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REPORT OF THE MEETING OF THE OIE STANDARDS COMMISSION

Paris, 20–23 September 1999

The OIE Standards Commission met at the OIE Headquarters from 20 to 23 September 1999.

Dr J. Blancou, Director General, welcomed the participants, mentioning the importance of the Commission's activities within the overall programme of the OIE, with particular emphasis on the *Manual of Standards for Diagnostic Tests and Vaccines* (the *Manual*). He was pleased to note that the text of the *Manual* is now available on the OIE Web Site. The OIE Third Strategic Planning Group preliminary meeting, held from 2 to 3 September, had confirmed the high priority of the work of the Standards Commission. Prof. M. Truszczynski, President of the Commission, also welcomed the Members and other participants, noting in particular the key agenda items on Newcastle disease, antimicrobial resistance and quality systems. He specifically welcomed Dr J. Pearson, Vice-President of the Commission, who had recently also taken up the post of Head of the OIE Scientific and Technical Department, a key position in relation to the Standards Commission. The Agenda and List of Participants are given in Appendices I and II, respectively.

1. OIE Reference Laboratories

1.1. New applications for OIE Reference Laboratory status

There had been one new application for designation as an OIE Reference Laboratory, namely for Echinococcosis/Hydatidosis at the Department of Veterinary Services, Nicosia, Cyprus. The Commission supported this proposal, but would need to seek clarification of the name of the specific Reference Expert. It is hoped that this new designation will foster links with the WHO[1] Mediterranean Zoonoses Control Programme.

1.2. Updating the list of Reference Laboratories and Collaborating Centres

The following changes to named experts at OIE Reference Laboratories have been notified to the OIE. The Commission recommends their acceptance:

Swine Vesicular Disease

Dr R.P. Kitching to replace Dr D.K.J. Mackay at the Institute for Animal Health, Pirbright, United Kingdom (UK).

Vesicular Stomatitis and Aujeszky's disease

Dr S.L. Swenson to replace Dr B. Schmitt at the National Veterinary Services Laboratory, Ames, Iowa, United States of America (USA).

1 World Health Organization

Enzootic bovine leukosis

Dr L.H.M. Renström to replace Dr K. Klintevall at the National Veterinary Institute, Uppsala, Sweden.

Bluetongue, Equine encephalomyelitis (Eastern, Western and Venezuelan) and Equine infectious anaemia

Dr E.N. Ostlund to replace Dr J. Pearson and Dr A.D. Alstad at the National Veterinary Services Laboratory, Ames, Iowa, USA.

Caprine arthritis/encephalitis and Maedi-visna

Mr M. Dawson had advised OIE that he had left the Veterinary Laboratories Agency, Weybridge, UK, and was no longer in a position to fulfil the responsibilities of Reference Expert. Further information was awaited from the Laboratory concerning future activities.

Infectious bursal disease of poultry

The Delegate of the UK had advised OIE that the Veterinary Laboratories Agency, Weybridge, UK would not be in a position to sustain the responsibilities of OIE Reference Laboratory for infectious bursal disease when the designated Reference Expert retires later this year. The Standards Commission took note of this withdrawal.

1.3. Annual reports of Reference Laboratories and Collaborating Centres

The Commission agreed a revised format that would be used in the call for annual reports from Reference Laboratories and Collaborating Centres. This should bring the reports more in line with the activities specified by the OIE in the Mandates and Rules for Reference Laboratories and Collaborating Centres, respectively. It was agreed that the reports would not be placed on the OIE Web Site, but mention of their availability from the OIE would be indicated on the appropriate Web Page. The laboratories will also be asked to provide their own Web Page addresses with a view to including hypertext links between them and the OIE Web Site.

1.4. Information on laboratory activities at regional level

Information had been received from Dr E. Gimeno, Co-ordinator of the OIE Regional Representation for the Americas. Results of a questionnaire had been tabulated regarding activities of different national laboratories in the Americas. The Commission hopes that this will assist laboratories in providing mutual support, although concern was expressed that a number of key laboratories appeared to be missing from the tables. It will be important to take care that any future initiatives, particularly in the areas of harmonisation of diagnostic methods and of production of standardised reagents, are linked to, rather than competing with, more global efforts initiated and undertaken by the Standards Commission.

