhibition (HI) using ferret and/or horse antisera and /or by sequencing of the haemagglutinin gene. Sequence data submitted to Genbank was also considered.

#### **Genetic characteristics**

All the HA sequences obtained for viruses from different countries were of the **American lineage** (Florida sublineage) and were similar to those of viruses isolated during 2007, comprising two clades. One (clade1), which includes sequences of recent viruses from Australia, Japan, North America and the UK, may be composed of two subclades. HA sequences of Japanese isolates from 2008 fell within subclade 1A, represented by A/equine/Ibaraki/2007 and A/equine/Sydney/2007, whereas the sequences of viruses isolated in Egypt and the USA during 2008 fell within subclade 1B, represented by, for example, A/equine/Kentucky/4/2007 or A/equine/Lincolnshire/1/2007. The other (clade 2), represented by, for example, A/equine/Richmond/1/2007, was composed predominantly of sequences of European isolates, but also included that of a virus isolated in Mongolia in late 2007.

No Eurasian lineage viruses were isolated during 2008. The HA sequence of one virus isolated in Switzerland during 2007 was closely related to earlier viruses of the Eurasian lineage, isolated in 1989.

#### **Antigenic characteristics**

Analyses, including antigenic cartography (Smith *et al.*, 2004), of HI data available for viruses isolated in 2008 indicated that HAs of the different clades/subclades continued to be antigenically closely related to that of the currently recommended prototype vaccine strain A/equine/South Africa/4/2003.

## Conclusions

The panel was of the view that the low number of Eurasian lineage viruses isolated sporadically during the past 5 years does not warrant a recommendation for continued inclusion of a representative of these viruses (A/equine/Newmarket/2/93) in vaccines.

Genetic and antigenic data available to date indicate that the American lineage viruses isolated during 2008 are similar to and exhibit a similar geographical distribution to the viruses circulating during 2007. With the data presently available, there is no evidence to indicate that the genetic differences between viruses isolated in America, Asia or Europe are yet sufficient to affect the efficacy of vaccines containing A/equine/South Africa/4/2003-like viruses.

## Level of surveillance

The existence of multiple subclades of American-lineage viruses indicates the continued evolution of these viruses, which eventually will have an impact on vaccine efficacy. More viruses need to be submitted to determine which clades and subclades of viruses are circulating (or co-circulating) in different parts of the world. The panel wishes to emphasise the importance of continued surveillance and rapid submission of viruses to reference laboratories for characterisation in order that antigenic and genetic drift can be monitored effectively and the information relayed to vaccine manufacturers in a timely manner.

## Recommendations

The panel does not recommend inclusion of an H7N7 virus in current vaccines.

The panel no longer supports the need for inclusion of a Eurasian lineage H3N8 virus represented by A/equine/Newmarket/2/93

Manufacturers should adopt the 2004 recommendations and update the American lineage H3N8 component of their vaccines to an A/equine/ South Africa/4/2003-like virus. (They are advised to consult reference laboratories to ensure that the isolate selected shows broad cross reactivity with viruses from different geographical regions.)

## Vaccines

Many vaccines still contain American lineage viruses such as Kentucky/94 and Newmarket/1/93 that were first recommended over 10 years ago. However because of the practice used by some vaccine manufacturers of updating strains on an *ad hoc* basis, other viruses such as A/eq/Kentucky/97, A/eq/Kentucky/98 A/eq/Kentucky/2002 have also been used. At the time of writing only two vaccines containing an A/eq/ South Africa/4/2003-like virus are available although it is understood that at least one additional vaccine manufacturer is in the process of updating.

## Standard reagents

Reference reagents specific for the recommended European lineage vaccine strains are available for standardisation of vaccine content by single radial diffusion (SRD) assay and can be obtained from the National Institute of Biological Standards and Control (NIBSC), email: [enquiries@nibsc.co.uk](mailto:enquiries@nibsc.co.uk). Preparation of reagents for A/South Africa/4/2003-like viruses is under review.

Four equine influenza horse antisera against A/eq/Newmarket/77(H7N7), A/eq/Newmarket/1/93(H3N8), A/eq/Newmarket/2/93(H3N8) and A/eq/South Africa/4/2003 (H3N8) are available as European Pharmacopoeia Biological Reference Preparations for serological testing of vaccine responses using the single radial haemolysis test. Sera may be sourced from European Directorate for the Quality of Medicines (EDQM) <http://www.pheur.org>.

