73 SG/12/CS3 B

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REPORT OF THE MEETING
OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 14-19 January 2005

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A meeting of the OIE Scientific Commission for Animal Diseases (Scientific Commission) hereafter referred to as the 'Commission', was held at the OIE Headquarters in Paris, France, from 12 to 19 January 2005. Dr Alejandro Schudel, Head of the OIE Scientific and Technical Department, welcomed the participants on behalf of Dr Bernard Vallat, Director General of the OIE and explained the agenda of the meeting.

The list of participants and the agenda are presented as Appendices I and II.

The meeting was chaired by Prof. Vincenzo Caporale, President of the Scientific Commission. However, due to the late arrival of Prof.Caporale due to circumstances beyond his control, the part of the meeting was chaired by the Vice-President of the Commission, Dr Kenichi Sakamoto. Dr F. Stoessel was designated as rapporteur.

1. Reports of the Ad hoc Group meetings

1.1. Endorsement of reports

The Commission reviewed and endorsed the following reports:

- Ad hoc Group on carcass disposal, May/June 2004 (73 SG/12 CS3B/AHG 1)
- Ad hoc Group on epidemiology, June 2004 (73 SG/12 CS3B/AHG 2)
- Ad hoc Group on classical swine fever, September and December 2004 (73 SG/12 CS3B/AHG 3 & 4)
- Ad hoc Group on evaluation of country status for foot and mouth disease (FMD), October 2004 and January 2005 (73 SG/12 CS3B/AHG 5 & 6)
- Ad hoc Group on bovine tuberculosis, November 2004 (73 SG/12 CS3B/AHG 7)
- Ad hoc Group on avian influenza surveillance guidelines November 2004 (73 SG/12 CS3B/AHG 8)

These reports are presented in Appendix III.

1.2. Approval of country status with respect to FMD

Based on the recommendations of the Ad hoc Group on country status evaluation for FMD, the Commission approved that:

1. A zone of Argentina situated north of the 42° parallel regain its previous status *viz*. a zone free from FMD with vaccination with immediate effect;

2. Paraguay regain its previous status of country free from FMD with vaccination with immediate effect. In making this decision, the Commission noted the assurances provided by the Delegation of Paraguay that the FMD vaccines produced by the Frenkel method will be phased out as soon as possible.

The Commission agreed with the proposals of the Ad hoc Group to recommend to the International Committee in May 2005 that:

1. One zone of Peru as described by the Delegate of that country in a dossier submitted to the OIE be recognised by the OIE as free from FMD without vaccination;

2. The State of Acre along with two adjacent municipalities in Brazil be recognised by the OIE as free from FMD with vaccination;

3. The Central and Southern zones of Colombia as described by the Delegate of that country in a dossier submitted to the OIE be recognised by the OIE as free from FMD with vaccination. Regarding the vaccines that are used in that country, the Commission noted the assurances provided by the Delegation of Columbia that henceforth only vaccines produced in compliance with the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the *Terrestrial Manual*) will be used.

The Commission noted that the request of one Member Country to be recognised free from FMD without vaccination could not be considered by the Ad hoc Group as supplementary information requested by the Ad hoc Group was not made available for consideration. It also endorsed the observations of the Ad hoc Group that another Member Country which had submitted a dossier for one zone in that country to be recognised as free from FMD with vaccination be asked to submit supplementary information for consideration at the next meeting of the Ad hoc Group.

The Commission also approved the draft questionnaire submitted by the Ad hoc Group on FMD to be included among the documentation required of countries wishing to apply to the OIE for freedom from the disease.

1.3. Other Ad hoc Group reports

1.3.1. Antigen and vaccine banks

The Commission reviewed the report of the Ad hoc Group on Antigen and vaccine banks for FMD. It complimented the Group for proposing guidelines for the setting up of antigen and vaccine banks but noted that the Group had insufficient time to adequately address issues relating to the characterisations of FMDV strains. It therefore recommended that the Group continue the work already initiated and complete it at its next meeting in April 2005. The Commission recommended that in the meantime, the report could be submitted to the OIE Biological Standards Commission for review and comments.

1.3.2. Evaluation of non-structural proteins (NSP) tests for FMD

The Commission took cognizance of the report of the Ad hoc Group on the evaluation of NSP Tests for FMD which functions under the auspices of the Biological Standards Commission. It noted that the NSP tests have been validated as screening tests for FMD in cattle and that the

3ABC test may be used as an index test. The Commission expressed its gratitude to PANAFTOSA for proposing three reference sera to be used in conjunction with those tests. It also recognised that validation of NSP tests for sheep is ongoing.

1.3.3. Rinderpest

The Commission reviewed the report of the Ad hoc Group on evaluation of country status for rinderpest (73 SG/12 CS3B/AHG 9)and accepted to recommend to the International Committee in May 2005 that:

- Lebanon, Nigeria, Tanzania, a zone of Ethiopia as described by the Delegate of that country and a zone of Sudan as described by the Delegate of that country be recognised by the OIE as free from rinderpest disease.

- Benin, Bhutan, Eritrea, Mongolia, Senegal, Togo and Turkey be recognised by the OIE as free from rinderpest infection.

The Commission endorsed the views of the Ad hoc Group that a Member Country that had submitted a dossier to recognise as free from rinderpest disease be asked to submit supplementary data and relevant clarifications.

The Commission was made aware that the Ad hoc Group had also proposed a revised *Terrestrial Code* Chapter on rinderpest and a new Appendix on rinderpest surveillance. While the Commission was highly appreciative of the efforts put in by the Group, it felt that all those changes were not warranted at this stage. The Commission recommended that an Ad hoc Group of experts be established to address issues relating to the use of peste des petits ruminants (PPR) vaccines for the control of rinderpest in cattle and to review the OIE Pathway for rinderpest accreditation.

The section of the report dealing with country status evaluations is presented as Appendix IV.

2. Evaluation of country status for contagious bovine pleuropneumonia

The Commission reviewed the dossier submitted by the Delegate of Switzerland for that country to be recognised by the OIE as free from CBPP in accordance with Resolution XXIII adopted during the 72nd General Session and the relevant Chapters of the *Terrestrial Code*. The Commission concluded that Switzerland fulfils the criteria of Article 2.3.15.2 to be recognised as free from CBPP and decided to recommend to the International Committee that Switzerland be added to the list of countries free from CBPP.

3. Report of the Ad hoc Group on Diseases/Pathogenic Agent Notification

The Commission reviewed the report of the Ad hoc Group on diseases/pathogenic agent notification and the new OIE list of diseases and made the following recommendations:

- The list includes Nipah virus but not Hendra virus. The Commission felt that these two infections have similarities and that Hendra virus is an emerging pathogen with proven zoonotic potential (other cases having been reported in humans recently). More than three countries are free from the disease and the potential of international spread exists through the movements of affected animals. The Commission therefore suggested that it be included in the list.

- The list includes Meadi/Visna virus but not ovine pulmonary adenomatosis. The Commission recommended that more information be sought on the trade implications of these two diseases (see section 4.0 on Maedi/Visna). In the meantime, both diseases should remain on the list.

- Bovine cysticercosis ia a serious condition in some developing countries and often poses a significant trade impediment and loss of income due to condemnation of carcasses infected with the parasite. The Commission recommended that expert opinion be sought on this matter before its definitive exclusion from the list.

- Malignant catarrhal fever is not on the list. While the Commission agreed that the sheep associated form of the disease does not warrant listing, the wildebeest associated form is a disease that can cause significant mortality in cattle and spread through the movement of partcicular species of wildebeest. More information would be provided by the Commission and in the meantime, it was recommended that the wildebeest associated form be included in the list.

The Commission reviewed the following definitions proposed by the Ad hoc Group and recommended that they be forwarded to the Code Commission for inclusion in the *Terrestrial Code*.

Case

means an individual *animal* infected by a pathogenic agent listed by the OIE.

Emerging disease

means a new *infection* resulting from the evolution or change of an existing pathogenic agent, a known *infection* spreading to a new geographic area or *population*, or a previously unrecognized pathogenic agent or *disease* diagnosed for the first time and which may have a significant impact on animal or public health.

Epidemiological Unit

A group of animals with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogen. This may be because they share a common environment (e.g. animals in a pen), or because of common management practices. Usually, this is a herd or a flock. However an epidemiological unit may also refer to groups such as animals belonging to residents of a village, or animals sharing a communal dipping tank system. The epidemiological relationship may differ from disease to disease, or even strain to strain of the pathogen.

Notifiable disease

means a *disease* listed by the *Veterinary Administration*, and that, as soon as detected or suspected, must be brought to the attention of the *Veterinary Authority*.

Outbreak

means the occurrence of one or more cases

4. Maedi-visna virus infection in sheep

The Commission reviewed a scientific document produced by Dr Michel .Pépin on a proposed Chapter on Maedi/visna for the *Terrestrial Code*.

The Commission complimented Dr Pépin for his work but felt that two important issues have not been adequately addressed namely: the geographical distribution of the disease and its impact on international trade. It therefore recommended that the paper be sent for review by known experts on the disease with the request to also evaluate ovine pulmonary adenomatosis against the same criteria as for Maedi-visna infection..

5. Report on FMD from OIE Reference Laboratories

The Commission reviewed the reports on FMD from the OIE Reference Laboratory of Pirbright, United Kingdom and the OIE Reference laboratory of PANAFTOSA, Brazil and complimented those laboratories for the excellent work . The documents will be sent to the Ad hoc Group on Antigens and Vaccine Banks.

6. Joint meeting with the Terrestrial Animal Health Standards Commission

The Commission reviewed the list of items to be discussed jointly with the Terrestrial Animal Health Standards Commission (the Code Commission) and made comments on some specific items. These included but were not limited to the following :

- The definition of 'poultry' as is presented in the proposed Chapter on avian influenza includes other birds such as ratites. However, the pathogenicity of avian influenza viruses in this and some other species may differ from that observed in chickens. The possibility exists therefore that some authorities may feel obliged to apply all the measures prescribed in the OIE standards to for example, ratites that may result in unrealistic and scientifically indefensible requirements and policies. The Commission also suggested that the OIE address through its existing mechanisms surveillance and trade issues in different animal species as well as the zoonotic potential of animal influenza viruses.

- The Commission discussed a concept document on 'compartmentalisation'. It concluded that the document provided background information on the essential issues. However, it recommended that the scope should be broadened to address more than one species and more animal diseases. More emphasis be placed on the approval and monitoring of compartments by national veterinary services, an auditing system for the establishment and maintenance of compartments, evaluation of vaccine coverage and quality and laboratory diagnostic services. It was decided to propose to the Code Commission that the Ad hoc Group on epidemiology co-opt some members of the Code Commission and produce with the support of the Central Bureau, a document that could be presented for discussion to the international Committee in May 2005.

- Regarding comments received on OIE documents that are distributed for country comments, the Commission observed that one Member Country systematically asks that mention be made in every Chapter that with respect to international trade, the international veterinary certificate should not include requirements for the exclusion of pathogens or animal diseases which are present within the territory of the importing country and are not subject to any official control programme. The Commission felt that this requirement is already covered in Article 1.2.1.2 of the *Terrestrial Code* on 'General Obligations' and therefore need not be duplicated within all the Chapters.

- In the light of comments received, the Commission suggested certain changes to the proposed Chapter 1.3.6 on 'General principles for surveillance and monitoring of animal health'. These changes were discussed with the Code Commission to enable the latter to submit a final document to Member Countries prior to the General Session in May 2005.

- The Commission decided to request the Code Commission to review the definitions of hides and skins in the light of Article 2.3.3.12 of the proposed Chapter on bovine tuberculosis. The Commission did not consider that hides and skins constitute a risk and suggested that the Code Commission consider eliminating the Article regarding hides and skins pending the adoptions of clearer definitions for these commodities. Furthermore, the Commission stressed that for the purpose of surveillance for tuberculosis, *ante-mortem* and *post-mortem* inspections at the abattoir should fall under the responsibility of the official veterinary services.

- The Commission decided that in view of the proposed changes in the Chapter on classical swine fever and the similarities with the Chapter on African Swine fever, the latter Chapter be reviewed. Dr Gideon Brukner, member of the Commission was asked to review the Chapter in consultation with international experts on the disease and submit a draft revised chapter on African swine fever for inclusion in in the *Terrestrial Code.* The Commission also endorsed a recommendation of the Ad hoc Group on classical swine fever to include the concept of compartmentalisation in the new Chapter on the disease.

Details of the joint meeting will be covered in the report of the Code Commission.

7. Other matters

7.1. Evaluation of country status for bovine spongiform encephalopathy and contagious bovine pleuropneumonia

The Commission was informed that a few country dossiers have recently been received at the OIE for evaluation of country status with respect to BSE. It recommended that these dossiers be evaluated during the next Ad hoc Group meeting for BSE recognition noting that any amendments to the *Terrestrial Code* Chapter on the disease that may be approved during the forthcoming General Session will be taken into consideration. The Commission assumed that in case new categories of BSE status are approved, appropriate adjustments for the status of countries already approved as 'provisionally free' will be taken on board by an appropriate Resolution. It also recommended that the dossiers previously submitted by two member Countries be again reviewed by the Group for compliance with the Code.

The Commission was also informed that several countries have expressed interest to be evaluated for freedom from CBPP based on Resolution XXIII adopted during the 72nd General Session and are in the process of compiling the appropriate dossier to be submitted to the OIE.

7.2. Views of the European Commission for the Control of Foot and Mouth Disease (EUFMD) on the surveillance of FMD after emergency vaccination

The Commission examined a document submitted by the EUFMD Commission on surveillance of FMD after emergency vaccination requesting that certain parts of the proposed guidelines on surveillance of FMD be modified. After examination of the proposals, the Commission decided that the surveillance guidelines could not be modified as proposed.

7.3. Frenkel method on FMD vaccine production

The Commission was informed of a correspondence from Paraguay requesting information on the suitability of the Frankel method for FMD vaccines production. The Commission endorsed the observations of the Ad hoc Group on FMD that the Frenkel method for producing FMD vaccines was not in compliance with the standards laid down in the OIE *Terrestrial Manual*, the main reason being that it was almost impossible to ensure Good Manufacturing Practices with this method.

7.4. Correspondence from Dr Klaas Johan Osinga on vaccination and safety of meat and dairy products

The Commission discussed a paper received from Dr Osinga of the Dutch Farmers Union "LTO Nederland" to be informed of the OIE position on the marketing of pigs meat from animals that have been vaccinated against FMD. The Commission recalled the view of OIE experts to the effect that there is no scientific evidence that meat derived from cattle vaccinated against FMD can produce any safety or security risk to consumers. Nevertheless, it recommended that the views of OIE experts be sought on this matter which relates specifically to pigs.

7.5. Some OIE definitions

The Commission considered a request from the OIE International Trade Department to review some general definitions contained in the *Terrestrial Code*. It recommended that with the exception of some newly proposed definitions mentioned in section 3.0 of this report, all existing definitions should be addressed to the Ad hoc Group on epidemiology which should as far as possible consult standard texts or dictionaries on epidemiological terms. It was understood however, that definitions relating to specific diseases will continue to appear in the relevant Chapters of the *Terrestrial Code.*

7.6. Correspondence from Taipei China on surveillance for avian influenza

The Commission discussed a correspondence received from Taipei China relating to some recommendations on surveillance standards for avian influenza and concluded that those recommendations had already been addressed in the proposed surveillance guidelines.

7.7. Special OIE/FAO meeting on CBPP situation in Southern African Developing Community (SADC) countries

The Commission reviewed the report of a special OIE/FAO meeting held during the General Session in May 2004 concerning the alarming CBPP situation in some SADC countries. It recommended that Zambia be asked to report on the follow-up actions carried out in that country as requested in the report of the meeting.

The report of the meeting is presented as Appendix V.

7.8. FMD in camelids

The Commission discussed a review article on the susceptibility of FMD in camelids. The article *Inter Alia* queries the inclusion of camelids as an FMD susceptible species in the *Terrestrial Code*. It was decided that the views of some OIE Reference Laboratories namely: Pirbright, PANAFTOSA and AARIAH be sought on this matter.

7.9. Mandate of Ad hoc Groups

The Commission suggested that the Terms of Reference of Ad hoc Groups responsible for country status evaluations with respect to specific diseases be discussed at its next meeting.

8. Dates of subsequent meetings

The Bureau of the Commission will meet from 30 to 31 May 2005 and the meeting of the Commission will be held from 16 to 20 January 2006.

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…/Appendices

Appendix I

MEETING OF THE

OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 13-19 January 2005

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Provisional Agenda

1. **Reports of the meetings of Ad hoc Groups**

   - Ad hoc Group on Carcass Disposal (31 May-2 June 2004)
   - Ad hoc Group on Antigen and Vaccine Banks for Foot and Mouth Disease (23-25 June 2004)
   - Ad hoc Group on Epidemiology (28-30 June 2004)
   - Ad hoc Group on Evaluation of Non Structural Proteins Tests for Foot and Mouth Disease Diagnosis (6-8 September 2004)
   - Ad hoc Group on Classical Swine Fever (27-29 September and 8 December 2004)
   - Ad hoc Group for Evaluation of Country Status for Foot and Mouth Disease (18-20 October 2004)
   - Ad hoc Group on Country Status Evaluation for Freedom from Rinderpest (20-22 October 2004)
   - Ad hoc Group on Avian Influenza Surveillance (11-13 November 2004)
   - Ad hoc Group on Tuberculosis (17-19 November 2004)

2. **Report of the meeting of OIE Ad hoc Group for Evaluation of Country Status for Foot and Mouth Disease, 10-13 January 2005**

3. **Evaluation of country status for contagious bovine pleuropneumonia: dossier submitted by Switzerland**

4. **Report of the Meeting of the OIE Ad Hoc Group on Diseases / Pathogenic Agent Notification on a new OIE List of Diseases, 3-5 November 2004**

5. **Paper from Dr Michel Pépin on Maedi-visna virus infection in sheep**

6. **Reports from OIE FMD Reference Laboratories**

7. **Joint meeting with the OIE Terrestrial Animal Health Standards Commission**

8. **Other matters**

   a) Evaluation of country status for bovine spongiform encephalopathy and contagious bovine pleuropneumonia

   b) Correspondence from the EUFMD Commission on the Surveillance after emergency vaccination

   c) Correspondence from Paraguay on the Frenkel method for FMD vaccine production

d) Correspondence from Dr Klaas Johan Osinga on vaccination and safety of meat and dairy products

e) Review of some OIE definitions

f) Correspondence from Taiwan on avian influenza standards

g) Special OIE/FAO meeting on Contagious Bovine Pleuropneumonia situation in SADC countries: OIE Headquarters: Paris, France, 24 May 2004

h) FMD in camelids

Appendix II

MEETING OF THE

OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 13-19 January 2005

List of participants

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Appendix III

REPORTS OF THE OIE AD HOC GROUPS MEETINGS
APPROVED BY THE SCIENTIFIC COMMISSION

- Ad hoc Group on carcass disposal, May/June 2004 (73 SG/12 CS3B/AHG 1)
- Ad hoc Group on epidemiology, June 2004 (73 SG/12 CS3B/AHG 2)
- Ad hoc Group on classical swine fever, September and December 2004 (73 SG/12 CS3B/AHG 3 & 4)
- Ad hoc Group on evaluation of country status for foot and mouth disease (FMD), October 2004 and January 2005 (73 SG/12 CS3B/AHG 5 & 6)
- Ad hoc Group on bovine tuberculosis, November 2004 (73 SG/12 CS3B/AHG 7)
- Ad hoc Group on avian influenza surveillance guidelines November 2004 (73 SG/12 CS3B/AHG 8)

73 SG/12 CS3B/AHG 1

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REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON CARCASS DISPOSAL

Paris, 31 May – 2 June 2004

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The meeting of the Ad hoc Group on Carcass Disposal was held at the OIE Headquarters, Paris from 31 May to 2 June 2004. Dr Alejandro Schudel Head of OIE Scientific and Technical Department welcomed all the participants on behalf of the Director General of the OIE, Dr Bernard Vallat. He indicated that the Ad hoc Group functions under the auspices of the Scientific Commission for Animal Diseases (Scientific Commission) and would therefore be chaired by a member of that Commission. Dr Schudel reminded the Group of the meeting on November 2002 of the previous Ad hoc Group on Carcass Disposal and indicated that the Group may if necessary utilise the recommendations of that Group to guide their deliberations.. He also indicated that the Group would be expected to propose an Appendix on Carcass Disposal for the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) that could be incorporated into Section 3.6. of the *Terrestrial Code*. He urged the Group to adopt a practical approach when proposing guidelines to Member Countries of the OIE on the subject of carcass disposal.

Dr Gideon Brückner, member of the Scientific Commission was nominated chairman of the Ad hoc Group.

The Agenda, List of Participants and Terms of Reference of the Ad hoc Group are presented as Appendices I, II and III respectively.

The Chairman outlined the working procedure for the meeting indicating that the mandate of the Group is essentially to provide guidelines on carcass disposal in support of disease control measures. He pointed out that alternatives to mass culling of animals and issues related to animal welfare and humane killing of animals have already been addressed by other Groups and would therefore not be discussed again. He proposed that the Group attempt to identify the essential guidelines that need to be addressed in the Appendix for the *Terrestrial Code* and use these as a reference for further discussions.

The Terms of Reference as outlined in Appendix III were discussed and accepted by the Group.

1. Proposed outline for the Appendix on Carcass Disposal for the *Terrestrial Code*

Taking into account the recommendations of the previous Ad hoc Group, available literature and documentation on the subject matter, it was decided to establish an outline for the proposed Appendix and to allocate responsibility for completion of the various subsections to members of the Group. It was agreed that a tentative draft of the individual contributions will be made available electronically to the Chairman of the Group by 30 August 2004 which will then be circulated again to Members of the Group by 15 September 2004 to enable a final draft to be submitted for consideration by the Scientific Commission by 30 September 2004.

It was agreed that the following issues will constitute the essential elements to be addressed in the proposed Appendix to the *Terrestrial Code*:

- *Introduction*

  The introduction should outline a) the scope and application of the guidelines b) reference to alternative methods such as vaccination c) the use of the guidelines to address routine carcass disposal other than mass destruction and disposal of animals and d)animal welfare and environmental concerns.

- *Definitions*

  Concepts or terms such as carcass, carcass disposal, technology, transport, bio-security, human safety and mass destruction as applicable to the scope of the Appendix need to be defined.

- *Regulation and jurisdiction*

  Member countries need to be sensitized on the need for a legislative mandate and the recognition of applicable concurrent legislation on an international, national and at sub-national level.

- *Pre-outbreak activities*

  Aspects that should be addressed include a communication strategy, political and public sensitization, efficacy and availability of equipment, preparedness, applicable technologies, financial support, pre-established partnerships, staff competency and other interest groups such as those involved in tourism.

- *Risk factors*

  Risk factors related to transportation, danger of airborne spread of pathogens, bio-security measures, dust, human health risks, inhalation, zoonoses, injury to assistants, environmental impact will be considered.

- *Social factors related to carcass disposal*

  Issues such as traditional beliefs and preferences, negative perceptions of public, security aspects, possible legal actions, alternative considerations to mass destruction and the farmer-animal relationship need to be addressed.

- *Practical considerations*

  Issues related to the disposal site, availability of meteorological data, transportation, site selection, dual usage of equipment and transport, logistical preparedness, disposal of products other than carcasses such as manure, eggs, feed, milk, cheese, non-animal products, risk-assessment on disposal site, use of antiseptics and other protective measures for humans, control of human movements (security at disposal site), vaccination of animals to suppress viral excretion, capacity of rendering plants, freezing and withholding before rendering, storage costs, supervision of transport/movement of carcass material, time schedules for rendering and incineration, suitability and availability of equipment to be used, disposal of wildlife.

- *Technology*

  The available technologies described by the previous Ad hoc Group and those described in the current literature will be used as references to describe in a harmonized manner the suitability of applying the different technologies under particular circumstances with respect to efficacy of pathogen inactivation for specific diseases. The technologies previously identified are: rendering, incineration (fixed incinerators, air curtain incinerators, municipal incinerators), pyre burning, composting, burial (mass burial, on-farm burial), mounding, commercial licensed landfill and fermentation.