2. International standardisation of diagnostic tests and vaccines

2.1. Progress on OIE standardisation programmes

LIST A DISEASES

Foot and mouth disease – Co-ordinator Dr A.I. Donaldson

Dr A.I. Donaldson reported that further information on the candidate standard sera would be provided following analysis of Phase XVI of the FAO[2] International Standardisation Programme for Foot and mouth disease (FMD) serology.

2 Food and Agriculture Organization of the United Nations

Peste des petits ruminants – Co-ordinator Dr A. Diallo

Dr A. Diallo reported that interlaboratory evaluation of candidate weak positive standard sera was in progress.

Contagious bovine pleuropneumonia – Co-ordinator Dr F. Thiaucourt

The Commission reviewed a dossier of data on the competitive ELISA[3] that had been used to evaluate the efficacy of vaccination in Africa. In addition, the assay had been compared with the CFT[4] as a measure of antibody status in individual animals. In summary, the competitive ELISA had shown a higher specificity than the CFT, i.e. reporting fewer false-positive results. The sensitivities of the two tests were similar, but it was noted that no serological test for this disease is reliable on its own as a diagnostic tool. Having considered the data, the Commission recommends that the ELISA should be adopted as an 'alternative test' suitable for international trade purposes. It was noted that further endorsement as a 'prescribed test' would require assurances that the specific reagents would be readily available to laboratories in Member Countries without commercial restriction.

LIST B DISEASES

Enzootic bovine leukosis (sera) – Co-ordinator Mrs R.E. Lysons

Mrs Lysons reported technical difficulties with the preparation of an International Standard weak positive serum. The problem is currently being addressed by the OIE Reference Laboratory.

Enzootic bovine leukosis (PCR[5]) – Co-ordinator Dr K. Klintevall

Dr K. Klintevall reported on the international interlaboratory comparisons and validation of the PCR protocol for use on infected tissues. The work is very promising, but as the number of samples tested is rather small, the Commission recommends that additional validation be undertaken to confirm the performance characteristics of the assay. The assay procedure will be added to the relevant chapter in the new edition of the *Manual*, and the draft text circulated for comments later this year.

The Commission also considered whether or not the PCR should be eligible for designation as a 'prescribed test'. Given that this type of test is not required by the *International Animal Health Code* (the *Code*) for international trade purposes, the Standards Commission decided that for the time being the status of diagnostic tests for bovine leukosis should remain as at present. The PCR will be particularly useful for screening of bovine lymphoid tumour cases as part of general disease surveillance in Member Countries.

Equine influenza – Co-ordinator Dr J. Mumford

Dr J. Mumford had submitted a progress report on the preparation of Standard Sera for the currently circulating virus strains. The Commission looks forward to seeing the final report at its next meeting.

2.2. Other initiatives

Foot and mouth disease

Following earlier advice from the Standards Commission, it was noted that additional evaluation of the EITB[6] assay for FMD antibody was being arranged in southern Africa.

3 Enzyme-linked immunosorbent assay
4 Complement fixation test
5 Polymerase chain reaction
6 Enzyme-linked immunoelectrotransfer blot

Rinderpest

Dr M. Robinson informed the Commission that the OIE Collaborating Centre for ELISA and Molecular Techniques in Animal Disease Diagnosis, FAO/IAEA[7], Vienna, Austria, would be supporting the co-ordination of an evaluation of a new rinderpest indirect ELISA using recombinant antigen. The principal aim of the study will be to demonstrate equivalence of the assay with the existing prescribed test.

Brucellosis

Dr K. Nielsen, Nepean, Canada, had submitted new data on comparisons of the indirect ELISA, competitive ELISA and FPA[8] for porcine brucellosis. The three tests had a broadly similar specificity and sensitivity and showed good performance on a limited panel of samples from animals confirmed as culture positive. All would be suitable as herd tests. The Commission considered there was now sufficient validation data to accept ELISA and FPA as 'alternative tests' for international trade. There is still a need to carry out an interlaboratory comparison at an international level before they could be considered for designation as prescribed tests. A panel of international standard sera for porcine brucellosis would also be of great value for the harmonisation process.