<i>SRD reference reagents</i>	<i>EP BRPs for serological testing of equine influenza vaccines</i>	<i>OIE primary standards for diagnostic serological testing</i>
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Smith *et al.* (2004). Mapping the antigenic and genetic evolution of influenza virus. *Science*, **305** (5682), 371–376.

**REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP  
ON VALIDATION OF DIAGNOSTIC ASSAYS  
Paris, 2–4 February 2009**

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The meeting of the OIE *ad hoc* Group on Validation of Diagnostic Assays was held at the OIE Headquarters in Paris from 2 to 4 February 2009.

The meeting was chaired by Dr Rich Jacobson and Dr Kath Webster acted as rapporteur. The Agenda and the list of participants are presented as Appendices I and II, respectively.

**1. Introduction**

Dr Gideon Brückner, Deputy Director General of the OIE, welcomed the members on behalf of the OIE Director General, Dr Bernard Vallat. He reminded the Group to keep in mind the discussions and proposals made related to diagnostic assays during the 1-day Symposium held in Melbourne, Australia in November 2007 and also informed the Group that an *ad hoc* Group on diagnostic tests related to new and emerging technologies will be set up in the future and will take into consideration the work done by this Group.

**2. Discussion and finalisation of the draft of chapter on “Principles and methods for validation of diagnostic assays for infectious diseases”**

The Group reviewed and discussed the draft chapter, made substantial improvements and agreed on the content. Once approved by the Biological Standards Commission, the final draft will be sent for comment to the Delegates of the OIE Member Countries and Territories. A final version will then be proposed for adoption at the next General Session in May 2009.

The subject of provisional recognition of diagnostic assays after stage 1 was discussed and incorporated into the draft of chapter. This modification will have an impact on the current OIE procedure for validation and certification that has to be considered and approved by the Biological Standards Commission.

**3. Discussion and adoption of a general template for the annexes and guidelines**

The Group agreed, as a general template for the annexes, to follow the essential criteria listed in the chapter and for the guidelines to follow the template of the dossier developed in the framework of the OIE Procedure for the validation and certification of diagnostic assays.

**4. Deadline to produce the drafts of annexes and guidelines**

The Group agreed on the following timetable to produce the drafts of annexes and guidelines for June 2009

- Draft annexes on best practices for the draft chapter:
  1. Development and optimisation of antibody detection assays: Dr Axel Colling
  2. Development and optimisation of antigen detection assays by immunological means: Dr Axel Colling

3. Development and optimisation of nucleic acid detection (NAD) tests: Dr Sandor Belak and Dr Kath Webster
  4. Measurement of uncertainty: Dr Axel Colling
  5. Statistical approaches to validation: Dr Ian Gardner
  6. Equivalency: Dr Ian Gardner
  7. Selection and use of reference panels: Dr Peter Wright and Dr Richard Jacobson
- Draft guidelines to support the dossier:
1. Antibody Detection based assays: Dr Peter Wright and Dr Ian Gardner
  2. Antigen Detection based assays: Dr Peter Wright and Dr Ian Gardner
  3. Nucleic acid detection assays: Dr Kath Webster, Dr Sandor Belak and Dr Ian Gardner
  4. TSE agents: Dr Kath Webster and Dr Ian Gardner

The Group recommended a last meeting in September 2009 to finalise and present to the Biological Standards Commission all the draft documentation described above.

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.../Appendices

Appendix I

**REPORT OF THE MEETING OF THE OIE AD HOC GROUP  
ON VALIDATION OF DIAGNOSTIC ASSAYS  
PARIS, 2–4 FEBRUARY 2009**

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**Agenda**

1. Introduction and Approval of Agenda
  2. Presentation of the draft of chapter on “Principles and methods for validation of diagnostic assays for infectious diseases” (Chapters 1.1.4. “Principles of validation of diagnostic assays for infectious diseases” and 1.1.5. “Validation and quality control of polymerase chain reaction methods used for the diagnosis of infectious diseases” melded)
  3. Presentation of the advancement on the appendix(es) for the chapter and/or guidelines to accompany the template
  4. Discussion and finalisation of the draft of chapter
  5. Discussion and adoption of a general template for the appendixes and guidelines
  6. Determine how to integrate the chapter and annex content to make transitions between the two as seamless as possible
  7. Deadline to achieve the drafts of appendixes and guidelines
  8. Any other business
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Appendix II

**REPORT OF THE MEETING OF THE OIE AD HOC GROUP  
ON VALIDATION OF DIAGNOSTIC ASSAYS**

**Paris, 2 – 4 February 2009**

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