- *Decision-making*

  A flexible decision-making process is proposed whereby the essential risk factors are evaluated against each of the applicable and available technologies to enable a Member Country to make an informed decision on the most suitable technology to be applied under the unique circumstances prevailing in the particular country. The following risk factors crucial for guiding decision-making for the application of the most suitable technology for carcass disposal were identified:

  - speed of resolving the problem,
  - occupational health safety (safety of procedures for the operator),
  - pathogen inactivation,
  - environmental concerns,
  - capacity available to meet the requirements of the available technology,
  - cost of applying a specific technology,
  - the effect of public reaction,
  - acceptance of the selected technology by the affected industry
  - impact of available transport in applying the selected technology and
  - the possible danger posed by the selected technology for spread of the disease to wildlife.

2. Legal aspects related to carcass disposal at sea

The Group was joined by Prof. Yves Gaudemet Legal Advisor to the OIE and Mr. Boris Stoykov trainee in legal matters at the OIE, for a discussion on the international legal aspects and Conventions related to carcass disposal at sea. The legal consultation was initiated by the Director General of the OIE following the recommendations of the 23rd Conference of the OIE Regional Commission for Asia, the Far East and Oceania held in Noumea (New Caledonia) from 25 to 28 November 2003. In response to a question concerning disposal of animal carcasses at sea, raised at the meeting of the Regional Commission, the Ad hoc Group on Carcass Disposal offers the following opinion and interpretation.

- Two international conventions have taken place on marine pollution by the dumping of waste , namely the London Convention (1972) and the Montego Bay Convention (1982). Of these the Montego Bay Convention is particularly important because it is a convention of the United Nations and isconsidered like a constitution for the oceans.

- There are no international maritime laws which specifically address the question of animal carcass disposal at sea as a consequence of a stamping-out procedure during epizootic disease eradication. Rather the Conventions refer to pollution as a result of dumping at sea, and the problem to be addressed is to know if carcasses are considered to be pollutants.

- Pollution of the marine environment is defined as the introduction by man, directly or indirectly, of substances or energy into the marine environment, including estuaries, which results or is likely to result in such deleterious effects as harm to living resources and marine life, hazards to human health, hindrance to marine activities, including fishing and other legitimate uses of the sea, impairment of quality for use of sea water, and reduction of amenities.

- If dumping is intended to occur within territorial waters exclusive economic zone or continental shelf, it is a question of national law where the State could authorise this action under certain conditions. If this is to occur in international waters where the action could be considered as a source of pollution, it must be authorised by the coastal States concernedon the assumption that the material is not harmful or dangerous. This will depend on the quantity of material and on the global danger.

- The Conventions oblige States to establish a system of authorisation to permit the activity or not if it is considered to be dangerous as far as pollution is concerned. In effect, it is a mechanism of declaration and authorisation.

The obligation of States is:

- for coastal States with regard to dumping within its territorial sea or its exclusive economic zone, or its continental shelf,

- for 'flag' States with regard to vessels flying its flag or in its registry,

- for any State with regard to acts of loading of wastes or other matter occurring within its territory or at its offshore terminals.

The definition of dumping given is wide and covers any deliberate disposal at sea of wastes or other matter.

The principle related to:

- a ban on the dumping of listed wastes,

- special permits to be required prior to, and for, dumping of listed wastes,

- general permits to be required prior to, and for, dumping of all other wastes.

Listed wastes do not apply to uncontaminated organic materials of natural origin. However, the issuing of general permits must take into account the characteristics and composition of the material to be dumped, notably:

- properties
    - physical (e.g. solubility and density)
    - chemical and biochemical (e.g. oxygen demand and nutrients)
    - biological (e.g. presence of viruses, bacteria, yeast, parasites)
- toxicity
- probability of production of taints or other changes reducing marketability of resources (e.g. fish, shellfish, etc.).

Therefore, disposal in a coastal sea or on a continental plateau cannot occur without the authorisation of the coastal State which must make a regulation on the dumping and which must consult with other neighbouring States. The Conventions express a fundamental principle which countries should abide by even if they are not signatories of the conventions. The International Conventions do not directly prohibit disposal of carcasses at sea, but do define the conditions to be met. This disposal is possible if it is technically and scientifically proven that the products to be disposed of are not harmful, and if the State has authorised this disposal with an official permit.

3. Recommendation

Considering the relevance of the information for Member Countries who might consider the disposal of carcasses at sea as expressed during the OIE Regional Commission meeting in Numea the Ad hoc Group on Carcass Disposal **requests** the Director General of the OIE to consider sending the information contained in this report on carcass disposal at sea to all OIE Member Countries as soon as possible.

4. General guidelines for the disposal of carcasses

The Group decided to communicate electronically and propose a draft Appendix on the 'General guidelines for the disposal of carcasses.

The draft guidelines are presented as Appendix IV.

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…/Appendices

Appendix I

OIE AD HOC GROUP ON CARCASS DISPOSAL

Paris, 31 May – 2 June 2004

Agenda

1. Proposed outline for the Appendix on Carcass Disposal for the *Terrestrial Code*
2. Legal aspects related to carcass disposal at sea
3. Recommendation
4. Next meeting of the Ad Hoc Working Group

Appendix II

OIE AD HOC GROUP ON CARCASS DISPOSAL

Paris, 31 May – 2 June 2004

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Appendix III

TERMS OF REFERENCE

Objective

To develop an Appendix for Section 3.6 of the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) on the disposal of animals and animal carcasses

Goals

- To define the concepts of animals and carcass disposal
- To define the scope/framework for application of OIE guidelines (routine vs disease outbreak disposal)
- To identify the different circumstances requiring animals and carcass disposal
- To identify guidelines on the risk factors related to disposal of carcasses
- To identify the relationship between animal and carcass disposal and animal welfare, environmental and human health considerations
- To identify the relevant stake holders and legal mandates involved in animal and carcass disposal
- To identify the approach of the guidelines – general guidelines, process-related or disease related guidelines
- To develop a decision-tree for animal and carcass disposal
- To develop a draft chapter for the *Terrestrial Code* for submission to the Scientific Commission for Animal Diseases by 28 January 2005.

Appendix 3.6.5

General guidelines for the disposal of carcasses

Introduction

The mass destruction and disposal of animals in the event of an animal disease outbreak are always subject to intense public and media scrutiny thereby obligating the *Veterinary Administration* of a Member Country to not only conduct carcass disposal operations within acceptable scientific principles to destroy the causative pathogen of disease but also to satisfy animal welfare, public and environmental concerns.

The guidelines in this Appendix are general and generic in nature. They are recommended for adoption after consideration of the application best suited to prevailing circumstances of a specific disease outbreak. The choice of one or more of the recommended technologies should be in compliance with the mandates provided for within relevant local and national legislation and be attainable with the resources available within the Member Country. The guidelines should also be read and applied in conjunction with the procedures described for the humane killing of animals in Appendix XXX of the *Code*.

The chapter aims to briefly describe the definitions applicable to the disposal of carcasses, outline the regulatory and jurisprudence requirements that should be considered, identify the most important risk factors associated with the disposal of carcasses, list the social factors and practical considerations relevant to carcass disposal, give guidelines on appropriate technologies that could be applied and give guidance on the decision-making process in electing the most appropriate technology for the disposal of carcasses under specific circumstances.

Where indicated within the relevant chapters of the *Code,* the vaccination of animals in combination with or without a stamping-out policy to contain a disease outbreak could be the preferred choice above mass destruction. The eventual decision to embark on the mass destruction and disposal of animals to contain a disease outbreak should be carefully evaluated against available alternatives, environmental, socio-political and socio-economical concerns, trade implications as well as prevailing ethical and ethnic beliefs and preferences.

Definitions

For the purpose of this Appendix the following definitions relevant to the disposal of carcasses shall apply:

- **Carcass -** means the body of an animal subsequent to euthanasia or death that requires safe destruction.
- **Disposal -** means the inactivation of the pathogen with reduction of the carcass and related materials to constituent components.
- **Technology -** means the process by which disposal is achieved.
- **Transport -** means the bio-secure removal of animals or carcasses or material from the site of infection to the site of disposal.
- **Bio-security -** means the absolute containment of infection.
- **Human safety -** means elimination of risks to the health and well-being of the persons involved in animal disposal procedures.
- **Animal welfare -** means reference to guidelines established for humane killing as defined in Appendix XXX.
- **Mass destruction -** means an emergency destruction and disposal of a large number of animals for disease control purposes

Appendix IV (contd)

Regulations and jurisdiction

The laws regulating animal health, prevention and eradication of animal diseases, and the organisation of the *Veterinary Administration* should give the *Veterinary Services* the authority and the legal powers to carry out the necessary activities for an efficient and effective disposal of carcasses. For most of the disposal options, legislation of other governmental bodies at national or local level is in force and should be respected. Therefore close co-operation between the *Veterinary Service* and these authorities is indispensable to develop a coherent set of legal measures for carcass disposal in peace time in order to apply these undisturbed where and when it is necessary. In this context the following aspects should be clearly regulated:

- Right of entry on a farm and its premises for personnel of the *Veterinary Service* and of contractors working for the *Veterinary Service*.

- Total movement ban to be applied on an infected or suspected farm and the authority to make exemptions under certain bio-security conditions - for instance for transport of carcasses to another location for disposal..

- The obligation for the involved farmer, his relatives and his personnel to co-operate with and to apply all the measures ordered by the *Veterinary Service*.

As regard to infected and suspected animals and their products:

- the transfer of the ownership of these to the competent authority (for instance through confiscation or buying up with compensation of the farmer) and
- the right to kill these animals on the farm or wherever the *Veterinary Service* determines.

If burning of the carcasses is the option of choice:

- the Veterinary Service should have the authority to determine the place where the pyre is situated,
- national and local governmental organisations competent for the protection of the environment should have given their approval for this solution in advance and should have adopted the necessary legal framework to allow this and
- all involved authorities should have determined on the conditions for removal of the ashes.

If mass burial, mounding or open farm burial is the preferred option:

- the Veterinary Service should have the authority to determine the place of burial in accordance with other involved authorities,
- national and local governmental organisations competent for the protection of the environment and subsoil water reserves should have agreed with this solution and should have adopted the necessary legislation and
- all involved authorities should have determined together the regime applicable to the site after the burial.

If rendering or any other centralised processing is the preferred option:

- the Veterinary Service should have the authority to require the necessary capacity at the processing company and to determine priorities,
- national and local governmental organisations regulating these types of processing should have agreed with the increased production volumes and other related consequences beforehand and should have covered the legal aspects and
- all involved authorities should have determined on the conditions applicable to the products from these carcasses.

It might happen that the chosen option for carcass disposal has to be applied near the border of a neighbouring country. In such cases the competent authorities of this country should be consulted and common legal solutions should be found in order to prevent misunderstanding and conflict.

If there is insufficient capacity in the country for processing of carcasses and if other options for carcass disposal are also limited, a solution could be the processing in another country. However, when an outbreak of an infectious animal disease occurs in a country, governments take preventive measures against import of potentially infected animals and products from the infected region. Those measures will also prevent the importation and transport of carcasses to a processing plant. If the export option is the choice, the conditions should be well established between the two involved countries and all legal aspects cleared beforehand. It should be realised that strong opposition can be expected from the farming community in the importing country against such transports. An agreement and preparation of the necessary legal aspects in peace time will help to apply this solution rapidly when it is needed. Clear communication about the process to be followed will help to elicit public support.

Pre-outbreak activities

The decision to embark on the mass destruction and disposal of animals in the event of a major disease outbreak or the mass disposal of animals in the event of natural disasters such as floods, and the implementation of the decision, need often to be taken in a short limit of time and activities to execute the decision, must similarly proceed with the minimum delay. The success or failure however, is primarily determined by the structures, policies and infrastructure that were established and agreed upon well in advance of such an event within contingency plans and working relationships and responsibilities established in preparation with other supportive structures.

- *Technical preparedness* – implies a predetermined decision process enunciated in a document, training of staff in the technical aspects of applicable technologies and the development of instructional manuals such as standing operating procedures (SOP's) for events of disposal. The sensitivity and public scrutiny on the process of carcass disposal requires that a trained and competent official must be available on site. Such an official must be familiar with procedures to conduct the chosen technologies for carcass disposal.

- *Financial preparedness* - the factors of a compensation mechanism to assist affected producers; access to emergency funding permitting rapid and effective action; and access to an expanded human resource through agreements with private veterinarians, are considered critical to the success of the program. To be effective, these factors must be considered, resolved and in place prior to a disease occurrence. Transparency on the criteria for compensation and the minimum delay in the execution of payments are critical factors to ensure cooperation from affected farmers.

- *Pre-established partnerships* - a relationship with industry is essential to obtain compliance with animal health policies. Partnerships should not only include farmer associations or commodity representatives but also animal welfare organisations, supportive structures such as security services, disaster management units within government structures, the media and consumer representative groupings. This relationship is encouraged and essential to enhance the receptivity to future risk communications. In some countries tourism is a very significant contributor to the national economy and can be adversely affected by animal disposal and emergency operations.

- *Communication plan* - the *Veterinary Administration* must accept that the information on any event of mass culling and disposal of animals cannot and should not be withheld from public scrutiny. Sharing the information based on scientific facts on an ongoing basis is essential. Information sharing with politicians and the media is especially important but information sharing with officials involved in the outbreak, affected farmers and professional organizations is equally essential but often neglected or forgotten. A well informed and knowledgeable spokesman should be available at all times to answer questions from the media and the public. Consistency in the information given is essential and should be guided by an available set of pre-empted well debated questions and answers that should be daily updated. An essential pre-requisite is to ensure ownership by politicians for the policies applied for the mass destruction and disposal of animals to contain a disease outbreak. The support by politicians should already be established in policy formulation and budgetary processes by the *Veterinary Administration* of the Member Country.

- *Equipment* – a supply of essential emergency equipment should be available immediately while contracts with rendering plants should be established as a default standing arrangement. The management of equipment should include provisions for expansion, temporary storing facilities, transport, and transport on farm, drivers, disinfection, mobile handling facilities for animals such as mobile crush-pens, protective and disposable material and logistical support. Procurement procedures should be simplified and special authorizations provided for the operation to enable the minimum delay in obtaining essential equipment and to supplement or replace existing equipment. Equipment would also include the type of burning material used for pyre burning of carcasses. In some countries sufficient wood would still be available but usage thereof is subject to environmental legislation and environmental concerns. Old vehicle tyres are a cheap and readily accessible alternative to wood but could be a source of environmental pollution and should only be used if sanctioned by applicable local or national legislation. The prior identification of sources of burning material are therefore essential so that it could be obtained with the minimum loss of time and effort when needed.

- *Transport arrangements* – The transport needed during mass disposal of animals are generally not included in the normal stock of vehicles of a *Veterinary Administration.* Heavy trucks, tractors, bulldozers, front-end loaders and the like, are all types of vehicles needed for transport of animals, collection of burning material, filling and closure of disposal sites and transport from the farm to a disposal site. It is important to ensure that the vehicles used do not pose a source for dissemination of the infection.

Risk factors

The list of risk factors has not the pretension to be complete. Other risk factors may influence the choice of a technique for carcass disposal as well.

- ***Speed*** - early detection of new infections, immediate killing of infected animals and rapid removal of the carcasses with inactivation of the pathogen are of utmost importance for the eradication of infectious diseases. Viral pathogens will not further multiply after the host is killed, but active and passive spread of the pathogen from the carcasses and their surroundings should be blocked as soon and as effectively as possible.

- ***Occupational health safety*** - carcasses in decomposition soon become a health risk for the persons who have to handle them during the process of disposal. Disposal should be organised in such a way that the workers are safeguarded against the risks of handling decomposed dead bodies. However special attention should be given to zoonotic aspects of certain pathogens as for instance avian influenza. Workers should be sufficiently protected against infection with a zoonotic pathogen (protective clothing, gloves, face masks, spectacles, vaccination, anti viral medicines, regular health checks).

- ***Pathogen inactivation*** - the chosen disposal procedure must give optimal safety as regards to the inactivation of the pathogen. If this cannot be achieved instantly, the spreading of the pathogen from the process should be blocked. Scientific information about the reduction of the pathogenic agent over time under the expected climatological conditions for any of the technologies should be the basis for the lifting of restrictions for the products or sites

- ***Environmental concerns*** - the different technologies for carcass disposal have different effects on the environment. For instance pyre burning will produce smoke and smells; burial might lead to gas production; escape of these gases and as a result smell; but also risk of contamination of air, soil, surface and sub surface water. Increased operating hours or increased throughput in a rendering plant may lead to increased smell or disturbances in the normal functioning of the waste water treatment and other protective facilities of the plant.

- ***Availability of capacity*** - practically all the technologies for carcass disposal have limitations on capacity. When the number of carcasses to be disposed of is high, the capacity of the acceptable technologies will soon be the bottle neck. An assessment of possibilities and capacities in peace time is very important to be able to take quick decisions in case of emergency. Temporary storage of carcasses in cold stores could sometimes relieve the lack of processing capacity.

- ***Cost*** - technologies for carcass disposal and specially those using sophisticated equipment are very costly. Budgetary provisions should be made for emergencies. When the Veterinary Service during a disease outbreak seeks the cooperation of private companies offering the needed capacity, the costs might escalate tremendously. Therefore it is necessary to negotiate a contract in peace time with those suppliers about capacities and costs when preparing a strategy for eradication.

- ***Public reaction*** - carcass disposal can easily lead to adverse reactions from the public when pictures of half burned or hoisted carcasses are shown on TV or in press. Urbanised populations estranged from rural practices will react often very emotionally on these images. In poorer countries the destruction of valuable meat of not yet sick animals may provoke public misunderstanding.

- ***Acceptance by farmers*** - the owners of an infected farm will in general prefer technologies at a distance and not on their own farm. Farmers outside an infected zone will prefer disposal within the infected area. All farmers will be very sensitive with regard to the safety measures taken to prevent spread of the disease by the used technology and the transport of the carcasses to the processing plant or disposal site. Proper compensation of owners for the loss of their animals or for the disposition of burial or burning sites will improve acceptability.

- ***Transport*** - for the application of all technologies for disposal, cranes, shovels and trucks must be used to transport the carcasses. This equipment can transfer the infection to other farms. Cleaning and disinfection of the outside surfaces of these vehicles when leaving an infected premise should receive special attention. The hygiene of the driver, his cabin, his lockers and his clothing and footwear should also be part of this process. The trucks transporting carcasses should be leak proof and be completely covered in order to prevent spread of the pathogen from the truck. The Veterinary Service should supervise the departure of the vehicle from the farm, the route the transport passes and the arrival at the disposal plant or site.

- ***Wildlife*** - many infectious diseases can affect wild animals as well as domesticated animals. Sometimes farm animals become infected through contact with game, but the population of wild animals might also become infected from an outbreak of a disease on a farm. When disposing of carcasses full attention should be given to the prevention of contamination of wildlife. Predators could try to get access to dead carcasses which might cause active or passive spread of the infection to other wild or domesticated animals.

Social factors related to carcass disposal

Culling and destroying of animals for the eradication of infectious disease often produce vehement reactions from the public. Reactions can be expected from the owners of animals which have to be culled, from farmers who are scared that their animals might contract the disease, animal welfare advocates who try to protect the lives of animals, people who abhor pictures of the culling of animals and the transport, burning and burial of carcasses, organisations who fight for environmental protection, culling perceived as a waste of edible food, etc.

In general a stamping out policy is applied to defend the export interests of the animal husbandry industry and is economically motivated. However, in some countries the general public and politicians express their doubts or their opposition against economical reasons as the leading argument to apply this strategy.

Even not all farmers will support the economic necessity of stamping out. For many farmers the rapid regaining of export markets is of no interest. Animals often represent a much more important and differentiated value than pure economics. For an animal breeder his animals represent a professional achievement based on the skills of himself and his ancestors. Many hobby farmers consider their animals as personal companions. In traditional communities animals are kept not for production but for a variety of reasons like a beast of draught or burden, for ceremonial reasons or as a symbol of wealth. For some religions the killing of certain animals is not acceptable. The export related economic argument will fail to convince such owners of the need for culling especially when animals, not showing any symptoms of disease but identified as carriers or serological positive, are included in the culling operation. Loss of certain animals cannot be compensated financially.

Practical considerations

In addition to the risk factors and pre-outbreak activities identified above, several practical issues, often not considered or often accepted as obvious but not attended to, need to be noted. The list is not exhaustive but gives an indication of some of the easily forgotten but essential considerations:

- ***Selection of disposal site*** – sufficient top soil to cover the site; water drainage; prevailing wind conditions; easy access to transport; availability of meteorological data; separation from sensitive public sites.

- ***Selection of contractors for transport –*** availability; can they supply in all the needs; exclusive use of vehicles or would they also be used for other purposes (risk of disease transmission); access to available roads; suitable for the purpose to be used.

- ***Logistical preparedness for the appropriate technology*** – availability of burning material (wood, old tyres); sufficient manual labour available; sites and availability of disinfection tents for personnel; storage and disposal of protective clothing; housing for personnel to prevent them from going back to home and spread infection; facilities for entry and exit control; availability of electricity for night operations; personal facilities for personnel such as toilets, drinking water; availability of communication – mobile phone reception; protection (eg vaccination) of personnel; rendering capacity at rendering plants; additional cold storage and holding facilities at rendering plants and abattoirs; availability of freezing facilities before rendering.

- ***Procedures and policies for disposal of other products*** – manure, eggs; milk; non-animal products; animal feed.

- ***Wildlife*** – do they pose a risk in the immediate environment; expertise availability for culling of wildlife; availability of capture teams?

Recommended technologies for the disposal of carcasses

These technologies are presented as a hierarchy based on their reliability for pathogen inactivation.

- ***Rendering -*** This is a closed system for mechanical and thermal treatment of animal tissues leading to stable, sterilized products, e.g. animal fat and dried animal protein. It grinds the tissue and sterilizes it by heat under pressure. The technology exists in fixed facilities and is in normal usage. It produces an effective inactivation of all pathogens with the exception of prions where infectivity is reduced. A medium sized rendering plant could process 12 tonnes per hour of operations. The availability of the capacity should be determined in advance. Such a plant can operate within environmental standards.

- ***Incineration -*** This technology can be applied as:

    - Fixed, whole-carcass incineration,
    - Mobile air curtain whole carcass incineration,
    - Municipal incinerators,
    - Co-incineration

    Fixed whole carcass incineration occurs in an established facility in which whole carcasses or carcass portions can be completely burned and reduced to ash. Effective inactivation of pathogens is produced. Without additional technology, the exhaust emissions are not subjected to environmental control. However these emissions can be subjected to air scrubbing procedures to meet environmental standards. Fixed facility incineration has been used to dispose of BSE infected carcasses, as well as rendered meat-and-bone meal (MBM) and tallow from cattle carcasses considered to be at risk of BSE. Fixed facility incineration is wholly contained and usually highly controlled. It is typically fuelled by diesel, natural gas, or propane. The exhausts may be fitted with afterburner chambers to completely burn hydrocarbon gases and particulate matter from the main combustion chamber. Whole carcass disposal can be problematic given the batch-feed requirements at most biological waste incineration plants. Many waste incineration facilities refuse whole animals which are 70% water, but prefer waste of 25% water.

Therefore, combining rendering and incineration is a promising approach. The resultant ash is less problematic and is considered safe. Although this is a more controlled procedure, there is still a potential fire hazard.

Municipal incinerators are pre-established facilities which are normally used for the burning of household or industrial waste. They may not be currently licensed to burn carcasses.

Co-incineration is a process in which meat and bone meal, carcasses or parts of carcasses are burned in conjunction with other substances such as hazardous waste incineration, clinical waste incineration, and other industrial incinerations such as power plants, cement kilns, blast furnaces and coke ovens. In practice meat and bone meal has been used as a secondary fuel on a large scale in cement kilns and power plants.

Air curtain incineration **-** air curtain incineration involves a machine that fan-forces a mass of air through a manifold, thereby creating a turbulent environment in which incineration is accelerated up to six times faster than open-air burning. The equipment for this process can be made mobile which can be taken on-site but the potential fire hazard must be considered. Because it can be used on site, there is no requirement for transportation of the animal material. It also produces effective inactivation of pathogens and may actually achieve higher temperatures (1000 ^{0}C). Fuelled by diesel engines, high velocity air is blown into either a metal refractory box or burn pit. The materials required are wood (in a wood:carcass ratio of from 1:1 to 2:1), diesel fuel for both the fire and the air-curtain fan, and properly trained personnel. For incineration of 500 adult swine, the requirements are 30 cords of dry wood and 200 gallons of diesel fuel. The product is ash. Since the procedure is not wholly contained, it is subject to variable factors such as human operation, weather, and local community preferences.