Mr A. MacMillan had informed the OIE of a successful application for funding of a COST[9] Action for brucellosis. This will involve a collaborative effort among European countries, with working groups on epidemiology, immunology and diagnosis, molecular biology and vaccine development, and standardisation, harmonisation and legislation. The Commission will appreciate being kept informed of the progress of this initiative.

Dourine

The Commission noted a proposal from the OIE Reference Laboratory for dourine, Moscow, Russia, to undertake an international comparison of antigens from different sources. This will be a useful activity in support of harmonisation of tests for international trade. Participation in the project by the other OIE Reference Laboratory, and other key suppliers of diagnostic antigens will be important.

Molecular diagnostic techniques

As molecular techniques, particularly the PCR, are increasingly being applied to infectious disease diagnosis, the Commission recognises the importance of developing international standard materials applicable to such tests. It was noted that in the medical field an international standard for hepatitis-C virus RNA had been developed for WHO by the National Institute for Biological Standards and Control, UK. As PCR is now a prescribed test for bluetongue, the Commission considers it important to develop a reference RNA[10] preparation to assist in standardisation of that assay. This will be referred to the OIE Reference Laboratories for action.

3. List of prescribed and alternative tests

3.1. Contagious bovine pleuropneumonia

As noted above (Section 2.1.) it is proposed that the ELISA for contagious bovine pleuropneumonia (CBPP) should be adopted as an alternative test for international trade purposes. It is recommended that the International Animal Health Code Commission review the wording of the relevant chapter, which at present specifies the CFT.

3.2. Heartwater

A number of Member Countries had commented that indirect fluorescent antibody tests are no longer the methods of choice for international trade or other diagnostic applications. The Standards Commission agreed to seek expert opinion on this, and to find out whether there is sufficient validation data available to support designation of ELISA as a prescribed test.

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7 International Atomic Energy Agency
8 Fluorescence polarisation assay
9 European Cooperation in the Field of Scientific and Technical Research (Coopération européenne dans la domaine de la recherche scientifique et technique)
10 Ribonucleic acid

3.3. Porcine brucellosis

As noted above (Section 2.2.) it is proposed that the ELISA and the FPA for porcine brucellosis should be adopted as alternative tests for international trade purposes.

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

For this section of the agenda the Commission was joined by the consultant editor, Dr G.A. Cullen. Progress on the preparation of chapters for the next edition of the *Manual* was reviewed. Six mailings have been distributed for Member Country comments, and many helpful comments have been received and draft chapters modified as appropriate. The remaining chapters will be sent for comment in the next few months. The Commission provided detailed advice to the editor on specific technical issues in individual chapters. An offer of assistance with wildlife aspects in the *Manual* had been received from the European Association of Zoo and Wildlife Veterinarians. This should be referred to the OIE Working Group on Wildlife.

5. Booklet of OIE guidelines for veterinary laboratories

The booklet of guidelines will be held pending finalisation of the proposed OIE Standard on quality systems for veterinary laboratories.

6. OIE disease information sheets

The draft sheets on ovine epididymitis and caprine and ovine brucellosis have now been reviewed by OIE experts. They are included at Appendix III to this report for Member Country comments. New sheets on infectious bovine rhinotracheitis and Aujeszky's disease have been drafted and will be sent for scientific review.

7. Liaison with other Commissions

The Commission noted the revised layout and chapter numbering system that will be adopted by the *Code* from the next edition. The *Manual* will be brought into line with this.

8. Antimicrobial resistance

The Commission noted that the International Committee agreed in May 1999 to the establishment of two Ad hoc Groups on antimicrobial resistance in bacteria. The Standards Commission will have a specific interest in the work of the group dealing with harmonisation of laboratory methods for determination of antimicrobial resistance, and will provide them with its full support.

9. Quality systems for veterinary laboratories

In view of Member Country comments received after the last meeting of the Commission, a further review was undertaken of the draft text on the 'Management and Technical Requirements for Laboratories Conducting Tests for Infectious Animal Diseases' (see Appendix V of the Standards Commission report for February 1999). It was considered that only minor amendments and clarifications of the text were required, and when these are complete the document will be circulated to Member Countries for comment in time for finalisation by the Commission at its meeting in February 2000.