Pyre burning **-** this is an open system of burning carcasses either on-farm or in collective sites fuelled by additional materials of high energy content. This is a well established procedure that can be conducted on site with no requirement for transportation of the input material. However, this process could be contrary to environmental standards for air, water and soil. It takes an extended period of time and has no verification of pathogen inactivation. In fact, there is a possibility of particulate transmission from incomplete combustion. Further, because the process is open to view, there is a negative reaction and lack of acceptance by the public.

Comparison of incineration methods

With all three incineration methods described above, the greater the percentage of animal fat, the more efficiently a carcass will burn. (Swine have a higher fat content than other species). For fixed facility incinerators, the capacity depends on the chamber's size and can range from 50 kg / hour up to 10 tonnes of poultry carcasses / day. Preprocessed, relatively homogeneous carcass material is more easily handled than large numbers of whole animal carcasses. Depending on the design and on-site management, air-curtain incinerators can burn 4 - 6 tons of carcasses / hour.

Open-air burning can be relatively inexpensive, but it is not suitable for TSE infected carcasses. It is labour and fuel intensive, and dependent on favourable weather. It has environmental problems and a poor public perception. It is generally accepted that open-air burning pollutes. Although this is dependent on a number of factors. This may be more perception than established fact. Open air burning can also pose significant public perception, psychological, and economic problems

Fixed facility incineration destroys TSE infected carcasses and is highly biosecure. However it is expensive and difficult to operate and manage from a regulatory perspective. Properly operated fixed facility incineration pose fewer pollution concerns

Air-curtain incineration is mobile, usually environmentally sound, and suitable for combination with debris removal. However it is fuel intensive, logistically challenging, and is not validated to dispose of TSE infected carcasses. Air curtain technology in general has been shown to cause little pollution with fire boxes burning cleaner than trench burners. It has higher combustion efficiencies with less carbon monoxide and particulate matter emissions.

- ***Composting*** - carcass composting is a natural biological decomposition process that takes place in the presence of oxygen. In the first phase, the temperature of the compost pile increases, organic materials break down into relatively small compounds, soft tissue decomposes, and bones soften partially. In the second phase, the remaining materials, mainly bones, break down fully to a dark brown or black humus containing primarily non-pathogenic bacteria and plant nutrients.

  Composting systems require a variety of ingredients including carbon sources, bulking agents and biofilter layers. Carbon sources can include materials such as sawdust, straw, cured cornstalks, poultry litter, ground corn cobs, wheat straw, hay, shavings, paper, leaves, vermiculite, and matured compost. A 50:50 mixture of separated solids from manure and a carbon source can be used as a base material for carcass composting. The finished compost retains nearly 50% of the original carbon source which can be recycled in the compost process. A carbon:nitrogen (C:N) ratio in the range of 25:1 - 40:1 generates enough energy and produces little odour during the composting process. As a general rule the weight of carbon source materials to mortalities is approximately 1:1 for high C:N materials such as sawdust, 2:1 for medium C:N materials such as litter and 4:1 for low CN materials such as straw.

  Bulking agents have bigger particle sizes than carbon sources and maintain adequate air spaces (around 25-35% porosity) within that compost pile by preventing packing of materials. Bulking agents include spent horse bedding, wood chips, rotting hay bales, peanut shells, and tree trimmings. The ratio of bulking agents to carcasses should result in a bulk density of the final compost mixture that does not exceed 600 Kg/m^3. The weight of the compost mixture in a 19 litre bucket should not be more than 11.4 kg.

  A biofilter is a layer of carbon source or bulking material that enhances microbial activity with proper moisture, pH, nutrients, and temperature. It deodorizes gases released at ground level and prevents access by insects and birds thus minimizing transmission of disease agents.

  The site selection criteria include a well drained area at 90 cm above the high water table level, at least 90 metres from sensitive water resources, and an adequate slope (1-3%) to allow proper drainage and prevent pooling of water. Runoff should be collected and treated. The location should be downwind of nearby residences. The site should have full accessibility but have minimal interference with other operations and traffic. Storage time of mortalities should be minimized. Co-composting materials should be ground to 2.5 - 5.0 cm and mixed. Compost materials should be lifted and dropped rather than be pushed into place. Compost piles should be covered by a biofilter layer during both phases of composting. The moisture content of the carcass compost pile should be 40-60% (wet basis).

  A temperature probe should be inserted straight down into each quadrant of the pile and internal temperatures should be monitored daily and weekly during both phases of composting. During the first phase, the temperature at the core of the pile should rise to at least 55-60 ^oC within 10 days and remain there for several weeks. A temperature of 65^oC at the core, maintained for 1 - 2 days, will reduce pathogenic bacterial activity and weed seed germination. However spore formers such as *Bacillus anthracis* and other pathogens such as *Mycobacterium tuberculosis* will survive. Proper aeration is important in maintaining uniform temperature and moisture content throughout the pile. After the first phase of composting, the volume and weight of the pile may be reduced by 50-75%. Following the first phase, the entire compost pile should be mixed, displaced and reconstituted for the secondary phase. If necessary, moisture can be added.

The end of the second phase is marked by an internal temperature of 25-35°C, a reduction in bulk density of approximately 25%, a colour of dark brown to black and the lack of an unpleasant odour. Although heat generated during carcass composting results in some microbial destruction, it is not sufficient to completely sterilize the end product. Pathogenic bacterial activity is reduced when the temperature in the middle of the pile reaches 65 °C within one to two days. An average temperature of 55-60 °C for a day or two reduces pathogenic viruses, bacteria, protozoa (including cysts) and helminth ova to an acceptably low level, but endospores produced by spore-forming bacteria would not be inactivated.

- ***Trench burial and mass burial*** **-** this is a system to deposit whole carcasses below ground level and to be covered by soil, with no additional inactivation of pathogens. It is an established procedure which if conducted on site does not require transportation and is used to control the spread of disease. It does however require an environmental assessment because of the potential contamination of groundwater, or of aquifers if leachate is not controlled. Further, it does not inactivate all pathogenic agents.

- ***Licensed commercial landfill*** **-** this process involves deposition of carcasses in predetermined and environmentally licensed commercial sites. Because the site has been previously licensed, all environmental impacts such as leachate management, gas management, engineered containment, flooding and aquifers have already been considered. However, the area is open and uncovered for extended periods, there is a potential emission of aerosols, and there is resistance from the public to such an approach.

- ***Mounding*** **-** this process is one of mass burial above ground and it has similar considerations to those of mass burial and composting.

- ***Fermentation*** **-** this process is a closed system of anaerobic microbiological decompositions which requires prior mechanical and thermal treatment and which results in the production of biogas. This process does not inactivate pathogens, but typically uses non-dried rendered product as the input material.

- ***Alkaline hydrolysis*** **-** alkaline hydrolysis uses sodium hydroxide or potassium hydroxide to catalyse the hydrolysis of biological material into a sterile aqueous solution consisting of small peptides, amino acids, sugars, and soaps. Heat is applied (150°C) to accelerate the process. The only solid byproducts are the mineral constituents of the bones and teeth of vertebrates. This residue (2% of the original weight of the carcass) is sterile and easily crushed into a powder. The temperature and alkali conditions of the process destroy the protein coats of viruses and the peptide bonds of prions. Both lipids and nucleic acids are degraded. Significantly large carbohydrate molecules, such as cellulose, although sterilized by the process, are not digestible by alkaline hydrolysis eg paper, string, undigested plant fibres, and wood shavings.

  The process is carried out in an insulated steam-jacketed, stainless steel pressure vessel with a sealed lid. The vessel operates at 70psig to achieve 150°C. The process does not release any emissions into the atmosphere and only causes minor odour production. The end product solution can be released into the sanitary sewer with proper monitoring of pH and temperature according to guidelines. The total process time for alkaline hydrolysis digestion of carcass material is 3-8 hours depending on the disease agent eg bacterial and viral contaminated waste (4 hours), transmissible spongiform encephalopathy waste (6 hours). A mobile trailer unit has a capacity of digesting 4000 pounds of carcasses every 8 hours.

- ***Lactic acid fermentation*** - lactic acid fermentation is a means to preserve carcasses up to 25 weeks until they can be rendered. Fermentation is an anaerobic process. Carcasses are ground to fine particles, mixed with a fermentable carbohydrate source and a culture inoculant, and added to a fermentation container. For lactic acid fermentation, lactose, glucose, sucrose, whey, whey permeates, and molasses are suitable carbohydrate sources. The carbohydrate source is fermented to lactic acid by *Lactobacillus acidophilus*.

  Under optimum conditions with a temperature of about 35 °C, the pH of fresh carcasses is reduced to less than 4.5 within two days. Some microorganisms are destroyed by the acid pH while the remainder will be destroyed by heat during rendering.

- ***Anaerobic digestion*** - this process is suited for large-scale operations. It reduces odours and reduces pollution by greenhouse gases due to the combustion of methane. It can eliminate carcasses and at the same time produce energy but may require size reduction and sterilization of carcasses on-site before applying anaerobic technology. Anaerobic digestion transforms waste into fertilizer. Although anaerobic digestion is less expensive with mesophilic organisms at 35°C, the use of thermophilic organisms at 55 °C is preferred because the additional heat destroys some pathogens. It is necessary to use additional heat treatment at the end of the process to fully inactivate pathogens however, even with this, prions are not inactivated. Carcasses have a higher nitrogen content than most other wastes and therefore result in a high ammonia concentration which can inhibit anaerobic digestion. This limits the loading rate for anaerobic digesters that are treating carcass wastes.

Non-traditional and novel technologies

- ***Pre-processing*** - this involves on farm pre-processing prior to transportation of carcasses to central facilities because of the complexity and cost (eg rendering or incineration). Preprocessing could include the grinding of carcasses. (A large portable grinder can grind up to 15 tons of animal carcasses per hour). This could then be transported in sealed containers, or be subjected to fermentation or freezing. The primary objectives are to minimize on-site contamination risks and to maximize the number of options for disposal.

- ***Carcass disposal at sea*** - disposal in a coastal sea or on a continental plateau cannot occur without the authorization of the coastal State which must make a regulation on the dumping and which must consult with other neighbouring States. International Conventions express a fundamental principle which countries should be obliged to respect even if they are not signatories. These Conventions do not directly prohibit disposal of carcasses at sea, but do define the conditions to be met. It is possible for this disposal if it is technically and scientifically proven that the products to be disposed are not harmful, and if the State has authorised this disposal with a permit.

- ***Bio-refining*** - this is a high pressure, high temperature hydrolytic process, conducted in a sealed pressurized vessel. The waste material is treated at 180 °C at 12 bar pressure for 40 minutes, heated by indirect steam application to the biolytic reactor. The process can accommodate whole animal carcasses, MBM, food processing wastes, other compostable material, paper and comparable materials, and cereal straws either alone or in combination.

  In the dehydration cycle, the steam water is condensed and either used for other purposes or discarded. Each cycle lasts four hours. The capacity of each reactor is 20,000 tonnes of raw material per year. The process inactivates all microbiological agents. It is currently under evaluation for its efficiency in inactivating the prions of transmissible spongiform encephalopathies.

Special considerations for prion diseases

One of the problems in demonstrating the effectiveness of the inactivation of prions is the lack of a simple, rapid and inexpensive test for the presence of the infective agent, especially at low concentrations. The ultimate test is bioassay in a sensitive detector species by an efficient route, but usually this is only relevant in research. Typically this is done using panels of mice bred to be susceptible to particular types of transmissible spongiform encephalopathies (TSEs). However it must be recognized that the mouse to cattle species barrier has been demonstrated to be 500, therefore affecting sensitivity.

Although rendering at 133°C and three bars of pressure for 20 minutes is a defined standard, reductions of infectivity by this technology are in the order of 1:200 – 1:1000. Commercial incinerators have an inactivation rate of one million fold, while burning on pyres has a reduction rate of 90 %. (It should be noted that pyres are not suitable for sheep because of the wool and fat.)

Alkaline hydrolysis produces a 3-4 log reduction in infectivity over a three hour period. Landfill and deep burial are suggested to have a reduction in infectivity of 98 – 99.8 % over three years. Based on this information, rendering, incineration, and alkaline hydrolysis are the most reliable technologies at this time. The significance

of small amounts of infectivity become evident when you consider that experimentally it has been shown that exposure of sensitive species to as little as 1.0, 0.1 or even 0.01 grams of infected nervous tissue can induce infection.

Given all of the above (except complete burning in closed furnaces), it must be recognized that no process has been demonstrated to be 100 % effective in removing TSE infectivity and there will be some residual levels of infectivity remaining after treatment.

Guidelines for decision-making for the disposal of carcasses

Strategies for carcass disposal require preparation well in advance of an emergency in order to maximize the efficiency of the response. Major issues related to carcass disposal can include the number of animals involved, bio-security concerns over movement of infected and exposed animals, people and equipment, environmental concerns, and the extreme psychological distress and anxiety experienced by producers and emergency workers.

The disposal of large numbers of carcasses will be expensive. As well, fixed and variable costs will vary with the choice of the disposal method. Each method used will result in indirect costs on the environment, local economies, producers, and the livestock industry. Decision makers need to understand the economic impact of various disposal technologies.

A disposal option hierarchy may be incapable of fully capturing and systematizing the relevant dimensions at stake, and decision makers may be forced to consider the least preferred means. It therefore requires a comprehensive understanding of any array of carcass disposal technologies and must reflect a balance between the scientific, economic, and social issues at stake. Timely slaughter, maintenance of security and prevention of further spread of disease, are the essential considerations in terms of disease control.

- ***Process for decision- making***:

  The following is an example of a possible process for aiding decision-making by comparing the suitability of various disposal options against factors that are considered important for the specific disposal event in question.

  Step 1 - Define the factors to be considered. Include all relevant factors and allow enough flexibility to permit modifications for different situations and locations. Examples of possible factors include operator safety; community concerns; international acceptance; transport availability; industry standards; cost effectiveness and speed of resolution. These factors can be modified or changed, as is shown in the following example, to best fit the situation of event involved.

  Step 2 - Assess the relative importance of the factors by weighting each on their considered importance to addressing the event in question. The sum of all the weightings, regardless of the number of factors, must total 100.

  Step 3 - Identify and list all disposal options under consideration. Rate each disposal option against each factor and assign a Utility Rating of between 1 to 10 to each comparison. The Utility Rating (U) is a number between 1 and 10 which is allocated according to how well the option achieves the ideal with respect to each factor, (eg 1 = the worst possible fit, and 10 = the best fit).

  Step 4 - For each factor and each disposal option, multiply the Factor Weight (F) x Utility Rating (U) to yield a numeric Balanced Value (V), (eg V = F x U)

  Step 5 -By adding the Balanced Values to a sum for each disposal option, it is possible to compare the suitability of disposal options by numerically ranking the sums of the Balanced Values for each disposal option. The largest sum would suggest that disposal option as the best balanced choice.

  Example - An example of the use of this process follows in Table 1. In this example rendering achieved the highest sum and would be considered as the best balanced choice and the most suitable disposal option for the factors considered.

Appendix IV (contd)

Table 1: **Decision Making Process**

Method		Rendering		Fixed Incineration		Pyre Burning		Composting		Mass Burial		On-Farm Burial		Commercial Landfill	
	Weight	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value	Utility	Value
Factors															
Operator Safety	20	7	140	4	80	8	160	3	60	7	140	8			
Speed of Resolution	20	8	160	8	160	2	40	5	100	5	100	6			
Pathogen Inactivation	15	10	150	10	150	8	120	5	75	4	60	4			
Impact on Environment	10	10	100	8	80	3	30	10	100	3	30	3			
Reaction of the Public	10	10	100	7	70	1	10	9	90	3	30	4			
Transport Availability	5	1	5	1	5	8	40	5	25	3	15	8			
Acceptable to Industry	5	7	35	7	35	7	35	7	35	6	30	7			
Cost	5	4	20	1	5	6	30	9	45	8	40	9			
Risk to Wildlife	5	10	50	10	50	5	25	4	20	5	25	5			
Capacity to Meet Requirements	5	5	25	3	15	9	45	9	45	9	45	9			
Total Weight to Equal 100 Units	100	sum	785	sum	650	sum	535	sum	595	sum	515	sum		sum	

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MEETING OF THE OIE AD HOC GROUP ON EPIDEMIOLOGY

Paris, 28 – 30 June 2004

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The meeting of the OIE Ad hoc Group of the Scientific Commission for Animal diseases (Scientific Commission) on Epidemiology was held at OIE Headquarters, Paris from 28 to 30 June 2004.

The Agenda and list of participants are presented as Appendices I and II, respectively.

Dr Bernard Vallat, the OIE Director General, welcomed members of the Group and explained the high expectations of the OIE International Committee on the output of the Group particularly with respect to the Appendix on 'Guidelines for the surveillance required to support the establishment or regaining of recognition for a foot and mouth disease (FMD) free country or zone. He also stressed the importance of collaborative work between various OIE Specialist Commissions and Ad hoc Groups to produce common and harmonised documents for the OIE.

In accordance with standard practices whereby Ad hoc Groups functioning under the auspices of the Scientific Commission are chaired by a member of that Commission, the meeting was chaired by Professor Vincenzo Caporale, Chairman of the Scientific Commission. Dr John Kellar was designated as rapporteur.

The Group worked in close collaboration with members of the OIE Ad hoc Group on Nonstructural Proteins (NSP) tests. This collaborative approach was regarded as a progressive step towards rationalizing scientifically based approaches to such multi-faceted issues as surveillance for FMD.

In the course of their deliberations, the Group incorporated information derived from a number of salient sources that included but were not limited to:

- Chapter 2.2.10 of the *Terrestrial Animal Health Code (Terrestrial Code)*, on FMD
- Chapter 1.3.6 (as newly proposed) of the *Terrestrial Code*, on Animal Health Surveillance
- Chapter 1.3.3 of the *Terrestrial Code*, on the Evaluation of Veterinary Services
- The *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, 2004 Edition
- The report of the Ad hoc Group on evaluation of non-structural protein tests for FMD diagnosis
- The preliminary report of a workshop on comparative evaluation of FMD NSP antibody detection ELISAs, Brescia, 3-15 May 2004

1. *Terrestrial Code*: FMD Chapter 2.2.10

The Group reviewed and found acceptable, the changes made to Article 2.2.10.21 of the FMD Chapter 2.2.10 of the *Terrestrial Code* in respect of fresh meat or meat products of pigs and ruminants other than bovines imported from FMD free countries or zones where vaccination is practised.

2. Guidelines for the establishment or the regaining of recognition for a foot and mouth disease free country or zone, Appendix 3.8.7

The Group's review of the Appendix suggested the need for a number of changes to ensure that it reflected the findings and observations from the information sources described above. The most significant were those associated with the need for test validation at the global level and test quality assurance under local circumstances. Additional emphasis was placed on compliance with surveillance theory, statistical validity and other epidemiological principles flowing from the proposed Chapter 1.3.6.

The text was reshaped in order to group more closely together those sections that addressed serological diagnosis. The relative worth of periodic serological surveys was placed in greater perspective vis-à-vis that of continual clinical surveillance, as a result of concerns over the potential de-emphasis of the latter in the text as written. The Group was concerned that the effectiveness of widespread clinical surveillance in detection of FMD incursions could otherwise be lost upon the reader. A review of international experience suggested that clinical - as opposed to serological - surveillance inevitably disclosed FMD incursions in naïve populations. This is a natural sequel of the extremely low national prevalence challenging delimited serosurveillance approaches early in an outbreak.

Greater emphasis was assigned to contingency planning at the outset of serological surveys, to better address the predictable false positive reactions produced by currently employed diagnostic tests of less than 100% specificity.

With continuing emphasis on test parameters, the Group advocated the application of screening tests of high sensitivity, followed in series by confirmatory tests of equal or greater sensitivity and enhanced specificity. The text was rendered less prescriptive in terms of survey goals, in order to leave greater flexibility of approach in the hands of those responsible for their delivery. In concert with this change, greater responsibility was assigned to survey planners regarding the epidemiological and statistical validation of approaches employed.

In accordance with recently adopted changes elsewhere in the *Terrestrial Code*, the Group added the term "compartment" to accompany references to "zone" within the existing text.

3. Proposed alternative interpretation regarding the absence of virus circulation in vaccinated populations

The Group reviewed a proposal, submitted by PANAFTOSA, regarding the existing Appendix 3.8.7 on the use and interpretation of serological tests. The revision conveys PANAFTOSA's reminder that associated conclusions need to consider all relevant findings. It incorporates the theme of that proposal, by broadening the basis of interpretation of positives to include all epidemiologically salient aspects of the situation. The rewritten text advocates the examination of titre progression in terms of magnitude, prevalence and distribution, within not only the implicated animals but rather the tested cohort and broader regional population to which they belong. It advocates the application of sentinel animals, virological examinations and the assessment of contiguous susceptible species. In concert with the general theme of the rewritten Appendix (attached as Appendix III) it is less prescriptive. Instead, it offers greater latitude of investigative approach while challenging petitioners to validate their methods, findings and interpretations in accordance with acknowledged scientific principles.

4. Recommendations to other Ad hoc Groups

During the course of its review of Appendix 3.8.7, the Group noted that benefit would be obtained through the incorporation of new or extended definitions as proposed in the new Chapter 1.3.6. These include the relationship between true and apparent prevalence; threshold prevalence; pooled testing; sampling frame; risk-based or targeted sampling; null hypothesis; strata; and statistical confidence.

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…/Appendices

Appendix I

MEETING OF THE OIE AD HOC GROUP ON EPIDEMIOLOGY

Paris, 28 – 30 June 2004

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Agenda

1. *Terrestrial Code*: FMD Chapter 2.2.10
2. Guidelines for the establishment or the regaining of recognition for a foot and mouth disease free country or zone, Appendix 3.8.7
3. Proposed alternative interpretation regarding the absence of virus circulation in vaccinated populations
4. Recommendations to other Ad hoc Groups

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Appendix II

MEETING OF THE OIE AD HOC GROUP ON EPIDEMIOLOGY

Paris, 28 – 30 June 2004

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Appendix III

APPENDIX 3.8.7

GUIDELINES FOR THE SURVEILLANCE REQUIRED TO SUPPORT THE ESTABLISHMENT OR REGAINING OF RECOGNITION FOR A FOOT AND MOUTH DISEASE FREE COUNTRY OR ZONE

Article 3.8.7.1.

Introduction

This document defines the principles and provides a guide for the surveillance of foot and mouth disease (FMD) in accordance with chapter 1.3.6, applicable to countries seeking recognition from the OIE for freedom from FMD, either with or without the use of vaccination. This may be for the entire country or a zone/compartment within the country. Guidance for countries seeking reestablishment of freedom from FMD for the whole country or a zone/compartment, either with or without vaccination, following an *outbreak*, as well as guidelines for the maintenance of FMD status are also provided. These guidelines are intended to expand on and explain the requirements of Chapter 2.2.10 of this *Terrestrial Code*. Applications to the OIE for recognition of freedom should follow the format and answer all the questions posed by the "Questionnaire on FMD" available from the OIE Central Bureau.

The impact and epidemiology of FMD differs widely in different regions of the world and therefore it is impossible to provide specific guidelines for all potential situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from FMD at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach to proving freedom from FMD following an outbreak caused by a pig-adapted strain of FMDV should differ significantly from an application designed to prove freedom from FMD for a country or zone where African buffaloes (*Syncerus caffer*) provide a potential reservoir of infection. It is incumbent upon the applicant country to submit a dossier to the OIE in support of its application that not only explains the epidemiology of FMD in the region concerned but also demonstrates how all the risk factors are managed. This should include provision of scientifically based supporting data. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that absence of FMDV infection/circulation is assured at an acceptable level of confidence.

Surveillance for FMD should be in the form of a continuing programme designed to establish that the whole territory or part of it, for which application is made, is free from FMDV infection/circulation.

For the purpose of the surveillance programme the definitions of case and outbreak of FMD will be the ones in Chapters 2.2.10 and 1.3.6 of this *Terrestrial Code.*

For the purpose of this Chapter virus circulation means transmission of FMDV as evidenced/demonstrated by the detection of clinical signs, virus isolation or serological evidence.

Article 3.8.7.2.

General conditions and methods

1) A surveillance system (Chapter 1.3.6 of this *Terrestrial Code)* should be under the responsibility of the *Veterinary Services* (Chapter 1.3.3. of this *Terrestrial Code*) with expertise in FMD. A procedure should be in place for the rapid collection and transport of samples from suspect cases of FMD to a laboratory suitably equipped and staffed to perform tests appropriate for FMD diagnoses as described in the *Terrestrial Manual.*

Appendix III (contd)

2) The FMD surveillance programme should:

a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with livestock, as well as diagnosticians, should be encouraged to report promptly any suspicion of FMD. They should be supported directly or indirectly (e.g. through private veterinarians or veterinary Para-professionals) by government information programmes and the *Veterinary Administration*. All suspected cases of FMD should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, samples should be taken and submitted to an approved laboratory. This requires that sampling kits and other equipment (are) be made available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in FMD diagnosis and control;

b) implement, when relevant, regular and frequent clinical inspection and serological testing of high-risk groups of animals, such as those adjacent to an FMD infected country or zone (for example, bordering a game park in which infected wildlife are present).

An effective surveillance system will periodically identify suspicious cases that require follow up and investigation to confirm or exclude that the cause of the condition is FMDV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from FMDV infection/circulation should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

During investigation into suspected *outbreaks* of FMD it is necessary to apply measures that will confine the infection to its original locality until such time as the diagnosis is confirmed or refuted, e.g. through application of quarantine measures. The details of actions that need to be applied in such situations are not covered by this guide.

Surveillance strategies

The target population for surveillance aimed at identification of *disease* and *infection* should cover all the susceptible species within the country or zone to be recognised as free from FMDV infection/circulation.

The strategy employed may be based on randomised sampling requiring surveillance consistent with demonstrating the absence of FMDV *infection*/circulation at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Targeted surveillance (e.g. based on the increased likelihood of infection in particular localities or species) may be an appropriate strategy. The applicant country should justify the surveillance strategy chosen as adequate to detect the presence of FMDV infection/circulation in accordance with Chapter 1.3.6 and the epidemiological situation.. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. cattle and pigs). If a Member Country wishes to apply for recognition of a specific zone/region within the country as being free from FMDV infection/circulation, the design of the survey and the basis for the sampling process would need to be aimed at the population within the zone/region.

For random surveys, the design of the sampling strategy will need to incorporate an epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect infection/circulation if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Chapter 1.3.6. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Appendix III (contd)

Irrespective of the survey (design) approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/infection history and production class of animals in the target population.

Irrespective of the testing system employed, surveillance system design should anticipate the occurrence of false positive reactions.. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of infection/circulation or not. This should involve both supplementary tests (see below) and further field (follow-up) investigation (see below) to collect diagnostic material from the original sampling unit as well as herds which may be epidemiologically linked to it(the suspect focus).

The principles involved in surveillance for disease/infection are technically well defined. The design of surveillance programmes to prove the absence of FMDV infection/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of FMD by close physical examination of susceptible animals. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated. It may be able to provide a high level of confidence of detection of disease if a sufficiently large number of clinically susceptible animals is examined.

Clinical surveillance and laboratory testing should always be applied in series to clarify the status of FMD suspects detected by either of these complementary diagnostic approaches. Laboratory testing may confirm clinical suspicion, while clinical surveillance may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should be classified as infected until contrary evidence is produced.

A number of issues must be considered in clinical surveillance for FMD. The often underestimated labour intensity and the logistical difficulties involved in conducting clinical examinations should not be underestimated and should be taken into account.

Identification of clinical cases is fundamental to FMD surveillance. Establishment of the molecular, antigenic and other biological characteristics of the causative virus, as well as its source, is dependent upon disclosure of such animals. It is essential that FMDV isolates are sent regularly to the regional reference laboratory for genetic and antigenic characterization.

Serological surveillance

Serological surveillance aims at the detection of antibodies against FMDV. Positive FMDV antibody test results can have four possible causes:

a) natural infection with FMDV;

b) vaccination against FMD;

c) maternal antibodies derived from an immune dam (maternal antibodies in cattle are usually found only up to 6 months of age but in some individuals and in some species, maternal antibodies can be detected for considerably longer periods);

d) heterophile (cross) reactions.

Appendix III (contd)

It is important that serological tests, where applicable, contain antigens appropriate for detecting antibodies against viral variants (types, subtypes, lineages, topotypes, etc.) that have recently occurred in the region concerned. Where the probable identity of FMDVs is unknown or where exotic viruses are suspected to be present, tests able to detect representatives of all serotypes should be employed (e.g. tests based on non-structural viral proteins – see below).

It may be possible to use serum collected for other survey purposes for FMD surveillance. However, the principles of survey design described in this Appendix and the requirement for a statistically valid survey for the presence of FMDV should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of field strain infection. As clustering may signal field strain infection, the investigation of all instances must be incorporated in the survey design. If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods should be employed that detect the presence of antibodies to non structural proteins (NSPs) of FMDVs as described in the *Terrestrial Manual*.

The results of random or targeted serological surveys are important in providing reliable evidence that FMDV infection is not present in a country or zone. It is therefore essential that the survey be thoroughly documented.

Article 3.8.7.3.

Documentation of FMD free status

Countries applying for freedom from FMD for the whole country or a zone/compartment where vaccination is not practised

In addition to the general conditions described in Chapter 2.2.10 of this *Terrestrial Code* a Member Country applying for recognition of FMD freedom for the country or a zone/compartment where vaccination is not practised should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to General conditions and methods in these Guidelines, to demonstrate absence of FMDV infection, during the preceding 12 months in susceptible populations (vaccinated and non-vaccinated) . This requires the support of a national or other laboratory able to undertake identification of FMDV infection through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*.

Article 3.8.7.4.

Countries or zones/compartments applying for freedom from FMD where vaccination is practised

In addition to the general conditions described in Chapter 2.2.10 of this *Terrestrial Code*, a Member country applying for recognition of country or zone/compartment freedom from FMD with vaccination should show evidence of an effective surveillance programme planned and implemented according to General conditions and methods in these Guidelines. Absence of clinical disease in the country or zone/compartment for the past 2years should be demonstrated. Furthermore, surveillance should demonstrate that FMDV has not been circulating in FMD susceptible populations (vaccinated and non-vaccinated) within the past 12 months. This will require serological surveillance incorporating tests able to detect antibodies to NSPs.as described in the *Terrestrial Manual.* .Reference to vaccination in this guide implies vaccination as part of an official disease control programme under the supervision of the *Veterinary Administration* aimed at interrupting the transmission of FMD virus (FMDV) in the zone/compartment or country concerned. The level of herd immunity required to achieve interruption of transmission will depend on the size, composition (e.g. species) and density of the susceptible population. It is therefore impossible to be prescriptive in this matter. However, in general the aim should be to vaccinate at least 80% of the susceptible population in the manner and at the frequency prescribed. The vaccine must also comply with the provisions stipulated for FMD vaccines in the *Terrestrial Manual*. Based on the epidemiology of FMD in the country, zone/compartment, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible population. In that case the rationale should be contained within the dossier accompanying the application to the OIE for recognition of a free country or zone/compartment or recovery of such status.

Evidence to show the effectiveness of the vaccination programme should be provided.

Appendix III (contd)

Article 3.8.7.5.

Countries or zones/compartments re-applying for freedom from FMD where vaccination is either practised or not practised, following an outbreak

In addition to the general conditions described in Chapter 2.2.10 of the *Terrestrial Code*, a country re-applying for country or zone/compartment freedom from FMD where vaccination is practised or not practiced should show evidence of an active surveillance programme for FMD as well as absence of FMDV infection/circulation. This will require serological surveillance incorporating, in the case of a country or zone/compartment practising vaccination, tests able to detect antibodies to NSPs as described in the *Terrestrial Manual*. Four strategies are recognised by the OIE in a programme to eradicate FMDV infection following an *outbreak*:

1) slaughter of all clinically affected and in-contact susceptible animals;

2) slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, with subsequent slaughter of vaccinated animals;

3) slaughter of all clinically affected and in-contact susceptible animals and vaccination of at-risk animals, without subsequent slaughter of vaccinated animals;

4) vaccination used without slaughter of affected animals or subsequent slaughter of vaccinated animals.

The wasting periods before which an application can be made for re-instatement of freedom from FMD depend on which of these alternatives is followed. The time periods and actions are indicated in Article 2.2.10.7 of this *Terrestrial Code*.

In all circumstances, a Member Country re-applying for country or zone/compartment freedom from FMD with vaccination or without vaccination should report the results of an active surveillance programme implemented according to General conditions and methods in these Guidelines.

Article 3.8.7.6

The use and interpretation of serological tests

The recommended serological tests for FMD surveillance are described in the *Terrestrial Manual*.

Animals infected with FMD virus produce antibodies to both the structural proteins (SP) and the non-structural proteins (NSP) of the virus. Tests for anti-SP antibodies include SP-ELISAs and the virus neutralisation test (VNT). The SP tests are serotype specific and for optimal sensitivity should utilise an antigen or virus closely related to the field strain against which antibodies are being sought. Tests for NSP antibodies include NSP I-ELISA 3ABC and the electro-immunotransfer blotting technique (EITB) as recommended in the *Terrestrial Manual* or equivalent validated tests. In contrast to SP tests, NSP tests can detect antibodies to all serotypes of FMD virus. Animals vaccinated and subsequently infected with FMD virus develop antibodies to NSPs, but in some, the titre may be lower than that found in infected animals that have not been vaccinated. Both the NSP I-ELISA 3ABC and EITB tests have been extensively used in cattle. Validation in other species is ongoing. Vaccines used should comply with the standards of the *Terrestrial Manual* insofar as purity is concerned to avoid interference with NSP antibody testing.

Serological testing is a suitable tool for FMD surveillance. The choice of a serosurveillance system will depend on, amongst other things, the vaccination status of the country. A country, which is free from FMD without vaccination, may choose serosurveillance of high-risk subpopulations (e.g. based on geographical risk for exposure to FMDV). SP tests may be used in such situations for screening sera for evidence of FMDV infection/circulation if a particular virus of serious threat has been identified and is well characterised. In other cases, NSP testing is recommended in order to cover a broader range of strains and even serotypes. In both cases, serological testing can provide additional support to clinical surveillance. Regardless of whether SP or NSP tests are used in countries that do not vaccinate, a diagnostic follow-up protocol should be in place to resolve any preliminary (presumptive) positive serological test results.

Appendix III (contd)

In areas where animals have been vaccinated, SP antibody tests may be used to monitor the serological response to the vaccination. However, NSP antibody tests should be used to monitor for FMDV infection/circulation. NSP-ELISAs may be used for screening sera for evidence of infection/circulation irrespective of the vaccination status of the animal. All herds with seropositive reactors should be investigated. Epidemiological and supplementary laboratory investigation results should document the status of FMDV infection/circulation for each positive herd. Tests used for confirmation should be of high diagnostic specificity to eliminate as many false positive screening test reactors as possible. The diagnostic sensitivity of the confirmatory test should be at least the same as that of the screening test. The EITB or another OIE-accepted test should be used for confirmation.

Information should be provided on the protocols, reagents, performance characteristics and validation of all tests used.

(i) The follow up procedure in case of positive test results if no vaccination is used in order to establish or re-establish FMD free status without vaccination

Any positive test result (regardless of whether SP or NSP tests were used) should be followed up immediately using appropriate clinical, epidemiological, serological and where possible virological investigations of the reactor animal at hand, of susceptible animals of the same epidemiological unit and of susceptible animals that have been in contact or otherwise epidemiologically associated with the reactor animal. If the follow up investigations provide no evidence for FMDV infection, the reactor animal shall be classified as FMD negative. In all other cases, including the absence of such follow up investigations, the reactor animal should be classified as FMD positive.

(ii) The follow up procedure in case of positive test results if vaccination is used in order to establish or re-establish FMD free status with vaccination

In case of vaccinated populations one has to exclude that positive test results are indicative of virus circulation. To this end the following procedure should be followed in the investigation of positive serological test results derived from surveillance conducted on FMDV-vaccinated populations.

The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated and the results should be collated in the final report.

It is suggested that in the primary sampling units where at least one animal reacts positive to the NSP test, the following strategies should be applied:

i. Following clinical examination, a second serum sample should be taken from the animals tested in the initial survey after an adequate interval of time has lapsed, on the condition that they (animals tested) are individually identified, accessible and have not been vaccinated during this period. Antibody titres against NSP at the time of retest should be statistically either equal to or lower than those observed in the initial test if virus is not circulating;

   The animals sampled should be expected to remain in the holding pending test results and should be clearly identifiable. If the three conditions of retesting mentioned above cannot be met, a new serological survey should be carried out in the holding after an adequate period of time, repeating the application of the primary survey design and ensuring that all animals tested are individually identified. These animals should remain in the holding and should not be vaccinated, so that they can be retested after an adequate period of time.

ii. Following clinical examination, serum samples should be collected from representative numbers of cattle that were in physical contact with the primary sampling unit. The magnitude and prevalence of antibody reactivity observed should not differ in a statistically significant manner from that of the primary sample if virus is not circulating;

iii. Following clinical examination, epidemiologically linked herds should be serologically tested and satisfactory results should be achieved if virus is not circulating;

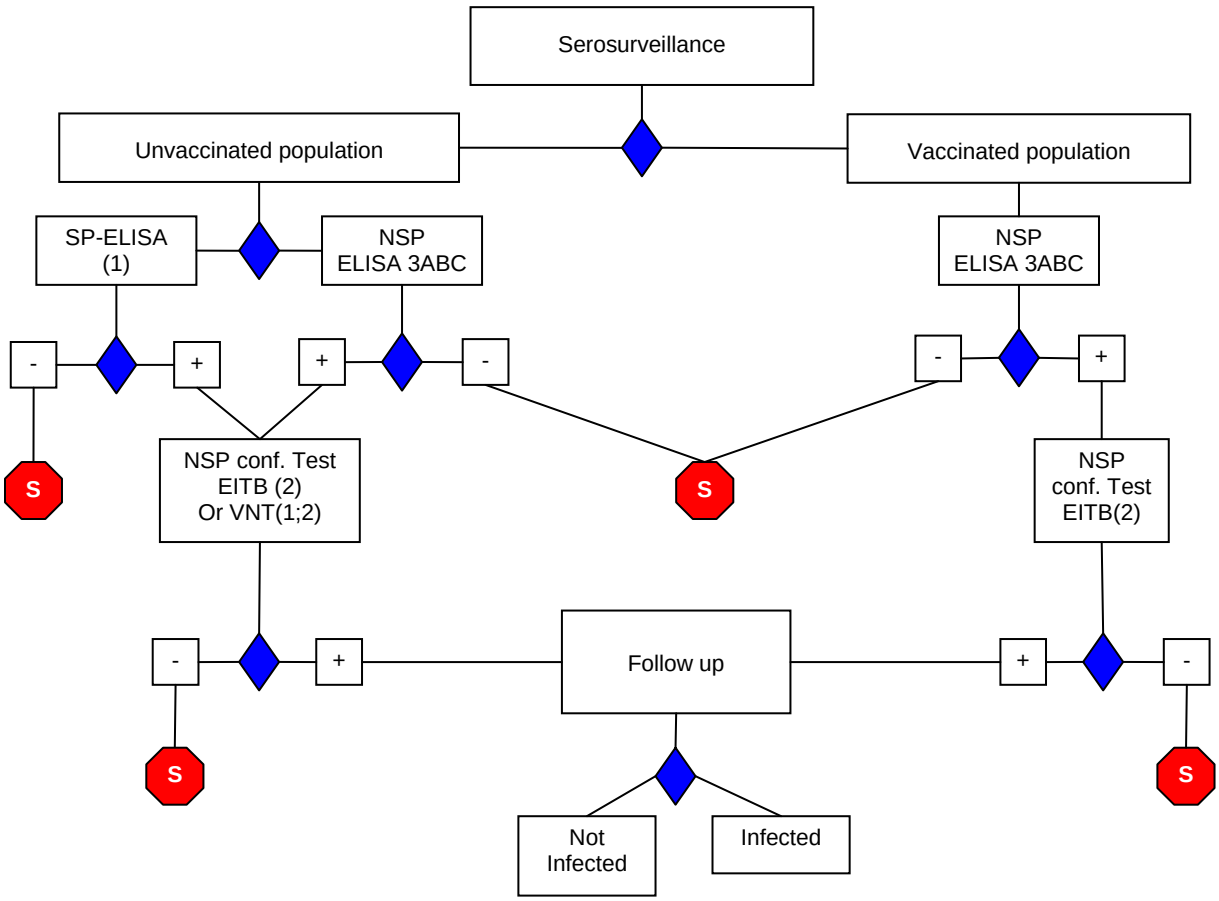
iv. Sentinel animals can also be used. These can be young, unvaccinated animals or animals in which maternally conferred immunity has lapsed and belonging to the same species resident within the positive initial sampling units. They should be serologically negative if virus is not circulating.. If other susceptible, unvaccinated ruminants (sheep, goats) are present they could act as sentinels to provide additional serological evidence.

Appendix III (contd)

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

a) characterization of the existing production systems;
b) results of clinical surveillance of the suspects and their cohorts;
c) quantification of vaccinations performed on the affected sites;
d) sanitary protocol and history of the establishments with positive reactors;
e) control of animal identification and movements;
f) other parameters of regional significance in historic FMDV transmission.

The entire investigative process should be documented as standard operating procedure within the surveillance programme (system implementation).



The above diagram indicates the tests which are recommended for use in the investigation of sampling units in which a positive test result has been obtained.

When feasible, detection of virus in OP fluid can also be used as a complementary test (on) for units in which a positive NSP test result has been obtained.

Key:

ELISA	Enzyme-linked immunosorbent assay
VNT	Virus neutralisation test
NSP	Non-structural protein(s) of foot and mouth disease virus (FMDV)
3ABC	NSP antibody test
EITB	Western blot for NSP antibodies of FMDV
OP	Oesophageal–pharyngeal sample
SP	Structural protein test

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REPORT OF THE MEETING OF THE

OIE AD HOC GROUP ON CLASSICAL SWINE FEVER

Paris, 27 – 29 September 2004

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The meeting of the OIE Ad hoc Group of the Scientific Commission for Animal Diseases (Scientific Commission) on Classical Swine Fever was held at OIE Headquarters, Paris from 27 to 29 September 2004.

The Agenda and list of participants are presented as Appendices I and II respectively.

Dr Alejandro Schudel, Head of the Scientific and Technical Department, welcomed members of the Group and explained the expectations of the OIE International Committee on the output of the Group particularly with respect to the Appendix on 'Guidelines for the surveillance required to support the establishment or regaining of recognition for a classical swine fever free country or zone. He also stressed the importance of collaborative work between various OIE Specialist Commissions and Ad hoc Groups to produce common and harmonized documents for the OIE.

In accordance with standard practices whereby Ad hoc Groups functioning under the auspices of the Scientific Commission are chaired by a member of that Commission, the meeting was chaired by Professor Vincenzo Caporale, President of the OIE Scientific Commission for Animal Diseases. Dr Philippe Vannier replaced Professor Caporale as chair for part of the meeting and Dr John Pasick was designated as rapporteur.

During the course of their deliberations, the Group incorporated information derived from a number of sources that included but were not limited to:

- Chapter 2.1.13 of the *Terrestrial Animal Health Code*, on CSF
- Chapter 1.3.6 of the *Terrestrial Animal Health Code*, on Animal Health Surveillance
- Chapter 1.3.3 of the *Terrestrial Animal Health Code*, on the Evaluation of Veterinary Services
- *The Manual of Diagnostic Test and Vaccines for Terrestrial Animals*, 2004 Edition
- The report of the Ad hoc Group on Epidemiology, Paris, 28-30 June 2004

1. *Terrestrial Animal Health Code*: CSF Chapter 2.6.7

The group reviewed Chapter 2.6.7 and has several recommendations to the Scientific Committee.

A definition of CSFV infection should be included. One possible definition can be found in paragraph 5 of the introduction in the draft Appendix on 'Guidelines for the surveillance required to support the establishment or regaining of recognition of freedom for a classical swine fever free country or zone'

Article 2.6.7.2 (2) should be changed to "CSF should be notifiable in the whole country and all clinical signs suggestive of CSF should be subjected to field and laboratory investigations"

In Article 2.6.7.4 (2e), the Group questions the efficacy of applying the absence of notified outbreaks as the singular criterion on which to base CSF freedom following a stamping out process without vaccination. Given the potential for CSF to circulate in a clinically inapparent form or one that is clinically indistinguishable from a number of other conditions that are prevalent in other countries, the Group advocates the application of active targeted or random serosurveillance as an adjunct to clinical surveillance described.

The Group also questions the inconsistency in the recovery interval for CSF freedom post-eradication versus post-outbreak. Article 2.6.7.4 (2e) states that "a country or zone may be considered free in domestic and wild pigs where a stamping-out policy without vaccination has been practised for CSF, and when no outbreak has been observed in domestic pigs for at least 6 months". In contrast, the first paragraph of Article 2.6.7.6 states that "should a CSF outbreak occur in an establishment of a free country or zone (free in domestic and wild pigs, or free in domestic pigs only), the status of the country or zone may be restored at least 30 days after completion of a stamping out policy".

In Article 2.6.7.4 (2f and 2g) the Group questions the efficacy of applying serosurveillance only if vaccination has occurred during the last five years. Given the potential for CSF to circulate in a clinically inapparent form, or one clinically indistinguishable from a number of other conditions prevalent in many countries, the Group advocates that serosurveillance be applied irrespective of the time which has elapsed since cessation of vaccination.

Article 2.6.7.6 (4) should be extended to include serologic testing in clinically negative animals in addition to laboratory tests on sick pigs.

The group proposes that consideration should also be given to the reciprocal of the situation described in Article 2.6.7.5 i.e. freedom of CSF in wild pigs but present in the domestic pig population.

The group considers that the recognition of a free status where a vaccination strategy has been adopted will depend on several factors, the most important ones being the quality of vaccines available and the performance of companion diagnostic kits. Validated kits are specified but there are no official bodies with the power of assessing the performance of such test kits at the international level. As a consequence, the guarantees provided by a vaccination policy under such conditions cannot be the same as a stamping out policy combined with a serological survey in the absence of vaccination. These points have to be considered in the chapter and a validation procedure has to be implemented at the international level.

The proposed Guidelines is presented as Appendix III.

2. Discussion of the document submitted by Dr Domenico Rutilli on viral hazard identification – classical swine fever virus

The Group recognized that the amount of information available regarding hazard identification was very much dependent on the specific product. A significant amount of information is available for some products while little or no information is available for others. Furthermore, previous reports regarding CSFV inactivation times have been based on *in* vitro isolation assays. This approach is flawed since it has been shown that product samples shown to be free of virus by *in vitro* isolation assays were still infectious to pigs. Because of this, the Group's recommendation to the Scientific Commission is that more research is required before guidelines for curing/aging pork products to inactivate CSFV can be put forward.

The Group is advocating the use of the "D" value, or time taken for the virus titre to drop by 1 $\log_{10}$, in determining the safety of pork products with regards to CSFV. This would entail calculating the D value for each product under various conditions of pH, temperature, etc.

3. Report on the epidemiological investigation of CSF cases in Japan during March, July, and August of 2004 linked to the use of an unapproved vaccine

Dr Fukusho presented the Group with background information related to CSFV detection associated with the use of an unapproved CSF vaccine in Japan. There was some question regarding the conclusion that the virus was vaccine derived when virus was not actually isolated from the vaccine due to its (vaccine) inavailability for analysis.

…/Appendix

Appendix I

REPORT OF THE MEETING OF THE
OIE AD HOC ON CLASSICAL SWINE FEVER

Paris, 27 – 29 September 2004

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Agenda

1. *Terrestrial Animal Health Code*: CSF Chapter 2.6.7

2. Discussion of the document submitted by Dr Domenico Rutilli on viral hazard identification – classical swine fever virus

3. Report on the epidemiological investigation of CSF cases in Japan during March, July, and August of 2004 linked to the use of an unapproved vaccine

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Appendix II

REPORT OF THE MEETING OF THE
OIE AD HOC ON CLASSICAL SWINE FEVER

Paris, 27 – 29 September 2004

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APPENDIX X.X.X

GUIDELINES FOR THE SURVEILLANCE REQUIRED TO SUPPORT THE ESTABLISHMENT OR REGAINING OF RECOGNITION FOR A CLASSICAL SWINE FEVER FREE COUNTRY OR ZONE

Article X.X.X.1.

Introduction

This document defines the principles and provides a guide for the surveillance of classical swine fever (CSF) in accordance with chapter 1.3.6, applicable to countries seeking recognition from the OIE for freedom from CSF. This may be for the entire country or a zone/compartment within the country. Guidance for countries seeking reestablishment of freedom from CSF for the whole country or a zone/compartment, following an *outbreak*, as well as guidelines for demonstrating the maintenance of CSF free status are also provided. These guidelines are intended to expand on and explain the requirements of Chapter 2.6.7 of this *Terrestrial Code*.