10. Definition of Newcastle disease

For this session the Commission was joined by Dr D.J. Alexander, OIE Reference Expert on Newcastle disease and Head of the World Reference Laboratory for Newcastle disease, Weybridge, UK. Dr Alexander had provided a comprehensive paper on the disease, detailing aspects of different clinical manifestations, the host range and distribution, the current world situation, the history of attempts to find an acceptable definition of the disease, and the molecular basis of virulence in the virus. Written advice had also been provided by other OIE experts on the disease. An extended discussion was held including a

careful review of the OIE definition of Newcastle disease as adopted by the International Committee in May 1999 (Resolution No. XIII).

It was agreed that it is not possible on scientific grounds to differentiate viruses within the avian paramyxovirus serotype 1 group on the basis of host of origin. For this reason the OIE definition refers to isolates from 'birds' rather than from 'poultry'. Nevertheless it is acknowledged that control measures and definitions of country freedom from the disease may need to refer to specific classes of bird, and that measures applicable to poultry may not be applied to other categories of birds. The Standards Commission recommends that the Code Commission should take account of this aspect.

In the light of Member Country comments, the Commission considered the criteria for virulence of virus isolates, which form part of the OIE definition of Newcastle disease. The comments centred on whether an intracerebral pathogenicity index (ICPI) of 0.7 or greater should define virulence, or whether a higher figure should be selected. It was noted that very few isolates from poultry fall in the range 0.7–1.2, and such isolates either cause, or have the potential to cause, disease in susceptible chickens. The large majority of isolates are clearly differentiated into virulent (ICPI >1.2) or low virulence (ICPI <0.7) and all the current lentogenic vaccine strains fall into the latter category. It was also noted that a definition based on ICPI of 0.7 or greater had been operated for a number of years in the European Union without significant difficulty.

On balance, the Commission decided that it would not recommend any change to the current OIE definition of Newcastle disease, but it is important that the text of the chapter in the *Code* be reviewed in the light of that definition.

11. Other matters

11.1. Response to the Third Strategic Planning Group

The President of the OIE International Committee had asked the Commission to provide inputs to the Strategic Planning Group for the period 2000–2004.

The Standards Commission considers that the dominant themes for the OIE in this period will be the setting of standards for international trade, provision of an international disease reporting network and the setting of standards for animal disease surveillance. Of these, standards for international trade will have the highest priority. Within these themes a number of specific activities will have particular prominence:

- The role of the OIE in declaring Member Country freedom from specific diseases will continue to have a major impact on trade. The Standards Commission should contribute to this through the provision of laboratory tools in support of disease surveillance, and through the network of experts based in Reference Laboratories and Collaborating Centres.
- It is to be expected that new diseases will continue to emerge. The ability of the OIE to make a rapid initial response to such events in support of Member Countries is very important. This should be complemented by the development of stronger links with other international bodies, such as FAO and WHO, which may become involved in medium to longer term strategies for disease control. In addition the Standards Commission should become more proactive in the early development of laboratory standards for new and emerging diseases.

- The programmes of standardisation of laboratory procedures, harmonisation of laboratory reporting criteria, and preparation of International Standard Sera and other reference materials will continue to be important activities of the Standards Commission in support of international trade. These programmes can only be achieved through the support and collaboration of the network of OIE Reference Laboratories and Collaborating Centres. The development of new tests and technologies, the validation of such tests, the provision of training, and the dissemination of technical information to Member Countries are also important activities that should be carried out by OIE Reference Laboratories and Collaborating Centres. The OIE should consider ways in which international collaborative projects on test standardisation could be funded. It will become increasingly difficult to expect Reference Laboratories to participate in such activities without a specific source of funding.
- The *Manual* should continue to be updated on a regular basis, taking into account the latest developments in biotechnology and diagnostics, but also emphasising the pivotal importance of comprehensive assay validation before introducing new techniques. The OIE should encourage Member Countries to review trade agreements on a regular basis to ensure that laboratory test requirements are based on the latest recommendations of the OIE, and that outdated procedures are removed from such agreements. The role of the Standards Commission in the setting of standards for vaccines should be reviewed. This has been a challenging area for some time, taking into account the predominant role played by regional and national regulatory authorities, and the commercially sensitive nature of many of the technical procedures.
- The Standards Commission assigns a high priority to the development of quality assurance schemes for veterinary laboratories. This will help ensure that laboratory test data used for international trade and for disease surveillance are consistent and reliable.
- Changes in global animal disease patterns, as well as changing political pressures, imply a need for flexibility and adaptability on the part of the OIE. Specific trends of current concern are the increasing focus of veterinary authorities and veterinary laboratories on food safety issues, the requirement for standards related to animal welfare, and the growing tendency towards privatisation and commercialisation (particularly in the laboratory sector). The OIE should maintain and strengthen its links with FAO and WHO to ensure that scarce resources are applied to best effect. The categorisation of diseases into Lists A and B should be kept under review. The organisation of Ad Hoc Groups focused on specific topics of current importance should continue to form an important part of OIE activities.