The impact and epidemiology of CSF differs widely in different regions of the world and therefore it is impossible to provide specific guidelines for all potential situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from CSF at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach must be tailored in order to prove freedom from CSF for a country or zone where wild pigs provide a potential reservoir of infection, where compartmentalization may be employed, or where CSF is present in adjacent countries. It is incumbent to not only explain the epidemiology of CSF in the region concerned but also to demonstrates how all the risk factors are managed. This should include provision of scientifically based supporting data. There is therefore latitude available to Member Countries to provide a well-reasoned argument to prove that absence of CSFV infection is assured at an acceptable level of confidence.

Surveillance for CSF should be in the form of a continuing programme designed to establish that the whole country, zone or compartment for which application is made, is free from CSFV infection. Consideration should be given to the specific characteristics of CSF epidemiology which include: the role of swill feeding and the impact of different production systems on disease spread, the role of semen in transmission of the virus, the lack of pathognomonic gross lesions and clinical signs, the frequency of clinically inapparent infections, the occurrence of persistent and chronic infections, and the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV. Serologic cross-reactivity with other pestiviruses has to be taken into consideration when interpreting data from serologic surveys. A common route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with bovine viral diarrhoea virus (BVDV).

For the purpose of the surveillance programme the definitions of case and outbreak of CSF will be those found in Chapters 2.6.7 and 1.3.6 of this *Terrestrial Code*.

For the purpose of this chapter virus infection means presence of CSFV as evidenced/demonstrated directly by virus isolation, the detection of virus antigen or virus nucleic acid, or indirectly by seroconversion not the result of vaccination.

Appendix III (contd)

Article X.X.X.2.

General conditions and methods

1) A surveillance system (Chapter 1.3.6 of this *Terrestrial Code)* should be under the responsibility of the *Veterinary Services* (Chapter 1.3.3. of this *Terrestrial Code*) which maintain or have access to expertise in CSF. A procedure should be in place for the rapid reporting and investigation of suspect cases along with the collection and the safe transport of samples to an accredited biocontainment laboratory (see Chapter 1.1.2 of the *Terrestrial Manual* and Chapter 1.4.6 of this *Terrestrial Code*) suitably equipped and staffed to perform tests appropriate for CSF diagnoses as described in the *Terrestrial Manual.*

2) The CSF surveillance programme should:

   a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with livestock, as well as diagnosticians, should be encouraged to report promptly any suspicion of CSF. They should be supported directly or indirectly (e.g. through private veterinarians or veterinary para-professionals) by government information programmes and the *Veterinary Administration*. Since many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, cases in which CSF cannot be ruled out should be immediately investigated, employing clinical, pathological, and laboratory diagnosis. This requires that sampling kits and other equipment are available to those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in CSF diagnosis, epidemiological evaluation, and control.

   b) implement, when relevant, regular and frequent clinical inspections and serological testing of high-risk groups of animals (for example, where swill feeding is practised), or those adjacent to a CSF infected country or zone (for example, bordering areas where infected wild pigs are present).

   An effective surveillance system will periodically identify suspicious cases that require follow up and investigation to confirm or exclude that the cause of the condition is CSFV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from CSFV infection should, as a consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

   During investigation into suspected *outbreaks* of CSF it is necessary to apply measures that will confine the infection to its original locality through application of quarantine measures until such time as the diagnosis is confirmed or refuted. The details of actions that need to be applied in such situations are not covered by this guide.

Surveillance strategies

The principles involved in surveillance for disease or infection are technically well defined. The design of surveillance programmes to prove the absence of CSFV infection needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

The target population for surveillance aimed at identification of *disease* and *infection* should include domestic and wild pig populations within the country or zone to be recognised as free from CSFV infection. Such surveillance may involve opportunistic testing of samples submitted for other purposes, but a more efficient and effective strategy is one which includes targeted surveillance.

Appendix III (contd)

Depending on the local epidemiological situation, targeted surveillance could be considered as more effective than a randomized surveillance strategy. Surveillance is targeted to the pig population which presents the highest risk of infection (for example, swill fed farms, pigs reared outdoors, farms in proximity to infected wild pigs). Each country will need to identify its individual risk factors. These may include: temporal and spatial distribution of past outbreaks, pig movements and demographics, etc.

For reasons of cost, the longevity of antibody levels, as well as the existence of clinically inapparent infections and difficulties associated with differential diagnosis of other diseases, serology is often the most effective and efficient surveillance methodology. In some circumstances, which will be discussed later, clinical and virological surveillance may also have value.

The applicant country should justify the surveillance strategy chosen as adequate to detect the presence of CSFV infection in accordance with Chapter 1.3.6 and the epidemiological situation. Cumulative survey results in combination with the results of passive surveillance, over time, will increase the level of confidence in the surveillance strategy. If a Member Country wishes to apply for recognition of a specific zone/region within the country as being free from CSFV infection, the design of the surveillance strategy and the basis for any sampling process would need to be aimed at the population within the zone/region.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect infection if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Chapter 1.3.6. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey (design) approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/infection history and production class of animals in the target population.

Irrespective of the testing system employed, the surveillance system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognized cross-reactivity with ruminant pestiviruses. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of CSFV infection. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as animals which may be epidemiologically linked.

Clinical and virological surveillance

Beyond their role in targeted surveillance, clinical and virological surveillance for CSF have two aims; a) to shorten the period between introduction of CSF virus into a disease-free country or zone and its detection, and b) to confirm that no unnoticed outbreaks have occurred.

One element of clinical surveillance involves the detection of clinical signs of CSF by close physical examination of susceptible animals. The spectrum of disease signs and gross pathology seen in CSF infections, along with the plethora of other agents that can mimic CSF, renders the value of clinical examination alone somewhat inefficient as a surveillance tool. Nevertheless, clinical presentation should not be ignored as a tool for early detection; in particular, any cases where clinical signs or lesions consistent with CSF are accompanied by high morbidity and/or mortality should be investigated without delay. In CSFV infections involving low virulence strains, high mortality may only be seen in young animals.

Appendix III (contd)

In the past, clinical identification of cases was the cornerstone of early detection of CSF. However, emergence of low virulence strains of CSF, as well as new diseases - in particular post-weaning multisystemic wasting syndrome and porcine dermatitis and nephropathy syndrome – have made such reliance less effective, and, in countries where such latter diseases are highly prevalent, can add significant risk of masking the presence of CSF. In zones or countries where such diseases exist, careful clinical and virological surveillance of such cases should be applied.

Clinical signs and pathology of CSF infection will also vary considerably, depending on the strain of virus as well as host factors, such as age, nutrition and health status. These factors, along with the compounding effects of concurrent infections and disease caused by ruminant pestiviruses, dictate the need for laboratory testing in order to clarify the status of CSF suspects detected by clinical monitoring. The difficulties in detecting chronic disease - manifested by non-specific clinical signs and delayed seroconversion - and seronegative, persistently infected piglets, both of which may be clinically normal, makes virological investigation essential. As part of a herd investigation, such animals are likely to be in a minority and would not confound a diagnosis based on serology. However, individually, or as part of recently-mixed batches, such animals may escape detection by this method. A holistic approach to investigation, taking note of herd history, pig, personnel and vehicle movements and disease status in neighbouring zones or countries, can also assist in targeting surveillance in order to increase efficiency and enhance the likelihood of early detection.

The labour-intensive nature of clinical, pathological, and virological investigations, along with the smaller ¨window of opportunity¨ inherent in virus, rather than antibody detection, has, in the past, resulted in greater emphasis being placed on mass serological screening as the best method for surveillance. However, surveillance based on clinical and pathological inspection and virological testing should not be underrated. If targeted at high risk groups in particular, it provides an opportunity for early detection that can considerably reduce the subsequent spread of disease. Herds predominated by adult animals, such as nucleus herds and AI studs, are particularly useful groups to monitor, since infection by low virulence viruses in such groups may be clinically inapparent, yet the degree of spread may be high.

Clinical and virological monitoring may also provide a high level of confidence of rapid detection of disease if a sufficiently large number of clinically susceptible animals is examined. In particular, molecular detection methods are increasingly able to offer the possibility of such large-scale screening for the presence of virus, at reasonable cost.

Wild pigs and, in particular, those with a wholly free-living existence, rarely present the opportunity for clinical observation, but should form part of any surveillance scheme and should ideally be monitored for virus as well as antibody.

Vaccine design and diagnostic methodologies, and in particular, methods of virus detection, are increasingly reliant on up-to-date knowledge of the molecular, antigenic and other biological characteristics of viruses currently circulating and causing disease. Furthermore, epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in outbreaks in disease-free areas. It is therefore essential that CSFV isolates are sent regularly to the regional OIE reference laboratory for genetic and antigenic characterization.

Serological surveillance

Serological surveillance aims at the detection of antibodies against CSFV. Positive CSFV antibody test results can have five possible causes:

a) natural infection with CSFV;

b) legal or illegal vaccination against CSF;

c) maternal antibodies derived from an immune sow (maternal antibodies) are usually found only up to 4.5 months of age but in some individuals, maternal antibodies can be detected for considerably longer periods;

Appendix III (contd)

d) cross reactions with other pestiviruses;

e) non-specific reactors.

The infection of pigs with other pestiviruses may complicate a surveillance strategy based on serology. Antibodies to bovine viral diarrhoea virus (BVDV) and Border disease virus (BDV) can give positive results in serological tests for CSF, due to common antigens. Such samples will require differential tests to confirm their identity. Although persistently infected immunotolerant pigs are themselves seronegative, they continuously shed virus, so the prevalence of antibodies at the herd level will be high. Chronically infected pigs may have undetectable or fluctuating antibody levels.

It may be possible to use sera collected for other survey purposes for CSF surveillance. However, the principles of survey design described in this Appendix and the requirement for statistical validity should not be compromised.

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of infection by field strains or other pestiviruses. Because clustering may signal field strain infection, the investigation of all instances must be incorporated in the survey design. Clustering of positive animals is always epidemiologically significant and therefore should be investigated.

In countries or zones that are moving towards freedom, serosurveillance can provide valuable information on the disease status and efficacy of any control programme. Targeted serosurveillance of young stock will indicate whether newly circulating virus is present, though the presence of maternal antibody will also need to be considered. If conventional attenuated vaccine is currently being used or has been used in the recent past, serology aimed at detecting the presence of field virus will likewise need to be targeted at unvaccinated animals and after the disappearance of maternal antibody. General usage in such situations may also be used, to assess levels of vaccine coverage.

Novel vaccines also exist which, when used in conjunction with dedicated serological tests, may allow discrimination between vaccinal antibody and that induced by field infection. Such tools offer some promise, but may not provide the same degree of protection as that provided by conventional vaccines, particularly with respect to preventing transplacental infections. Furthermore, serosurveillance using such differentiation requires cautious interpretation, and on a herd basis.

The results of random or targeted serological surveys are important in providing reliable evidence that no CSFV infection is present in a country or zone. It is therefore essential that the survey be thoroughly documented.

Country/zone free of CSF in domestic and wild pigs

1. Historically free status

The risk assessment referred to in Article 2.6.7.2 should be reviewed whenever evidence emerges to indicate change in any of its components, which may alter the underlying assumption of continuing historical freedom. Such changes include but are not limited to:

- an emergence, or an increase in the prevalence of, CSF in countries or zones from which live pigs or products are imported
- an increase in the volume of imports or a change in their country or zone of origin
- an increase in the prevalence of CSF in the domestic or wild pigs of adjacent countries or zones
- an increased entry from, or exposure to, wild pig populations of adjacent countries or zones.

Appendix III (contd)

2. Free status as a result of an eradication programme

In addition to the general conditions described in Chapter 2.6.7 of this *Terrestrial Code*, a Member Country applying for recognition of CSF freedom for the country or a zone/compartment, whether or not vaccination had been practised, should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to General Conditions and Methods in these Guidelines, to demonstrate the absence of CSFV infection, in domestic and wild pig populations. This requires the support of a national or other laboratory able to undertake identification of CSFV infection through virus/antigen/nucleic acid detection and antibody tests described in the *Terrestrial Manual*.

Country or zone/compartment free of CSF in domestic pigs but with infection in wild pig population

The objective of surveillance in this instance is to demonstrate that the two subpopulations are effectively separated by measures that ensure the biosecurity of domestic pigs. A CSF free compartment should implement a biosecurity program which includes but is not limited to the following provisions:

- Proper containment of domestic pigs
- Control of movement of vehicles with cleaning and disinfection as appropriate
- Control of personnel entering into the establishments and awareness of risk of fomite spread
- Prohibition of introduction to the establishments of hunted animals and products
- Registry of animal movements into and out of establishments
- Information and training programs for farmers, hunters, processors, veterinarians, etc.

The biosecurity program implemented by the CSF free compartment would also require internal and external monitoring by the veterinary authorities. These elements should include but are not limited to:

- Periodic clinical and serological monitoring of herds in the compartment, and adjacent wild pig populations following these guidelines
- Herd registration in the compartment
- Official accreditation of biosecurity program
- Periodic monitoring and review

In situations where domestic free-ranging and backyard pigs are kept in close proximity to areas with CSF-infected wild pigs, such populations cannot be recognized as a compartment different from wild pigs.

Monitoring the CSF status of wild populations will be of value in assessing the degree of risk they pose to the CSF-free compartment. The design of a monitoring system for wild pigs is dependent on several factors such as the organization of the veterinary service and resources available. The occurrence of CSF in wild pigs may vary considerably among countries. Surveillance design should be scientifically based and the member country must justify its choice of design prevalence and level of confidence based on Chapter 1.3.6.

The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include wildlife conservation organizations, hunter associations and other available sources. The objective of a surveillance program when the disease is already known to exist should be to determine the geographic distribution and the extent of the infection.

Appendix III (contd)

Recovery of free status

Countries, zones, or compartment re-applying for freedom from CSF following an outbreak

In addition to the general conditions described in Chapter 2.6.7 of the *Terrestrial Code*, a country re-applying for country or zone/compartment freedom from CSF should show evidence of an active surveillance programme for CSF as well as absence of CSFV infection.

Populations under this surveillance program should include, but not be limited to:

- Establishments in the area of the outbreak
- Establishments epidemiologically linked to the outbreak
- Animals used to re-populate affected establishments and any establishments where contiguous culling is carried out
- Wild pig populations in the area of the outbreak

In all circumstances, a Member re-applying for country or zone/compartment freedom from CSF with vaccination or without vaccination should report the results of an active and passive surveillance programme in which the pig population undergoes regular clinical, pathological, virological, and/or serological examination, planned and implemented according to General conditions and methods in these Guidelines. The surveillance should be based on a statistically representative sample of the populations at risk.

Country or zone free of CSF in wild pigs

While the same principles apply, surveillance in wild pigs presents challenges beyond those encountered in domestic populations in each of the following areas:

- Determination of the distribution, size and movement patterns associated with the wild pig population
- Assessment of the possible presence of CSF within the population
- Determination of the practicability of establishing zones

The design of a monitoring system for wild pigs is dependent on several factors such as the organization of the veterinary service and resources available. The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include wildlife conservation organizations, hunter associations and other available sources. The objective of a surveillance program is to determine the geographic distribution and estimation of target population.

Estimates of wild pig population can be made using advanced methods (radio tracking, linear transect method, capture/recapture) or traditional methods based on the number of animals that can be hunted to allow for natural restocking (hunting bags).

For implementation of the monitoring programme, it will be necessary to define the limits of the territory over which wild pigs range in order to delineate the risk compartments or epidemiological units within the monitoring programme. It is often difficult to define epidemiological units for wild animals. The most practical approach is based on natural and artificial barriers.

The monitoring programme should also include animals found dead, road kills, animals showing abnormal behaviour or exhibiting gross lesions during dressing.

Appendix III (contd)

There may be situations where a more targeted surveillance programme can provide additional assurance. The criteria to define high risk areas for targeted surveillance can be:

- Areas with past history of CSF
- Sub-regions with high wild pig density
- Border regions with CSF affected countries, zones or compartments
- Areas of contact between sub-populations
- Picnic and camping areas
- Around farms with free-ranging pigs
- Special risk areas determined by local veterinary authorities
- Garbage dumps

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REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON CLASSICAL SWINE FEVER

Paris, 8 December 2004

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The meeting of the OIE Ad hoc Group of the Scientific Commission for Animal Diseases (Scientific Commission) on Classical Swine Fever (CSF) was held at OIE Headquarters, Paris, on 8 December 2004 to review the report of the Ad hoc Group on CSF which met in September 2004.

The Agenda and list of participants are presented as Appendices I and II respectively.

Dr Bernard Vallat, Director General of OIE, welcomed members of the Group as well as Dr A. Thiermann, President of the Terrestrial Animal Health Standards Commission who agreed to attend the meeting to provide any advice that befalls his Commission. The Director General complimented the previous Ad hoc Group for the excellent work carried out. He explained however that although the OIE endorses the application of risk assessment as an inherent component of the overall process whereby a country determines the scientifically justified measures to be applied to ensure the biosecurity of its imports of animal origin, some Member Countries are still confused about the applications of that concept. He pointed out that the relative significance of risk assessment in the case of classical swine fever (CSF) has to be studied in its right perspective as most of the risk factors in CSF are already well known and there may not be any need for an obligatory risk assessment on the part of Member Countries. He urged the Group to address this issue as other possibilities to improve the Chapter on CSF in the *Terrestrial Animal Health Code* (the *Terrestrial Code*) including trade of commodities irrespective of the CSF status of a country. He also asked the Group to consider inclusion of the concept of compartmentalisation in the surveillance guidelines and to review the possible use of novel vaccines against CSF.

In accordance with standard practices whereby Ad hoc Groups functioning under the auspices of the Scientific Commission are generally chaired by a member of that Commission, the meeting was chaired by Professor Vincenzo Caporale, President of the OIE Scientific Commission for Animal Diseases. Dr John Kellar was designated as rapporteur.

During the course of their deliberations, the Group incorporated information derived from a number of sources that included but were not limited to:

- Report and Draft Appendix from the ad hoc Group Meeting; 27-29, September 2004
- Chapter 1.3.6 of the *Terrestrial Code,* on Animal Health Surveillance
- Chapter 1.3.3 of the *Terrestrial Code,* on the Evaluation of Veterinary Services
- *The Manual of Diagnostic Test and Vaccines for Terrestrial Animals (Terrestrial Manual)*, 2004 Edition

The Group made the following observations:

1. *Terrestrial Code*: CSF Chapter 2.6.7

General

Beyond the specific observations made at the September meeting, the Group highlighted a series of additional inconsistencies which include, but are not limited to, those regarding conditions of recovery of free status irrespective of the control strategy used.

Commodities

The Group observed that in the *Terrestrial Code* Chapter for bovine spongiform encephalopathy (BSE), recognition is given to the fact that certain commodities may be traded irrespective of the BSE status of the country from which they derive. The allowance reflects documented knowledge of the pathogenesis of the disease and the proven influence of industrial processes on the causative agent's survival. A review of the recent literature on CSF, presented to the Group, acknowledged that CSF is readily killed in heated or cooked meat and meat products at core temperatures of 65°C for 30 minutes or 71°C for 1 minute. The Group suggested that the *Terrestrial Code* Chapter for CSF follow the lead of the Chapter on BSE by incorporating an article that acknowledges these facts and the resultant safety of trade in commodities so treated, irrespective of the CSF status of their country of origin.

Compartmentalization

Compartmentalization is advocated in other Chapters of the *Terrestrial Code* as an additional tool or measure for the mitigation of disease transmission. The Group proposed the parallel introduction of the concept in the Chapter for CSF in order to be consistent with other chapters in the incorporation of this potentially applicable measure. Pending decision on its recommendation, however, the Group deleted references to compartmentalization that had been introduced in the Guidelines during the September meeting.

Risk assessment

The Group noted that OIE endorses the application of risk assessment as an inherent component of the overall process whereby a country determines the scientifically justified measures to be applied to ensure the biosecurity of its imports of animal origin. Risk assessment's relative significance in the decision process is determined by the accumulated knowledge of and experience with the disease(s) in question.

The Chapter for BSE emphasises the paramount importance of risk assessment in respect of trade in BSE-susceptible commodities, as a reflection of the disease's recent appearance, protracted latency and its unique and diagnostically challenging nature. On the other hand, the Chapter on FMD makes no reference to the measure, as a reflection of the depth of knowledge of, as well as experience with, this disease and its diagnosis.

The Group determined that CSF aligns more with FMD than with BSE in terms of the accumulated knowledge of its natural history, pathogenesis and diagnosis. That being the case, the Group suggests that the Chapter on CSF align more with the Chapter on FMD than that on BSE, by deletion of the actual reference to risk assessment in the *Terrestrial Code* in deference to an emphasis on proven prescriptive measures.

2. *Terrestrial Code*: Animal Health Surveillance Chapter 1.3.6

The Group reconsidered the position of the September meeting in respect of the provision of guidelines for the monitoring of the wild pig population. The Group determined that the subject could be best addressed in a generic fashion, across all wildlife populations and diseases, through its addition to the current provisions of Chapter 1.3.6.

3. Revision of the Proposed New Guidelines (Additional comments)

In the light of the importance attributed by the Chapter on CSF to the use of novel vaccines in the mitigation of an outbreak, the Group felt that their limitations should be critically evaluated on the basis of recently published literature. The wording in the September document was adjusted accordingly.

The Group felt that the introduction of the concept of compartmentalization would be consistent with the general principles laid down in Chapter 1.3.5 on Zoning, regionalization and compartmentalization, improve the Chapter on CSF and be congruent with the Chapter on FMD. However, since the concept of compartment is not currently considered in the Chapter on CSF, the Group felt that it is not prudent to define surveillance guidelines that take it into account. These references were removed from the September wording.

4. *Terrestrial Manual*: Chapter 2. 1. 13

The Group considered that the recognition of a free status, where a vaccination strategy had been adopted, would be subject to a number of factors. The most important of these would include the quality of the vaccines applied and the performance of diagnostic kits employed in such vaccinated populations.

While the quality and performance of recently derived vaccines and diagnostic kits have been validated in accordance with OIE standards, not all vaccines and diagnostics described in the Manual have been subjected to the same scrutiny. The Group recommended that a full assessment of CSF diagnostics and vaccine performance be carried out by the corresponding OIE Specialist Commission in the light of the published scientific literature.

5. The amended CSF surveillance guidelines

The amended CSF surveillance guidelines are presented as Appendix III.

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…/Appendices

Appendix I

REPORT OF THE MEETING OF THE
OIE AD HOC GROUP ON CLASSICAL SWINE FEVER

Paris, 8 December 2004

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Agenda

1. *Terrestrial Animal Health Code*: CSF Chapter 2.6.7
2. *Terrestrial Animal Health Code*: Animal Health Surveillance Chapter 1.3.6
3. Revision of the Proposed New Guidelines (Additional comments)
4. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, Chapter 2. 1. 13
5. The amended CSF surveillance guidelines

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Appendix II

REPORT OF THE MEETING OF THE
OIE AD HOC GROUP ON CLASSICAL SWINE FEVER

Paris, 8 December 2004

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Appendix III

APPENDIX X.X.X

GUIDELINES FOR THE SURVEILLANCE REQUIRED TO SUPPORT THE ESTABLISHMENT OR REGAINING OF RECOGNITION FOR A CLASSICAL SWINE FEVER FREE COUNTRY OR ZONE

Article X.X.X.1.

Introduction

This document defines the principles and provides a guide for the surveillance of classical swine fever (CSF) in accordance with Chapter 1.3.6, applicable to countries seeking recognition of freedom from CSF. This may be for the entire country or a zone within the country. Guidance for countries seeking reestablishment of freedom from CSF for the whole country or a zone, following an *outbreak*, as well as guidelines for demonstrating the maintenance of CSF free status are also provided. These guidelines are intended to expand on and explain the requirements of Chapter 2.6.7 of this *Terrestrial Code*.

The impact and epidemiology of CSF differs widely in different regions of the world and therefore it is impossible to provide specific guidelines for all potential situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from CSF at an acceptable level of confidence will need to be adapted to the local situation. For example, the approach must be tailored in order to prove freedom from CSF for a country or zone where wild pigs provide a potential reservoir of infection, or where CSF is present in adjacent countries. The method must examine the epidemiology of CSF in the region concerned and adapt to the specific risk factors encountered. This should include provision of scientifically based supporting data. There is therefore latitude available to Member Countries to provide a well-reasoned argument to prove that absence of CSFV infection is assured at an acceptable level of confidence.