The Standards Commission identified particular strengths of the OIE in the network of Reference Laboratories and Collaborating Centres, and their associated experts. The availability of International Standard Reagents endorsed by the OIE is of great importance in the harmonisation of test methods among laboratories; the OIE should consider how Member Countries might make more use of this resource.

A potential weakness of the OIE is that resources may become over-stretched by commitment to too many initiatives. The organisation should ensure that priorities are carefully identified, and lower priority issues deferred.

11.2. Foreign Animal Diseases book

The Commission reviewed the latest edition of 'Foreign Animal Diseases', published in 1998 by the United States Animal Health Association. The OIE had been asked for possible interest in publishing translations of the book in languages other than English. The Commission noted the value of the book in familiarising veterinarians with exotic diseases. It fulfils a role similar to the OIE Disease Information Sheets, but with expanded information and including colour pictures of disease signs and lesions. As it is written from an American perspective, it was suggested that advice should be sought from the OIE Regional Representative for the Americas. Enquiries will also be made to the African and European Regional Commissions.

11.3. Biological products

The recommendations were noted from the International Conference on Biological Products for the 21st Century, held at Cairo University, Egypt, from 23 to 26 May 1999. The recommendations identified some important issues for the future of the serum and vaccine industry in the African region.

11.4. Rinderpest

A report had been received summarising the recommendations of the research co-ordination meeting of the FAO/IAEA/PARC[11] Co-ordinated Research Project on the surveillance of rinderpest in Africa. The importance of laboratory results to the surveillance programme was highlighted, which in turn requires an adequate level of support for national, regional and world reference laboratories. The Commission noted in particular the need for evaluation of the existing diagnostic tests in the context of animals infected with 'lineage 2' strains of rinderpest virus.

11.5. Contagious bovine pleuropneumonia

The Commission noted correspondence received from FAO regarding the importance of quality control for CBPP vaccines and the need for producers of vaccines to submit batch samples to the Pan-African Vaccine Centre for checking.

11.6. Conference of the World Association of Veterinary Laboratory Diagnosticians

Dr S. Edwards, Secretary General of the Standards Commission, attended the joint OIE/WAVLD[12] Biotechnology Seminar, which was held on 2 June 1999 in conjunction with the WAVLD Conference at College Station, Texas, USA. He presented a paper entitled 'The role of diagnosis in the control of pestivirus infections of pigs, cattle and sheep'. Dr Pearson, Vice-President of the Commission, presented a paper during the WAVLD session on quality systems, entitled 'OIE veterinary laboratory quality assurance standards'.

12. Next meeting of the Standards Commission

It is recommended that the consultant editor for the *Manual* should participate in appropriate parts of the meeting.

The proposed date for the next meeting of the Standards Commission is from 2 to 4 February 2000.

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.../Appendices

11 Pan-African Rinderpest Campaign
12 World Association of Veterinary Laboratory Diagnosticians

Appendix I

MEETING OF THE OIE STANDARDS COMMISSION

Paris, 20–23 September 1999

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 Standards*
5. Booklet of OIE guidelines for veterinary laboratories
6. OIE disease information sheets
7. Liaison with other Commissions
8. Antimicrobial resistance
9. Quality systems for veterinary laboratories
10. Definition of Newcastle disease
11. Other matters
12. Next meeting of the Standards Commission

MEETING OF THE OIE STANDARDS COMMISSION

Paris, 20–23 September 1999

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