Surveillance for CSF should be in the form of a continuing programme designed to establish that the whole country or zone is free from CSFV infection. Consideration should be given to the specific characteristics of CSF epidemiology which include: the role of swill feeding and the impact of different production systems on disease spread, the role of semen in transmission of the virus, the lack of pathognomonic gross lesions and clinical signs, the frequency of clinically inapparent infections, the occurrence of persistent and chronic infections, and the genotypic, antigenic, and virulence variability exhibited by different strains of CSFV. Serological cross-reactivity with other pestiviruses has to be taken into consideration when interpreting data from serological surveys. A common route by which ruminant pestiviruses can infect pigs is the use of vaccines contaminated with bovine viral diarrhoea virus (BVDV).

For the purpose of the surveillance programme the definitions of *case* and *outbreak* of CSF will be those found in Chapters 2.6.7 and 1.3.6 of this *Terrestrial Code*.

For the purpose of this Appendix virus infection means presence of CSFV as evidenced/demonstrated directly by virus isolation, the detection of virus antigen or virus nucleic acid, or indirectly by seroconversion which is not the result of vaccination.

Article X.X.X.2.

General conditions and methods

1) A surveillance system (Chapter 1.3.6 of this *Terrestrial Code)* should be under the responsibility of the *Veterinary Services* (Chapter 1.3.3. of this *Terrestrial Code*) which maintain or have access to expertise in CSF. A procedure should be in place for the rapid reporting and investigation of suspect cases along with the collection and the safe transport of samples to an accredited biocontainment laboratory (see Chapter 1.1.2 of the *Terrestrial Manual* and Chapter 1.4.6 of this *Terrestrial Code*) suitably equipped and staffed to perform tests appropriate for CSF diagnoses as described in the *Terrestrial Manual*.

Appendix III (contd)

2) The CSF surveillance programme should:

a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with livestock, as well as diagnosticians, should be encouraged to report promptly any suspicion of CSF. They should be supported directly or indirectly (e.g. through private veterinarians or *veterinary para-professionals*) by government information programmes and the *Veterinary Administration*. Since many strains of CSFV do not induce pathognomonic gross lesions or clinical signs, cases in which CSF cannot be ruled out should be immediately investigated employing clinical, pathological, and laboratory diagnosis. This requires that sampling kits and other equipment are available to those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in CSF diagnosis, epidemiological evaluation, and control.

b) Implement, when relevant, regular and frequent clinical inspections and serological testing of high-risk groups of animals (for example, where swill feeding is practised), or those adjacent to a CSF infected country or zone (for example, bordering areas where infected wild pigs are present).

An effective surveillance system will periodically identify suspicious cases that require follow up and investigation to confirm or exclude that the cause of the condition is CSFV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be reliably predicted. Recognitions for freedom from CSFV infection should, as a consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

During investigation into suspected *outbreaks* of CSF it is necessary to apply measures that will confine the infection to its original locality through application of quarantine measures until such time as the diagnosis is confirmed or refuted. The details of actions that need to be applied in such situations are not covered by this guide.

Surveillance strategies

The principles involved in surveillance for disease or infection are technically well defined. The design of surveillance programmes to prove the absence of CSFV infection needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

The target population for surveillance aimed at identification of *disease* and *infection* should include domestic and wild pig populations within the country or zone to be recognised as free from CSFV infection. Such surveillance may involve opportunistic testing of samples submitted for other purposes, but a more efficient and effective strategy is one which includes targeted surveillance.

Depending on the local epidemiological situation, targeted surveillance could be considered as more effective than a randomized surveillance strategy. Surveillance is targeted to the pig population which presents the highest risk of infection (for example, swill fed farms, pigs reared outdoors, farms in proximity to infected wild pigs). Each country will need to identify its individual risk factors. These may include: temporal and spatial distribution of past outbreaks, pig movements and demographics, etc.

For reasons of cost, the longevity of antibody levels, as well as the existence of clinically inapparent infections and difficulties associated with differential diagnosis of other diseases, serology is often the most effective and efficient surveillance methodology. In some circumstances, which will be discussed later, clinical and virological surveillance may also have value.

Appendix III (contd)

The country should justify the surveillance strategy chosen as adequate to detect the presence of CSFV infection in accordance with Chapter 1.3.6 and the epidemiological situation. Cumulative survey results in combination with the results of passive surveillance, over time, will increase the level of confidence in the surveillance strategy. If a Member Country wishes to apply for recognition of a specific zone/region within the country as being free from CSFV infection, the design of the surveillance strategy and the basis for any sampling process would need to be aimed at the population within the zone/region.

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect infection if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Chapter 1.3.6. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey (design) approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/infection history and production class of animals in the target population.

Irrespective of the testing system employed, the surveillance system design should anticipate the occurrence of false positive reactions. This is especially true of the serological diagnosis of CSF because of the recognized cross-reactivity with ruminant pestiviruses. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether or not they are indicative of CSFV infection. This should involve confirmatory and differential tests for pestiviruses, as well as further investigations concerning the original sampling unit as well as animals which may be epidemiologically linked.

Clinical and virological surveillance

Beyond their role in targeted surveillance, clinical and virological surveillance for CSF have two aims; a) to shorten the period between introduction of CSF virus into a disease-free country or zone and its detection, and b) to confirm that no unnoticed outbreaks have occurred.

One element of clinical surveillance involves the detection of clinical signs of CSF by close physical examination of susceptible animals. The spectrum of disease signs and gross pathology seen in CSF infections, along with the plethora of other agents that can mimic CSF, renders the value of clinical examination alone somewhat inefficient as a surveillance tool. Nevertheless, clinical presentation should not be ignored as a tool for early detection; in particular, any cases where clinical signs or lesions consistent with CSF are accompanied by high morbidity and/or mortality should be investigated without delay. In CSFV infections involving low virulence strains, high mortality may only be seen in young animals.

In the past, clinical identification of cases was the cornerstone of early detection of CSF. However, emergence of low virulence strains of CSF, as well as new diseases - in particular post-weaning multisystemic wasting syndrome and porcine dermatitis and nephropathy syndrome have made such reliance less effective, and, in countries where such latter diseases are highly prevalent, can add significant risk of masking the presence of CSF. In zones or countries where such diseases exist, careful clinical and virological surveillance of such cases should be applied.

Clinical signs and pathology of CSF infection will also vary considerably, depending on the strain of virus as well as host factors, such as age, nutrition and health status. These factors, along with the compounding effects of concurrent infections and disease caused by ruminant pestiviruses, dictate the need for laboratory testing in order to clarify the status of CSF suspects detected by clinical monitoring. The difficulties in detecting chronic disease manifested by non-specific clinical signs and delayed seroconversion and seronegativity, in persistently infected piglets, both of which may be clinically normal, makes virological investigation essential. As part of a herd investigation, such animals are likely to be in a minority and would not confound a diagnosis based on

Appendix III (contd)

serology. However, individually, or as part of recently-mixed batches, such animals may escape detection by this method. A holistic approach to investigation, taking note of herd history, pig, personnel and vehicle movements and disease status in neighbouring zones or countries, can also assist in targeting surveillance in order to increase efficiency and enhance the likelihood of early detection.

The labour-intensive nature of clinical, pathological, and virological investigations, along with the smaller ¨window of opportunity¨ inherent in virus, rather than antibody detection, has, in the past, resulted in greater emphasis being placed on mass serological screening as the best method for surveillance. However, surveillance based on clinical and pathological inspection and virological testing should not be underrated. If targeted at high risk groups in particular, it provides an opportunity for early detection that can considerably reduce the subsequent spread of disease. Herds predominated by adult animals, such as nucleus herds and artificial insemination studs, are particularly useful groups to monitor, since infection by low virulence viruses in such groups may be clinically inapparent, yet the degree of spread may be high.

Clinical and virological monitoring may also provide a high level of confidence of rapid detection of disease if a sufficiently large number of clinically susceptible animals is examined. In particular, molecular detection methods are increasingly able to offer the possibility of such large-scale screening for the presence of virus, at reasonable cost.

Wild pigs and, in particular, those with a wholly free-living existence, rarely present the opportunity for clinical observation, but should form part of any surveillance scheme and should ideally be monitored for virus as well as antibody.

Vaccine design and diagnostic methodologies, and in particular, methods of virus detection, are increasingly reliant on up-to-date knowledge of the molecular, antigenic and other biological characteristics of viruses currently circulating and causing disease. Furthermore, epidemiological understanding of the pathways of spread of CSFV can be greatly enhanced by molecular analyses of viruses in endemic areas and those involved in outbreaks in disease-free areas. It is therefore essential that CSFV isolates are sent regularly to the regional OIE Reference Laboratory for genetic and antigenic characterisation.

Serological surveillance

Serological surveillance aims at the detection of antibodies against CSFV. Positive CSFV antibody test results can have five possible causes:

a) natural infection with CSFV;

b) legal or illegal vaccination against CSF;

c) maternal antibodies derived from an immune sow (maternal antibodies) are usually found only up to 4.5 months of age but in some individuals, maternal antibodies can be detected for considerably longer periods;

d) cross reactions with other pestiviruses;

e) non-specific reactors.

The infection of pigs with other pestiviruses may complicate a surveillance strategy based on serology. Antibodies to bovine viral diarrhoea virus (BVDV) and Border disease virus (BDV) can give positive results in serological tests for CSF, due to common antigens. Such samples will require differential tests to confirm their identity. Although persistently infected immunotolerant pigs are themselves seronegative, they continuously shed virus, so the prevalence of antibodies at the herd level will be high. Chronically infected pigs may have undetectable or fluctuating antibody levels.

It may be possible to use sera collected for other survey purposes for CSF surveillance. However, the principles of survey design described in this Appendix and the requirement for statistical validity should not be compromised.

Appendix III (contd)

The discovery of clustering of seropositive reactions should be foreseen. It may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or the presence of infection by field strains or other pestiviruses. Because clustering may signal field strain infection, the investigation of all instances must be incorporated in the survey design. Clustering of positive animals is always epidemiologically significant and therefore should be investigated.

In countries or zones that are moving towards freedom, serosurveillance can provide valuable information on the disease status and efficacy of any control programme. Targeted serosurveillance of young stock will indicate whether newly circulating virus is present, although the presence of maternal antibody will also need to be considered. If conventional attenuated vaccine is currently being used or has been used in the recent past, serology aimed at detecting the presence of field virus will likewise need to be targeted at unvaccinated animals and after the disappearance of maternal antibody. General usage in such situations may also be used, to assess levels of vaccine coverage.

Novel vaccines also exist which, when used in conjunction with dedicated serological tests, may allow discrimination between vaccinal antibody and that induced by field infection. Such tools, described in the OIE *Terrestrial Manual*, will need to be fully validated. They do not confer the same degree of protection as that provided by conventional vaccines, particularly with respect to preventing transplacental infections. Furthermore, serosurveillance using such differentiation requires cautious interpretation on a herd basis.

The results of random or targeted serological surveys are important in providing reliable evidence that no CSFV infection is present in a country or zone. It is therefore essential that the survey be thoroughly documented.

Country/zone free of CSF in domestic and wild pigs

1. Historically free status

The free status should be reviewed whenever evidence emerges to indicate that changes which may alter the underlying assumption of continuing historical freedom, has occurred. Such changes include but are not limited to:

- an emergence, or an increase in the prevalence of CSF in countries or zones from which live pigs or products are imported
- an increase in the volume of imports or a change in their country or zone of origin
- an increase in the prevalence of CSF in the domestic or wild pigs of adjacent countries or zones
- an increased entry from, or exposure to, wild pig populations of adjacent countries or zones.

2. Free status as a result of an eradication programme

In addition to the general conditions described in Chapter 2.6.7 of this *Terrestrial Code*, a Member Country seeking recognition of CSF freedom for the country or a zone, whether or not vaccination had been practised, should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and will be planned and implemented according to General Conditions and Methods in these Guidelines, to demonstrate the absence of CSFV infection, in domestic and wild pig populations. This requires the support of a national or other laboratory able to undertake identification of CSFV infection through virus/antigen/nucleic acid detection and antibody tests described in the *Terrestrial Manual*.

Country or zone free of CSF in domestic pigs but with infection in the wild pig population

In addition to the general conditions described in Chapter 2.6.7 of this *Terrestrial Code*, a Member Country seeking recognition of CSF freedom for the country or a zone, whether or not vaccination had been practised, should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and will be planned and

Appendix III (contd)

implemented according to General Conditions and Methods in these Guidelines, to demonstrate the absence of CSFV infection, in domestic pigs. This requires the support of a national or other laboratory able to undertake identification of CSFV infection through virus/antigen/nucleic acid detection and antibody tests described in the *Terrestrial Manual*.

The objective of surveillance in this instance is to demonstrate that the two subpopulations are effectively separated by measures that ensure the biosecurity of domestic pigs. To this end, a biosecurity programme which includes but is not limited to the following provisions should be implemented:

- A programme for the management of CSF in wild pigs
- Delineation of CSF wild pig control areas around every CSF case reported in wild pigs
- Assessment of the presence and mitigative role of natural boundaries
- Documentation of the ecology of the wild pig population
- Proper containment of domestic pigs
- Control of movement of vehicles with cleaning and disinfection as appropriate
- Control of personnel entering into the establishments and awareness of risk of fomite spread
- Prohibition of introduction to the establishments of hunted animals and products
- Registry of animal movements into and out of establishments
- Information and training programmes for farmers, hunters, processors, veterinarians, etc.

The biosecurity programme implemented would also require internal and external monitoring by the veterinary authorities. These elements should include but are not limited to:

- Periodic clinical and serological monitoring of herds in the country or zone, and adjacent wild pig populations following these guidelines
- Herd registration
- Official accreditation of biosecurity program
- Periodic monitoring and review

Monitoring the CSF status of wild populations will be of value in assessing the degree of risk they pose to the CSF-free domestic population. The design of a monitoring system for wild pigs is dependent on several factors such as the organization of the *Veterinary Services* and resources available. The occurrence of CSF in wild pigs may vary considerably among countries. Surveillance design should be scientifically based and the Member Country must justify its choice of design prevalence and level of confidence based on Chapter 1.3.6.

The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include wildlife conservation organizations, hunter associations and other available sources. The objective of a surveillance programme when the disease is already known to exist should be to determine the geographic distribution and the extent of the infection.

Recovery of free status

1. Countries or zones re-seeking freedom from CSF following an outbreak

In addition to the general conditions described in Chapter 2.6.7 of the *Terrestrial Code*, a country re-seeking country or zone freedom from CSF should show evidence of an active surveillance programme for CSF as well as absence of CSFV infection.

Appendix III (contd)

Populations under this surveillance programme should include, but not be limited to:

- Establishments in the area of the outbreak
- Establishments epidemiologically linked to the outbreak
- Animals used to re-populate affected establishments and any establishments where contiguous culling is carried out
- Wild pig populations in the area of the outbreak

In all circumstances, a Member Country re-seeking country or zone freedom from CSF with vaccination or without vaccination should report the results of an active and passive surveillance programme in which the pig population undergoes regular clinical, pathological, virological, and/or serological examination, planned and implemented according to General conditions and methods in these Guidelines. The surveillance should be based on a statistically representative sample of the populations at risk.

2. Country or zone free of CSF in wild pigs

While the same principles apply, surveillance in wild pigs presents challenges beyond those encountered in domestic populations in each of the following areas:

- Determination of the distribution, size and movement patterns associated with the wild pig population
- Assessment of the possible presence of CSF within the population
- Determination of the practicability of establishing zones

The design of a monitoring system for wild pigs is dependent on several factors such as the organization of the *Veterinary Services* and resources available. The geographic distribution and approximate size of wild pig populations need to be assessed as a prerequisite for designing a monitoring system. Sources of information may include wildlife conservation organisations, hunter associations and other available sources. The objective of a surveillance programme is to determine the geographic distribution and estimation of target population.

Estimates of wild pig population can be made using advanced methods (radio tracking, linear transect method, capture/recapture) or traditional methods based on the number of animals that can be hunted to allow for natural restocking (hunting bags).

For implementation of the monitoring programme, it will be necessary to define the limits of the territory over which wild pigs range in order to delineate the epidemiological units within the monitoring programme. It is often difficult to define epidemiological units for wild animals. The most practical approach is based on natural and artificial barriers.

The monitoring programme should also include animals found dead, road kills, animals showing abnormal behaviour or exhibiting gross lesions during dressing.

There may be situations where a more targeted surveillance programme can provide additional assurance. The criteria to define high risk areas for targeted surveillance can be:

- Areas with past history of CSF
- Sub-regions with high wild pig density
- Border regions with CSF affected countries or zones
- Areas of contact between sub-populations
- Picnic and camping areas
- Around farms with free-ranging pigs
- Special risk areas determined by local veterinary authorities
- Garbage dumps

Appendix III (contd)

Appendix III

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Original: English
October 2004

REPORT OF THE MEETING OF THE OIE AD HOC GROUP FOR EVALUATION OF COUNTRY STATUS FOR FOOT AND MOUTH DISEASE

Paris, 18-20 October 2004

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The meeting of the OIE Ad hoc Group for evaluation of country status for foot and mouth disease (FMD) met at the OIE headquarters, Paris from 18 to 20 October 2004. It was chaired by Dr Gideon Brückner, member of the OIE Scientific commission for Animal Diseases (Scientific Commission) and Dr David Mackay acted as Rapporteur.

The Agenda and list of participants are presented at Appendices I and II.

The Director General of the OIE, Dr Bernard Vallat, welcomed the participants in the Ad hoc Group. Dr Vallat commented that the group was meeting at a time when a draft revised appendix giving guidelines on surveillance for FMD (3.8.7.) had recently been prepared. Dr Vallat recommended that the group first review this draft and make any necessary proposals for change. The group would then be in a position to review the two dossiers from applicant countries for consideration at the present meeting against these revised guidelines and make appropriate recommendations to the OIE Scientific Commission. Two other issues required consideration; First, whether or not it was appropriate for applicant countries to make representatives available to the Ad hoc Group to present additional data, or answer questions, when their dossiers were being considered; Second, the opinion of the Ad hoc Group was sought on a document from PANAFTOSA on a novel risk assessment strategy for commodities of animal origin.

The Group agreed on the following working practices: Where possible, applicants should be informed of a deadline for submission of dossiers in order for them to be considered at a particular meeting of the Ad hoc Group. This would normally be approximately one month before the date of the meeting but shorter deadlines may be accepted on a case-by-case basis in the event of urgent requests with suitable justification. One member of the group will be asked by the Chair to lead on each dossier as 'rapporteur' and other members to contribute questions. Generally, the rapporteur will try to circulate a short list of issues/questions approximately one week before the date of the meeting. This list will be sent to the applicant. Applicants will be advised that the list gives an indication of those areas which the group **may** wish to discuss and where additional documentary evidence may be required.

The Group considered that additional guidance should be developed to instruct applicants on best practice for submission of dossiers. Factors to be included should be (i) format for electronic submission (PDF was recommended by the Group) (ii) date for submission in relation to meetings of the Ad hoc Group.

1. Report of previous meeting of the OIE Ad hoc Group for evaluation of country status for foot and mouth disease, 8 - 9 March 2004

This was accepted without change.

2. Evaluation of Country Status for foot-and-mouth disease

2.1. Application by Argentina for recovery of status for a zone free from FMD with vaccination

Dr Correa introduced the background to the application and the recent history of FMD in the region in general and in Argentina in particular. A single outbreak had occurred in a zone previously recognised as FMD free with vaccination. The likely source of infection was importation of infected cattle from a neighbouring country to an adjacent slaughterhouse.

The Group considered the application under the previously used headings.

- **Support Structures**

  The support structures were well described and deemed appropriate.

- **Routine surveillance systems**

  An effective routine surveillance system was in operation and data was presented that it had been used to detect and investigate suspect cases of vesicular disease.

- **Freedom from infection/virus circulation**

  Batch potency tests are only conducted for two (O_1 Campos and $A_{Argentina\ 2001}$) out of the four strains (vaccine also contains A_{24}, A_{2000}) present in the vaccines used. The representative from Argentina, Dr Gaston Maria Funes clarified that this is for practical reasons and is based on the assumption that if responses are adequate to the tested strains they are likely also to be adequate for the other strains present.

- **Border control**

  Additional information on the controls applied to swill feeding, particularly products from international travel, was provided by Dr Funes. SENASA oversees treatment of swill from slaughterhouses under biosecure conditions. No swill from international transport enters the animal food chain.

  The targeted survey conducted in the protection zone around the infected holding and the random survey conducted to demonstrate freedom of the proposed zone was well designed and executed. The Group questioned the basis on which the intra-herd prevalence of between 10 and 20% (depending on the stratum sampled) had been chosen. However, any loss of sensitivity from using a relatively high intra-herd prevalence figures was compensated by setting a low inter-herd prevalence of 1% with 95% confidence. A higher prevalence of positive reactors was detected in the Border region (0.5%) than in other regions (around 0.1%). All positives were followed up with negative results. Dr Funes assured the group that the higher level of reactivity was not statistically significant and there was no clustering of positive reactors either within farms or geographically.

  Information on controls that applied to owners who have holdings on both side of the northern borders with Paraguay and Bolivia would be useful for risk assessment of transfer of infection across the border. Dr Funes indicated that all such owners are known and controls are stringently applied to their holdings. The United Nations are providing additional help in the border region in the form of funding, transport and communication. Good coordination was ensured with neighbouring countries in terms of coordinating vaccination programs.

Dr Funes indicated that additional controls had been put in place to ensure that illegally imported cattle could not be slaughtered in slaughterhouses in the border region. Tighter controls now restrict the holding of susceptible animals in the vicinity of slaughterhouses.

- **Conclusion**

Following a single outbreak in a zone previously recognised as FMD free with vaccination, control and surveillance measures in line with the OIE *Terrestrial Code* have been applied. An appropriately structured survey found no evidence of viral circulation in the zone proposed as FMD free with vaccination.

- **Recommendation**

The Group recommended that the proposed zone be recognised as FMD free with vaccination.

2.2. Application by the State Union of Serbia and Montenegro as a country free from FMD in which vaccination is not practiced

An application from Serbia and Montenegro had been reviewed at the meeting of the Ad hoc Group in March 2004. The Group had been unable to recommend recognition of FMD free status and the OIE Central Bureau had sent a letter specifying four areas in which further information was required.

- **Support Structures**

Sufficient information has still not been provided in the revised dossier on the interaction between the *Veterinary Services* of the State Union and those of Serbia and Montenegro in the control of FMD outbreaks.

- **Routine surveillance systems**

Data has still not been provided to demonstrate that the system of surveillance and investigation of suspect cases of vesicular disease has been tested in the recent past to evaluate its performance either my means of contingency exercises or by examination of suspect cases subsequently shown to be negative for FMD.

There are no reports of random or targeted surveillance conducted since the post-outbreak survey in 1997.

- **Freedom from infection/virus circulation**

Additional data was provided on the measures taken in terms of control and post-outbreak surveillance following the 1996 outbreak of type A which would suggest that infection with this virus was eradicated. However, the *Terrestrial Code* requires that evidence be supplied that surveillance for both FMD and FMD infection is in operation and that regulatory measures for control of FMD are implemented.

- **Border control**

A detailed description of veterinary controls both within and at the borders of the country has still not been provided. Information on the extent and nature of veterinary powers in operation are required to determine the extent to which future incursions could be prevented or controlled. Data on the nature and extent of trade and actions to control this trade would be helpful.

- **Conclusion**

Whilst the group found no reason to suspect the existence of FMD infection on the territory of the State Union of Serbia and Montenegro, insufficient data was provided on the structure and operation of the control and surveillance systems to provide assurance that they comply with the requirements of the OIE *Terrestrial Code*.

- **Recommendation**

  The Group recommend that the proposed application be resubmitted to reflect the information requested in the OIE Questionnaire.

3) Other matters

3.1. Chapter 2.2.10.: Foot and Mouth Disease

The Group noted the changes to the chapter to introduce the concept of 'freedom from FMDV circulation' for countries and zones seeking recognition of freedom with vaccination. The Group observed that there was inconsistency between and within chapters in the *Terrestrial Code* in relation to the terms 'disease', 'case' (may refer to more than one animal in some chapters but not in others), 'infection' and 'outbreak' (refers only to clinical disease in some chapters but refers to both clinical disease and infection in others).

- **Recommendation**

  That the Code Commission review the definition of the terms *disease, case, infection* and *outbreak* to ensure, as far as possible, their consistent use and meaning in different chapters of the *Terrestrial Code*.

3.2. Chapter 1.3.6.: Animal Health Surveillance

The Group reviewed Chapter 1.3.6. and made the proposed changes and comments.

Section 2

Definitions for '*Early detection system'* and '*Surveillance*' already exist

- **Recommendation**

  That the Code Commission consider amending the definitions of '*Early Detection System'* and '*Surveillance*' in Chapter 1.1.1 in light of the definition proposed in draft Chapter 1.3.6

  Section 4.5.Demonstratiion of freedom from infection

  Para 3: "However, finding evidence of infection at any level in the target population automatically invalidates any freedom from infection claim."

  In the case of FMD, this could be taken to mean that if evidence of previous infection is found as part of post-outbreak serosurveillance the 'clock' is reset in terms of time limits for certifying freedom. This will act as a serious disincentive to reporting openly the results of post outbreak surveillance.

- **Recommendation**

  The following additional sentence is added to Section 4.5 para 3

  'Unless follow-up epidemiological investigations have been conducted and control measures taken which ensure that the infectious agent is no longer present'.

3.3. Appendix 3.8.7.

The Group also reviewed the recently revised draft of Appendix 3.8.7.

3.4. Panaftosa document on commodities

This document proposes a similar approach to risk assessment for trade in commodities as was put forward during a recent joint meeting between the Middle East and African Regional OIE Commissions held in Cairo, 11-13 October 2004, in conjunction with AU-IBAR. There is a proposal to amend the OIE *Terrestrial Code* to include a specific chapter on risk mitigation for trade in animal products (the term commodities currently includes live animals as defined in the *Terrestrial Code*). The Group supported examining the feasibility of this recommendation.

3.5. OIE questionnaire

The Group went through the OIE Questionnaire used to submit information to OIE to support applications for recognition of FMD status. A version with tracked changes is attached as an Appendix III to this report.

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…/Appendices

Appendix I

MEETING OF THE OIE AD HOC GROUP FOR EVALUATION OF COUNTRY STATUS FOR FOOT AND MOUTH DISEASE

Paris, 18-20 October 2004

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Agenda

1) Report of previous meeting of the OIE Ad hoc Group for evaluation of country status for foot and mouth disease, 8 - 9 March 2004

2) Evaluation of Country Status for foot-and-mouth disease

2.1. Application by Argentina for recovery of status for a zone free from FMD with vaccination

2.2. Application by the State Union of Serbia and Montenegro as a country free from FMD in which vaccination is not practiced

3) Other matters

3.1. Chapter 2.2.10.: Foot and Mouth Disease

3.2. Chapter 1.3.6.: Animal Health Surveillance

3.3. Appendix 3.8.7.

3.4. Panaftosa document on commodities

3.5. OIE questionnaire

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Appendix II

MEETING OF THE OIE AD HOC GROUP FOR EVALUATION OF COUNTRY STATUS FOR FOOT AND MOUTH DISEASE

Paris, 18-20 October 2004

List of participants

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Appendix III (contd)

FMD FREE COUNTRY NOT PRACTISING VACCINATION

I. RESUME OF REPORT

Resumé of Report of Country which applies for status, under Chapter 2.2.10 of the *Terrestrial Animal Health Code*, as an FMD free country not practising vaccination.[1]

1. Regular and prompt animal disease reporting
(Describe here the national system and to whom you provide international disease reporting)

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.....

.....

2.a) No FMD outbreak in country for the past 12 months
(State date of last outbreak and refer to FMD eradication section)

.....

.....

.....

2.b) No evidence of FMD infection for the past 12 months

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.....

2.c) No vaccination against FMD has been carried out during the past 12 months
(State here whether vaccination in the country is prohibited, since what date, and briefly describe how this is enforced)

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.....

.....

3. No entry of vaccinated animals into country since cessation of vaccination
(State dates of prohibition of entry of vaccinated animals, and refer to method of enforcement under section on FMD prevention)

.....

.....

.....

4. Surveillance and regulatory measures

A. Surveillance
(Briefly describe system, refer to section on FMD surveillance, give details of actual and suspected cases)

.....

.....

[1] Terms in italics are defined in *Terrestrial Animal Health Code*

Appendix III (contd)

B. Regulatory measures
(Briefly describe measures, refer to section on FMD prevention)

.....

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Enclosed: Report contents

NOTE: ANNEXES FOR THE FOLLOWING REPORT WHICH ARE NOT IN ONE OF THE THREE OFFICIAL OIE LANGUAGES SHOULD HAVE A BRIEF SUMMARY IN ONE OF THESE LANGUAGES.

Appendix III (contd)

II. REPORT CONTENTS

Please address concisely the following topics. National regulations laws and *Veterinary Administration* directives may be referred to and annexed as appropriate

Foreword

1. Introduction

1.1. Regional framework
1.2. Livestock industry

2. Veterinary system

2.1. Legislation
2.2. *Veterinary Services*
2.3. Role of society, farmers, industry in FMD surveillance and control
2.4. Role of private veterinary profession in FMD surveillance and control

3. FMD eradication

3.1. History
3.2. Strategy
3.3. Vaccines and vaccination
3.4. Organisation of eradication campaign
3.5. Execution
3.6. Animal identification and movement control
3.7. Supervision by *Veterinary Authority*

4. FMD surveillance

4.1. Diagnosis
  4.1.1. Clinical (notification and investigation procedures, recent numbers)
  4.1.2. Laboratory (procedures, numbers with results of submissions)
4.2. Serological surveillance
4.3. Livestock demographics and economics
4.4. Slaughterhouses and markets
4.5. Supervision by *Veterinary Authority*

5. FMD prevention

5.1. Regional coordination with neighbouring countries
5.2. Import control
  5.2.1. Policy and risk assessment
  5.2.2. Risk management in relation to animals and products
    - ports/frontiers (number and location)
    - international garbage
    - animals
    - genetic material (semen and embryos)
    - animal products for human consumption (e.g. milk, meat products)
    - animal products not intended for human consumption (e.g. pet food, hides and skins)
    - veterinary medicinal products (i.e. biologics)
5.3. Biological security of laboratories and production and testing facilities
5.4. Supervision by *Veterinary Authority*

6. Response to outbreak

6.1. Policy (contingency and emergency response plans including arrangements for emergency vaccination, financial provisions)
6.2 Deployment of resources (human and material)
6.3. Epidemiological studies (origin, diffusion)

7. Conclusion

Appendix III (contd)

FMD FREE COUNTRY PRACTISING VACCINATION

I. RESUME OF REPORT

Resumé of Report of Country which applies for status, under Chapter 2.2.10 of the *Terrestrial Animal Health Code*, as an FMD free country practising vaccination.

1. Regular and prompt animal disease reporting
(Describe here the national system and to whom you provide international disease reporting)

.....

.....

2.a) No FMD outbreak in country in past two years
(State date of last outbreak and refer to FMD eradication section)

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2.b) No evidence of virus circulation for the past 12 months

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2.c) Information on routine vaccination programme

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2.d) Vaccine compliance with OIE Standards
(State that FMD vaccine complies, refer to section on FMD eradication)

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.....

.....

3. Surveillance and regulatory measures

A. Surveillance
(Briefly describe system, refer to section on FMD surveillance)

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.....

.....

.....

Appendix III (contd)

B. Regulatory measures
(Briefly describe measures, refer to section on FMD prevention)

.....

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.....

.....

Enclosed: Report contents

NOTE: ANNEXES FOR THE FOLLOWING REPORT WHICH ARE NOT IN ONE OF THE THREE OFFICIAL OIE LANGUAGES SHOULD HAVE A BRIEF SUMMARY IN ONE OF THESE LANGUAGES.

Appendix III (contd)

II. REPORT CONTENTS

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1. Introduction

1.1. Regional framework
1.2. Livestock industry

2. Veterinary system

2.1. Legislation
2.2. *Veterinary Services*
2.3. Role of society, farmers, industry in FMD surveillance and control
2.4. Role of private veterinary profession in FMD surveillance and control

3. FMD eradication

3.1. History
3.2. Strategy
3.3. Vaccines and vaccination (Please refer to the *Terrestrial Manual* Chapter 2.1.1)
  3.3.1. Vaccination policy (frequency, species, type and valency of vaccines, coverage etc.)
  3.3.2. Vaccine production and/or importation (details of producers, importers)
  3.3.3. Vaccine quality control
  3.3.4 Vaccine deployment (distribution control, cold chain etc.)
  3.3.5 Post vaccination surveillance
3.4. Organisation of eradication campaign
3.5. Execution
3.6. Animal identification and movement control
3.7. Supervision by *Veterinary Authority*

4. FMD surveillance

4.1. Diagnosis
  4.1.1. Clinical (notification and investigation procedures, recent numbers)
  4.1.2. Laboratory (procedures, numbers with results of submissions)
4.2. Serological surveillance
4.3. Livestock demographics and economics
4.4. Slaughterhouses and markets
4.5. Supervision by *Veterinary Authority*

5. FMD prevention

5.1. Regional coordination with neighbouring countries
5.2. Import control
  5.2.1. Policy and risk assessment
  5.2.2. Risk management in relation to animals and products
    - ports/frontiers (number and location)
    - international garbage
    - animals
    - genetic material (semen and embryos)
    - animal products for human consumption (e.g. milk, meat products)
    - animal products not intended for human consumption (e.g. pet food, hides and skins)
    - veterinary medicinal products (i.e. biologics)
5.3. Biological security of laboratories and production and testing facilities
5.4. Supervision by *Veterinary Authority*

6. Response to outbreak

6.1. Policy (contingency and emergency response plans including arrangements for emergency vaccination, financial provisions)
6.2. Deployment of resources (human and material)
6.3. Epidemiological studies (origin, diffusion)

7. Conclusion

Appendix III (contd)

FMD FREE ZONE WHERE VACCINATION IS NOT PRACTISED

I. RESUME OF REPORT

Resumé of Report of Country which applies for status, under Chapter 2.2.10 of the *Terrestrial Animal Health Code*, as having an FMD free zone where vaccination is not practised, in an FMD free country where vaccination is practised or in a country of which parts are still infected.

1. Regular and prompt animal disease reporting
(Describe here the national system and to whom you provide international disease reporting)

.....

.....

.....

2.a) No FMD outbreak in country for the past twelve months
(State date of last outbreak and refer to FMD eradication section)

.....

.....

.....

2.b) No evidence of FMD infection for the past 12 months

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.....

2.c) No vaccination against FMD in the last twelve months (State here whether vaccination in the zone is prohibited, since what date, and briefly describe how this is enforced)

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2.d) Measure to control movement of vaccinated animals into the FMD free zone where vaccination is not practiced (State date of prohibition of entry of vaccinated animals, and refer to method of enforcement under section on FMD prevention)

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3. Free zone, buffer zone and surveillance zone boundaries, where present
(Concise geographic description of free zone, buffer zone and surveillance zones, where present. Annex map with dimensions which includes zones and use of natural boundaries where relevant)

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Appendix III (contd)

4. Free zone

A. Surveillance
(Briefly describe system, refer to section on FMD surveillance in the free zone)

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B. Regulatory measures
(Briefly describe measures, refer to section on FMD prevention in the free zone)

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.....

5. Surveillance zone (where present)

A. Surveillance
(Briefly describe system, refer to section on FMD surveillance in the surveillance zone)

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B. Regulatory measures

(Briefly describe measures, refer to section on FMD prevention in the surveillance zone)

.....

6. Buffer zone (where present)

A. Surveillance

(Briefly describe system, refer to section on FMD surveillance in the surveillance zone)

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B. Regulatory measures

(Briefly describe measures, refer to section on FMD prevention in the surveillance zone)

.....

Enclosed

1. FMD prevention section
2. FMD surveillance section
3. FMD eradication section
4. Section on the livestock industry and veterinary system

NOTE: ANNEXES FOR THE FOLLOWING SECTIONS WHICH ARE NOT IN ONE OF THE THREE OFFICIAL OIE LANGUAGES SHOULD HAVE A BRIEF SUMMARY IN ONE OF THESE LANGUAGES.

Appendix III (contd)

II. REPORT CONTENTS

II.1. SECTION FMD PREVENTION

A. FMD FREE ZONE

Describe here in summary form FMD prevention measures in the FMD free zone. National regulations, laws and *Veterinary Administration* directives may be referred to and annexed as appropriate. Please address concisely the following topics.

A.1. National (and international, if applicable) coordination

A.2. Import control (into the zone)

A.2.1. Policy and risk assessment

A.2.2. Risk management in relation to animals and products

- ports/frontiers (number and location)
- national and international garbage
- animals
- genetic material (semen and embryos)
- animal products for human consumption (e.g. milk, meat products)
- animal products not intended for human consumption (e.g. pet food, hides and skins)
- veterinary medicinal products (i.e. biologics)

A.2.3. Biological security of laboratories and production and testing facilities

A.3. Supervision by *Veterinary Authority*

B. SURVEILLANCE ZONE

Describe here in summary form FMD prevention measures in the surveillance zone. National regulations, laws and *Veterinary Administration* directives may be referred to and annexed as appropriate. Please address concisely the following topics.

B.1. National (and international, if applicable) coordination

B.2. Import control (into the zone)

B.2.1. Policy and risk assessment

B.2.2. Risk management in relation to animals and products

- ports/frontiers (number and location)
- national and international garbage
- animals
- genetic material (semen and embryos)
- animal products for human consumption (e.g. milk, meat products)
- animal products not intended for human consumption (e.g. pet food, hides and skins)
- veterinary medicinal products (i.e. biologics)

B.2.3. Biological security of laboratories and production and testing facilities

B.3. Supervision by *Veterinary Authority*

Appendix III (contd)

II.2. SECTION FMD SURVEILLANCE

A. FMD FREE ZONE

Describe here in summary form FMD surveillance in the FMD free zone. National regulations, laws and *Veterinary Administration* directives may be referred to and annexed as appropriate. Please address concisely the following topics.

A.1. Diagnosis

A.1.1. Clinical (notification and investigation procedures, recent numbers)
A.1.2. Laboratory (procedures, numbers with results of submissions)

A.2. Serological surveillance

A.3. Livestock demographics and economics

A.4. Slaughterhouses and markets

A.5. Supervision by *Veterinary Authority*

B. SURVEILLANCE ZONE

Describe here in summary form FMD surveillance measures in the surveillance zone. National regulations, laws and *Veterinary Administration* directives may be referred to and annexed as appropriate. Please address concisely the following topics.

B.1. Diagnosis

B.1.1. Clinical (notification and investigation procedures, recent numbers)
B.1.2. Laboratory (procedures, numbers with results of submissions)

B.2. Serological surveillance

B.3. Livestock demographics and economics

B.4. Slaughterhouses and markets

B.5. Supervision by *Veterinary Authority*

Appendix III (contd)

II.3. SECTION FMD ERADICATION

Describe here on a summary of approximately one page how FMD was eliminated from the FMD free zone. National regulations, laws and *Veterinary Administration* directives may be referred to and annexed as appropriate. Please address concisely the following topics.

1. History (epidemiological description of events)

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2. Strategy of eradication

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3. Use of vaccines and vaccination (employment and vaccine quality control), if used

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4. Organisation of eradication campaign

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5. Execution of eradication campaign

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6. Animal identification and movement control

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7. Supervision by Veterinary Authority

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Appendix III (contd)

II.4. SECTION ON LIVESTOCK INDUSTRY AND THE VETERINARY SYSTEM

In this section you are invited to describe, as applicable, additional information you feel may be of use for the report. Annexes may be enclosed and referred to as applicable. Please address concisely the following topics.

1. Veterinary Service response to FMD outbreaks

- Policy (emergency, plans, funds)
- Deployment of resources (human and material)
- Epidemiological studies (origin, diffusion)

2. Veterinary System

- Legislation
- *Veterinary Services*
- Role of society, farmers, industry in FMD surveillance and control
- Role of private veterinary profession in FMD surveillance and control

3. Livestock industry

4. Regional program framework

5. Other international FMD status reports

Appendix III (contd)

FMD FREE ZONE WHERE VACCINATION IS PRACTISED

I. RESUME OF REPORT

Resumé of Report of Country which applies for status, under Chapter 2.2.10 of the *Terrestrial Animal Health Code*, as having an FMD free zone where vaccination is practised, in an FMD free country where vaccination is practised or in a country of which parts are still infected.

1. Regular and prompt animal disease reporting
(Describe here the national system and to whom you provide international disease reporting)

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2.a) No FMD outbreak in country for the past two years
(State date of last outbreak and refer to FMD eradication section)

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2.b) No evidence of virus circulation for the past 12 months

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2.c) Information on routine vaccination programme

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2.d) Vaccine compliance with OIE Standards
(State that FMD vaccine complies, refer to section on FMD eradication)

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3. Free, surveillance and buffer zone boundaries, where present
(Concise geographic description of free surveillance and buffer zones. Annex map with dimensions which includes both zones)

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.....

Appendix III (contd)

4. Free zone

A. Surveillance
(Briefly describe system, refer to section on FMD surveillance in the free zone)

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B. Regulatory measures
(Briefly describe measures, refer to section on FMD prevention in the free zone)

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.....

C. Demonstration of the absence of viral activity
(Briefly describe measures, refer to section on FMD surveillance in the free zone)

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.....

5. Buffer zone

A. Surveillance
(Briefly describe system, refer to section on FMD surveillance in the buffer zone)

.....

.....

B. Regulatory measures
(Briefly describe measures, refer to section on FMD prevention in the buffer zone)

.....

.....

6. Surveillance zone

A. Surveillance
(Briefly describe system, refer to section on FMD surveillance in the buffer zone)

.....

.....

B. Regulatory measures
(Briefly describe measures, refer to section on FMD prevention in the buffer zone)

.....

.....

Enclosed

1. FMD prevention section
2. FMD surveillance section
3. FMD eradication section
4. Section on the livestock industry and veterinary system

NOTE: ANNEXES FOR THE FOLLOWING SECTIONS WHICH ARE NOT IN ONE OF THE THREE OFFICIAL OIE LANGUAGES SHOULD HAVE A BRIEF SUMMARY IN ONE OF THESE LANGUAGES.

Appendix III (contd)

II. REPORT CONTENTS

II.1. SECTION FMD PREVENTION

A. FMD FREE ZONE

Describe here in summary form FMD prevention measures in the FMD free zone. National regulations, laws and *Veterinary Administration* directives may be referred to and annexed as appropriate. Please address concisely the following topics.

A.1. National, regional and international coordination, if applicable

A.2. Import control (into the zone)

A.2.1. Policy and risk assessment

A.2.2. Risk management in relation to animals and products

- ports/frontiers (number and location)
- national and international garbage
- animals
- genetic material (semen and embryos)
- animal products for human consumption (e.g. milk, meat products)
- animal products not intended for human consumption (e.g. pet food, hides and skins)
- veterinary medicinal products (i.e. biologics)

A.2.3. Biological security of laboratories and production and testing facilities

A.3. Supervision by *Veterinary Authority*

A.4. Use of FMD vaccines

A.4.1. Vaccine employment
A.4.2. Vaccine production (*Manual* Chapter 2.1.1)
A.4.3. Vaccine quality control (*Manual* Chapter 2.1.1)

B. BUFFER ZONE

Describe here in summary form FMD prevention measures in the buffer zone. National regulations, laws and *Veterinary Administration* directives may be referred to and annexed as appropriate. Please address concisely the following topics.

B.1. National (and international, if applicable) coordination

B.2. Import control (into the zone)

B.2.1. Policy and risk assessment

B.2.2. Risk management in relation to animals and products

- ports/frontiers (number and location)
- national and international garbage
- animals
- genetic material (semen and embryos)
- animal products for human consumption (e.g. milk, meat products)
- animal products not intended for human consumption (e.g. pet food, hides and skins)
- veterinary medicinal products (i.e. biologics)

B.2.3. Biological security *of laboratories and production and testing facilities*

B.3. Supervision by *Veterinary Authority*

Appendix III (contd)

B.4. Use of FMD vaccines

B.4.1. Vaccine employment

B.4.2. Vaccine production (*Manual* Chapter 2.1.1)

B.4.3. Vaccine quality control (*Manual* Chapter 2.1.1)

C. SURVEILLANCE ZONE

Describe here in summary form FMD prevention measures in the Surveillance Zone. National regulations, laws and *Veterinary Administration* directives may be referred to and annexed as appropriate. Please address concisely the following topics.

C.1. National (and international, if applicable) coordination

C.2. Import control (into the zone)

C.2.1. Policy and risk assessment

C.2.2. Risk management in relation to animals and products

- ports/frontiers (number and location)
- national and international garbage
- animals
- genetic material (semen and embryos)
- animal products for human consumption (e.g. milk, meat products)
- animal products not intended for human consumption (e.g. pet food, hides and skins)
- veterinary medicinal products (i.e. biologics)

C.2.3. Biological security of laboratories and production and testing facilities

C.3. Supervision by *Veterinary Authority*

C.4. Use of FMD vaccines

C.4.1. Vaccine employment

C.4.2. Vaccine production (*Manual* Chapter 2.1.1)

C.4.3. Vaccine quality control (*Manual* Chapter 2.1.1)

Appendix III (contd)

II.2. SECTION FMD SURVEILLANCE

A. FMD FREE ZONE

Describe here in summary form FMD surveillance in the FMD free zone. National regulations, laws and *Veterinary Administration* directives may be referred to and annexed as appropriate. Please address concisely the following topics.

A.1. Diagnosis

A.1.1. Clinical (notification and investigation procedures, recent numbers)
A.1.2. Laboratory (procedures, numbers with results of submissions)

A.2. Serological surveillance

A.3. Livestock demographics and economics

A.4. Slaughterhouses and markets

A.5. Supervision by *Veterinary Authority*

B. BUFFER ZONE

Describe here in summary form FMD surveillance measures in the buffer zone. National regulations, laws and *Veterinary Administration* directives may be referred to and annexed as appropriate. Please address concisely the following topics.

B.1. Diagnosis

B.1.1. Clinical (notification and investigation procedures, recent numbers)
B.1.2. Laboratory (procedures, numbers with results of submissions)

B.2. Serological surveillance

B.3. Livestock demographics and economics

B.4. Slaughterhouses and markets

B.5. Supervision by *Veterinary Authority*

C. SURVEILLANCE ZONE

Describe here in summary form FMD surveillance measures in the surveillance zone. National regulations, laws and *Veterinary Administration* directives may be referred to and annexed as appropriate. Please address concisely the following topics.

C.1. Diagnosis

C.1.1. Clinical (notification and investigation procedures, recent numbers)
C.1.2. Laboratory (procedures, numbers with results of submissions)

C.2. Serological surveillance

C.3. Livestock demographics and economics

C.4. Slaughterhouses and markets

C.5. Supervision by *Veterinary Authority*

Appendix III (contd)

II.3. SECTION FMD ERADICATION

Describe here on a summary of approximately one page how FMD was eliminated from the FMD free zone. National regulations, laws and *Veterinary Administration* directives may be referred to and annexed as appropriate. Please address concisely the following topics.

1. History (epidemiological description of events)

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2. Strategy of eradication

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3. Use of vaccines and vaccination (employment and vaccine quality control)

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4. Organisation of eradication campaign

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5. Execution of eradication campaign

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6. Animal identification and movement control

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7. Supervision by *Veterinary Authority*

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Appendix III (contd)

II.4. SECTION ON LIVESTOCK INDUSTRY AND THE VETERINARY SYSTEM

In this section you are invited to describe, as applicable, additional information you feel may be of use for the report. Annexes may be enclosed and referred to as applicable. Please address concisely the following topics.

1. Veterinary Service response to FMD outbreaks

- Policy (contingency and emergency response plans including arrangements for emergency vaccination, financial provisions)
- Deployment of resources (human and material)
- Epidemiological studies (origin, diffusion)

2. Veterinary System

- Legislation
- *Veterinary Services*
- Role of society, farmers, industry in FMD surveillance and control
- Role of private veterinary profession in FMD surveillance and control

3. Livestock industry

4. Regional program framework

5. Other international FMD status reports

Appendix III

73 SG/12 CS3B/AHG 6

Original: English
January 2005

REPORT OF THE MEETING OF THE OIE AD HOC GROUP FOR EVALUATION OF COUNTRY STATUS FOR FOOT AND MOUTH DISEASE Paris, 10-13 January 2005

The meeting of the OIE Ad hoc Group for Evaluation of Country Status for Foot and Mouth Disease (FMD) met at the OIE Headquarters, Paris from 10 to 12 January 2005. It was chaired by Dr Gideon Brückner, member of the OIE Scientific Commission for Animal Diseases (Scientific Commission). Dr David Mackay acted as Rapporteur.

The Agenda and list of participants are presented at Appendices I and II.

The Director General of the OIE, Dr Bernard Vallat, welcomed the participants of the Ad hoc Group and complimented them for the work carried out during their previous meetings. Dr Vallat stressed that evaluations of country status especially with respect to FMD were crucial to Member Countries and emphasised the need for members to be transparent and independent in their assessments in order to ensure the international credibility of the OIE.

1. Matters arising from the previous meeting

There were no matters arising from the previous minutes.

2. Review of the dossier from Serbia and Montenegro

At the previous meeting in October 2004 the group had assessed a dossier from Serbia and Montenegro for recognition as a country free from FMD without vaccination and had requested additional information in order to reach a final decision. The additional information requested had not been received and therefore this item was deferred.

3. Correspondence from Paraguay on the Frenkel method of FMD vaccine production

The Group was asked to advise the OIE in relation to an enquiry from Paraguay as to whether or not the Frenkel method of FMD vaccine manufacture was acceptable in terms of OIE standards for vaccines. This method is no longer included in the FMD Chapter of the OIE *Terrestrial Manual*. For this reason the Group considered that Member Countries should only use vaccines manufactured with antigens produced in tissue culture and that the use of Frenkel vaccines should be phased out as soon as practically possible.

The Frenkel method uses tongue epithelium which is usually sourced from commercial slaughterhouses as the substrate for virus production. The Group advised that this method of manufacture does not comply with OIE standards as the continual sourcing of fresh tongue epithelium, often of uncertain origin, is not compliant with the requirements of Good Manufacturing Practices (GMP). The source animals are not of defined health status and it is not practical to conduct the necessary testing to control the quality of the primary cells used in this production process.

4. Miscellaneous correspondence on FMD situation in South America

The Group noted a communication recently received from the Brazilian authorities informing the OIE that laboratory results on samples from a recent suspicion of FMD in the Mato Grosso do Sul region had been negative for FMD and that consequently the possibility of FMD had now been disproven.

The Group was grateful to PANAFTOSA for providing valuable information on the occurrence of FMD and other vesicular diseases in South America and on genetic and antigen characterisation of the strains isolated.

5. Evaluation of country status

The dossiers for evaluation of FMD status were reviewed by the Group against the requirements of the OIE *Terrestrial Code* and taking note of the principles of Article 3.8.7.6, as amended by the Ad hoc Group on Epidemiology.

5.a) FMD notification to the OIE

Data on recent notifications to OIE of outbreaks of FMD in the countries from which applications had been received were reviewed.

5.b) Application by Peru for recognition of a zone free from FMD without vaccination

Background

The authorities of Peru applied for an area to be recognised as free from foot and mouth disease without vaccination. The area comprising about 33% of the entire surface of Peru is situated in the south of the country bordering Bolivia, Chile, the Pacific Ocean and Lima to the north. This is the first area within Peru that is submitted to the OIE for recognition of FMD disease freedom with the main emphasis being to facilitate the trade and export of camelidae from the proposed free area. This is also the first area proposed to the Scientific Commission where the buffer zones protecting the proposed free area are situated outside the country (within Bolivia) reflecting the regional approach to disease control within South America and also the commitment to honour the tri-partite agreement on FMD cooperation between the governments of Bolivia, Peru and Chile. The last recorded outbreak of FMD in Peru was in 2000. The dossiers submitted to the Group reflected the relevant facts required in terms of the Code for consideration and were further complimented during intensive discussions with a delegation from Peru to clarify uncertainties.

Support Structures

The information supplied in the dossier and additional information complimented by discussions with the delegation, satisfied the Ad hoc group that the structure of the veterinary services in cooperation with PANAFTOSA, renders sufficient support to maintain the sanitary guarantees submitted by Peru.

Routine surveillance systems

The information in the dossier was convincing but the Ad hoc group had reservations about the efficacy of border control posts especially in the areas bordering Bolivia and Lima Province, the control of movements of animals into the proposed free zone and the risk that a new free zone might create an incentive for indiscriminate animal movement and influx of export opportunists. Sero-surveillance campaigns were carried out in 1999, 2000, 2001, 2002 and 2004 using the ELISA 3ABC/EITB tests. The concerns of the Ad hoc group were sufficiently addressed by additional information supplied by the Member Country delegation.

Freedom from infection/virus circulation

The Ad hoc group posed specific questions to the Member Country delegation on the sampling survey strategy, history of previous vaccinations, animal movement controls, reasons for occurrence of reported sporadic outbreaks in other districts of the country and received satisfactory information from the delegation to allay fears of unmitigated risk management procedures.

Border control

The Ad hoc group were concerned about the efficacy of control procedures especially on the northern border with Lima and the southern border with Bolivia. Sufficient assurances were given to allay the concerns of the Ad hoc Group.

Conclusion

The Ad hoc group was satisfied that the information submitted in the dossiers complimented by additional information supplied by the Member Country delegation, were sufficient to make a positive recommendation to the Scientific Commission.

Recommendation

The Group recommended to the Scientific Commission that the zone proposed be recognised as FMD-free without vaccination.

5.c) Application by Bolivia for recognition of a zone free from FMD with vaccination

Background

Based on economic interests and within the framework of the national and regional programmes for FMD eradication, Bolivia presented a request for the recognition of a second (after the Chiquitania free zone) foot and mouth disease free zone with vaccination which is situated in the department of Oruro in the West of Bolivia bordering Chile and consists of 22 provinces.

The camelid population of Western Oruro reaches 1,075,895 heads (total national herd 2,398,572 heads). There are also 13, 565 heads of bovine and 431,454 heads of ovine animals. There are 17,608 livestock producers.

Support structures

The sanitary structure of the department of Oruro is under the management of a district head from SENASAG. The Departmental Program for the Eradication of FMD is directed by a departmental coordinator, an epidemiologist, a person responsible of the control posts, 5 veterinarians responsible for the Provincial Veterinary Services and 17 control posts inspectors, distributed in 7 control posts. Moreover, mobile posts exist, which are activated as a response to sanitary emergencies and event frequency.

Samples from suspected cases, outbreaks or from epidemiological surveillance are analysed by the reference laboratory for the diagnosis of vesicular diseases by means of the ELISA test, which determines the type and sub- type of virus O, A and C. Moreover, viruses of vesicular stomatitis, Indiana and New Jersey are also included. VIAA technique (Virus infection associated antigen) as a technique to detect viral activity is still employed for serological sampling for ovine, caprine and swine. The 3ABC ELISA and EITB have the objective of confirming the absence of viral activity in herds.

All FMD vaccines (A24, 01, C3) are imported. The vaccine importing companies are officially registered with the SENASAG and the vaccines must comply with OIE standards. Vaccination in the zone is carried out by brigades once a year, aiming to vaccinate the entire bovine herd in the months of July-August.

Routine surveillance

Since 1997 the National Epidemiological Surveillance System is based on coordinated work between local sensors, local informative units and departmental epidemiologists who analyse and process the information to forward it to the national office.

Freedom from infection/virus circulation

Historically, there were no occurrences of FMD episodes in this zone. Since the year 2001 – 17 outbreaks in bovines in the eastern part of the department now considered a buffer zone had occurred. SENASAG has kept records which demonstrate the absence of this disease in the zone, by means of the departmental network created for this purpose.

Passive surveillance

Since 2001, 61 vesicular disease suspects (drooling and lameness) in the department of Oruro were recorded, 18 cases were investigated in the proposed zone and FMD was ruled out.

Serological survey

484 bovine samples were tested by the 3ABC-ELISA; a single sample was positive to this test, which was negative in EITB. 275 camelids , 66 ovine and 25 swine samples were VIAA tested with negative results.

Border control

Although the proposed zone is well isolated by geographical barriers, animals are received for slaughtering and for traction in agriculture. Entry to the zone is controlled at 6 strategically located control posts. The entry conditions include pre-movement quarantine, serological testing of the animals, absence of vesicular conditions in and around the holding of origin, movement certificate, post-movement quarantine.

The proposed free zone is surrounded by a buffer zone consisting of 5 provinces and the municipalities of Oruro and Caracollo of the Cercado province, which represent the rest of the department with a bovine population of 45,900 head.

Conclusions

No outbreak has occurred in the proposed area for at least 2 years.

The bovine population in Oruro- is vaccinated to about 86% - representing about 1% of the susceptible population (the remainder comprising camelids and sheep).

The animals of the zone are not specifically marked, in order to be recognisable as animals from the zone.

It was not clear whether the animals entering are tested by use of a 3ABC-ELISA or another test or if the whole herd is tested and this was not clarified through discussion with the national delegation. This led to concerns about the overall level of control on animal movement into and out of the buffer zone, particularly around the Oruro municipality.

The statistical parameters for the serological survey are unclear, and cannot support the hypothesis of absence of virus circulation. In general the number of samples appears to be insufficient and no clinical survey was carried out in complement.

Recommendations

The group recommended to the Scientific Commission that the Member Country be asked to review the sampling strategy and to carry out more active surveillance in the proposed free zone.

Legislation on animal movement into the zone should be clarified and made consistent between the proposed zone and the zone already recognised by OIE in Chiquitania. Additional information is needed about the pre-movement tests and the consequences of non-compliance.

5.d) Application by Brazil for recognition of a zone as free from FMD with vaccination

Background

In March 2004, Brazil submitted to OIE a dossier for the extension of the free area of the country, including the territory of Acre State and two municipalities of Amazon State, and the southern region of Pará State. On that occasion, the Scientific Commission, considering the report of the FMD Ad hoc Group requested complementary information to demonstrate the absence of viral circulation.

At this meeting, the document presented by Brazil is limited to confirming the absence of viral circulation in the Acre State and two municipalities of the Amazon State, showing the results obtained for the work developed between May and October 2004. In consequence, the document and the analysis do not contain the aspects of Support Structures; Routine Surveillance System and Border Control that were well considered in the submission of March 2004.

Absence of Viral Circulation

The dossier presented by the country is very detailed about the following aspects:

i) Information about the serological survey realized in 2003, for the first presentation to OIE, with the Primary Sampling Units (PSU´s), Farms, Number of samples in the PSU´s and farms, and the results in that moment.

ii) Follow up of the clusters where one or more reagents animals were detected, by:

- Interview of the owners;
- Analysis of entry and exit of animals;
- Clinical examination of the animals;
- Re-sampling of the positives animals;
- OP, with Probang test (81) on the 68 animals that were positives to the second EITB.

iii) Complementary serological research in the positives Primary Sampling Unit:

- Sample collection of the susceptible non-vaccinated animals, including bovines of 6 to 12 months, and small ruminants to evaluate the NSP presence (system I-Elisa 3ABC / EITB, in bovines and VIAA test in small ruminants).

- Two blood samples of bovines of 6 to 24 months (age level of 6-12; 13-18 and 19-24 months), collected with 60 days of interval, and with the animal identified individually with ear markers.

- The dossier had sufficient and detailed information to demonstrate absence of viral circulation.

Conclusion

The original dossier, together with the additional information provided, demonstrated to the satisfaction of the Group the absence of viral circulation in the territory of Acre State and the two adjacent municipalities of the Amazon State.

Recommendation

The ad-hoc Group recommended to the Scientific Commission to accept the submission of Brazil and to recognize the Acre State and the two adjacent municipalities of the Amazon State as free from FMD with vaccination.

5.e) Application by Colombia for recognition of two zones as free from FMD with vaccination

Background

Two dossiers were submitted by the Colombian authorities for recognition of two separate zones as free from FMD with vaccination, a Central Zone and a Southern Zone. Applications for recognition of these zones had been considered by the Group at a meeting in March 2004. The Group had been unable to reach a conclusion on the data presented and had asked for additional information. In the case of both zones this related to additional data to refute the possibility of continued viral circulation and, in the case of the Southern Zone alone, additional information was requested on the available infrastructure for FMD control.

Support Structures

The additional information supplied provided assurance that the veterinary infrastructure present in the Southern Zone was appropriate for FMD control, particularly in view of the low density of livestock in the area, that there is only one access road and that the production system is closed.

Routine surveillance systems

This information had been reviewed as part of the previous assessment with satisfactory results.

Freedom from infection/virus circulation

Additional, active surveillance had been conducted to demonstrate freedom from virus circulation in those holdings on which animals seropositive to NS proteins had been detected in the first survey. The serological survey was designed to test the hypothesis that the number of seropositive samples per holding in the second survey was not significantly greater than the number in the first survey. The survey design assumed that the first survey aimed to detect a minimum prevalence of 10% and the second aimed to detect a significant increase resulting in a prevalence greater than 25%. In addition to the serological survey, detailed epidemiological investigations were conducted including examination for clinical signs, repeated serological sampling from unvaccinated sentinels, collection of oropharyngeal fluid from seropositive animals, testing other susceptible species on the premises for antibody to VIAA, and risk analysis to identify the likelihood that the premises could support viral circulation.

The prevalence of seropositive animals per holding in the follow up survey did not surpass the threshold established for considering that virus circulation was taking place. No seroconversion was detected in sentinels, no animals with clinical signs consistent with FMD were detected, and all probang samples were negative. The Group was satisfied that these results were consistent with the absence of virus circulation in the Central and Southern Zones.

The Group observed that there was a correlation for the Central Zone in the risk assessment between “high risk herds” and a higher percentage of seropositive animals per holding by the EITB. One of the risk factors taken into account was movement onto the premises and all animals moving through markets received additional vaccinations. In view of data presented showing that the vaccine most commonly used in Colombia induces seroconversion to NS proteins in up to 50% of the animals vaccinated, the Group accepted that this was likely to be the result of animals on “high risk” holdings having received a greater number of vaccinations than those on lower risk holdings.

Border control

Additional information was provided demonstrating that there were adequate control posts in operation for controlling entry of animals into the Central and Southern Zones.

Conclusion

Delegates from Colombia provided clarification on the statistical basis of the surveys conducted and on the reasons for the higher prevalence of seropositive animals in the premises at higher risk. Delegates informed the Group that Colombia would shortly introduce a legal requirement for manufacturers to better purify the antigen used in vaccines to reduce or eliminate the induction of NS antibody before they are authorised for use. The Group commended this action and noted that it would bring vaccines used in the country fully in line with OIE requirements.

Recommendation

The Group recommended to the Scientific Commission that the Central and Southern Zones as described in the dossiers presented by Colombia be recognised as FMD free with vaccination.

5.f) Application by Paraguay for recognition as a country free from FMD with vaccination

Background

Paraguay was recognised by OIE as free from FMD with vaccination in 1997. Vaccination ceased in 1999 with the intention of seeking recognition as FMD free without vaccination but vaccination was restarted shortly thereafter in view of the deteriorating situation in neighbouring countries. In October 2002 and again in July 2003 outbreaks of FMD type O took place that were rapidly controlled through slaughter and vaccination. There have been no outbreaks since July 2003 and this application therefore seeks to regain from OIE recognition of the status as a country free from FMD with vaccination.

Support Structures

The dossier describes a well organised veterinary service under a central command structure. There is an Inter-institutional Commission which coordinates the funds for the National FMD Eradication Program. The structure and systems of the Eradication Program appear suitable for running an eradication campaign and for dealing with emergency outbreaks should they arise. The system was tested and found to be effective during the responses to the 2002 and 2003 outbreaks. Adequate facilities are described in terms of veterinary infrastructure and laboratory diagnostic capacity and support.

All vaccines used, whether nationally produced or imported, are subject to national quality control. Information is provided on the number of doses imported and produced nationally. National vaccine production is currently by both the Frenkel method and by growth in tissue culture. The Group pointed out to the national delegation that vaccine produced by the Frenkel method is not considered compliant with OIE Standards. The delegation gave a commitment that use of the Frenkel vaccine would be phased out immediately and that it would no longer be procured or produced once adequate stocks of tissue culture vaccine had been sourced.

A national target of 100% vaccination coverage is set within the program but no information is provided in the dossier on the percentage coverage actually achieved. On questioning the national delegation, the Group was informed that vaccination coverage now reached 95-97% and a document substantiating this for the May 2004 vaccination round was produced.

Routine surveillance systems

There is a subprogram on Epidemiological Surveillance within the National Eradication Program. Evidence was presented of both active surveillance for virus circulation through pro-active serological surveys and passive surveillance for the detection and follow-up of cases of suspected vesicular disease to confirm or refute the occurrence of FMD.

Freedom from infection/virus circulation

Several serological surveys to detect viral circulation have been conducted since 2002 in various regions that together provide coverage of the whole country. Details of surveys prior to 2004 were not provided but no evidence of virus circulation was detected. Details were provided of the last nationwide survey conducted in 2004. Detailed epidemiological investigations were conducted on the 13 holdings containing animals seropositive to NS proteins including clinical examination, repeat sampling, and sampling of other susceptible species and the collection of probangs. The delegation provided evidence showing that there was no geographical clustering of seropositive holdings. On the basis of the evidence presented the Group was satisfied that no evidence of FMD virus circulation has been detected since 2003.

Border control

History would suggest that transborder infection represents the most likely route of introduction of FMD into Paraguay. There is a system of border control posts and a subsection of the Eradication Program that covers Transit Control. The delegation explained that the limited serological testing of exported animals (222 samples in 2003 and 195 in 2004 covering both import and export) was due to very limited trans-border trade in the last two years. The delegation provided details of the cooperative agreements that exist between Paraguay and its neighbours to control movement and ensure synchronisation of vaccination campaigns. The delegation confirmed that animals present on premises which straddle the border are suitably marked to identify under which jurisdiction they belong.

Conclusion

A period of greater than 18 months has occurred since the last case of FMD in Paraguay. Data has been presented to demonstrate that Paraguay has an effective FMD eradication program based on mass vaccination of cattle. Surveys have been conducted which detected no evidence of viral circulation.

Recommendation

The Group recommended to the Scientific Commission that Paraguay regain recognition as a country free from FMD with vaccination.

6. Any other business

At the request of the Central Bureau the recent outbreak of SAT2 in South Africa was discussed. At the time of the first outbreak in July 2004 a part of the OIE recognised free zone was re-defined by the South African authorities as an emergency measure and incorporated as part of the “control zone” in which subsequent outbreaks were reported. This action had been indicated in parts of reports from the country without a specific notification to OIE of their intention to change the borders of the recognised free zone. The Group was concerned that information had not been made available to OIE to justify the changes made. The Group recommended that the Member Country be asked to provide with the utmost urgency a dossier detailing and justifying the amendments made to the borders of the free, surveillance and buffer zones. Of particular importance will be the demonstration that adequate measures have been taken to confirm freedom from infection of the area proposed to remain recognised as a zone free from FMD without vaccination by the OIE.

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…/Appendices

Appendix I

MEETING OF THE
OIE AD HOC GROUP FOR EVALUATION OF COUNTRY STATUS
FOR FOOT AND MOUTH DISEASE

Paris, 10-13 January 2005

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Agenda

1. Matters arising from the previous meeting
2. Review of the dossier from Serbia and Montenegro
3. Correspondence from Paraguay on the Frenkel method of FMD vaccine production
4. Miscellaneous correspondence on FMD situation in South America
5. Evaluation of country status

5.a) FMD notification to the OIE

5.b) Application by Peru for recognition of a zone free from FMD without vaccination

5.c) Application by Bolivia for recognition of a zone free from FMD with vaccination

5.d) Application by Brazil for recognition of a zone as free from FMD with vaccination

5.e) Application by Colombia for recognition of two zones as free from FMD with vaccination

5.f) Application by Paraguay for recognition as a country free from FMD with vaccination

6. Any other business

Appendix II

MEETING OF THE
OIE AD HOC GROUP FOR EVALUATION OF COUNTRY STATUS
FOR FOOT AND MOUTH DISEASE

Paris, 10-13 January 2005

List of participants

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Appendix III

73 SG/12 CS3B/AHG 7

Original: English
November 2004

REPORT OF THE MEETING

OF THE OIE AD HOC GROUP ON TUBERCULOSIS

Paris, 17 - 19 November 2004

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A meeting of the OIE Ad Hoc Group on Tuberculosis was held at the OIE Headquarters in Paris, France, from 17 to 19 November 2004. Dr Alejandro Schudel, Head of the OIE Scientific and Technical Department, welcomed the participants on behalf of the OIE Director General and explained the agenda of the meeting.

The Agenda and the List of participants are presented as Appendices I and II.

The meeting was chaired by, Prof. Vincenzo Caporale, President of the Scientific Commission and Mr K Jahans was designated as rapporteur.

1. Review of Chapter 2.3.3 on Bovine Tuberculosis in the OIE *Terrestrial Animal Health Code*

The Ad hoc Group reviewed Chapter 2.3.3 of the *Terrestrial Code* and discussed the changes in the light of new scientific concepts and also taking into consideration comments received from Member Countries on the draft Chapter that was circulated last year. The amendments proposed have been based on the following assumptions:

- The term 'cattle' would include *Bos taurus*, *Bos indicus*, *Bos grunniens* and *Bubalus bubalis*.

- No raw commodity should be imported without any restriction. However, expert opinion was needed about the presence of *M. bovis* in certain animal products (e.g. collagen or gelatin).

- Reference to free status was included for 'compartments' and there was thus no need to make any recommendations about surveillance for wild life.

- There was no justification at this stage to include vaccination in the Chapter although vaccination may be introduced in some countries in the future. Animals and their products coming from free herds located in a free country, zone or compartment should not be subjected to additional safeguard measures.

- The figures mentioned in section 2 of Article 2.3.3.2 relating to the percentage of herds or animals to be free from tuberculosis, were not changed because of the absence of OIE surveillance guidelines on the disease. However, it was decided to alter the time from 6 years to 3 as there seemed to be no evidence to support the 6-year timescale. It was also felt that at this stage, the OIE should not embark on the development of such guidelines unless specifically asked for by the OIE International Committee.

- If an animal is kept isolated it could be introduced into a tuberculosis free herd provided it was tested according to the same recommended regime.

- The word ‘annual’ was removed from paragraphs describing surveillance programmes based on tuberculin testing as some countries tuberculin test less frequently and some decide to increase testing in order to boost exports. However, it was agreed that a free herd in a country or zone not free from bovine tuberculosis should be subjected to annual tuberculin testing.

- Meat was considered a safe product for human consumption provided that ante mortem and post mortem inspections are carried out. The Group insisted that although ante and post mortem inspections are carried under the supervision of the *Veterinary services*, the final decision as to whether the meat is fit for human consumption should be made by veterinarians duly authorised by the *Veterinary Services.*

- Cattle for slaughter should come from farms that do not form part of a tuberculosis eradication programme. In addition, testing was required for cattle coming from non free herds in order to reduce the potential occurrence of TB lesions in the abattoirs especially in countries, zones or compartments where the prevalence of the disease is high.

- Whenever there is a TB surveillance programme in force, the veterinary inspection at slaughter represents a level of surveillance sufficient to guarantee the safety of raw milk and raw milk products for species other than cattle as far as *M. bovis* is concerned.

The proposed Chapter is presented at Appendix III.

The Group also made the following observations/suggestions:

- Referring to Appendix 3.2.1 dealing with collection and processing of bovine semen, reference to disease testing should be omitted and the reader referred to the Chapter dealing with the specific disease. The Group also noted that the Appendix does not take into account semen in relation to tuberculosis A further observation was that the basic principle that animals must be clinically healthy is not stated in all the Appendices of Chapter 3.2.

- The Group wished to make known its concerns about the transfer of disease from all animals, including wild animals, to humans and suggested that all *Mycobacterium* species having a zoonotic potential be considered by the OIE.

2. Cognate matters

The Group considered the problem of disease transmission during transport of animals and suggested that the OIE consider making a general recommendation that animals for slaughter and for breeding should not be mixed during transport as these groups of animals are generally imported under different import conditions.

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…/Appendices

Appendix I

OIE AD HOC GROUP ON TUBERCULOSIS

Paris, 17 – 19 November 2004

Provisional Agenda

1. Review of Chapter 2.3.3. on Bovine Tuberculosis in the OIE *Terrestrial Animal Health Code*
2. Cognate matters

Appendix II

OIE AD HOC GROUP ON TUBERCULOSIS

Paris, 17 – 19 November 2004

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Appendix III

Final Draft

CHAPTER 2.3.3.

BOVINE TUBERCULOSIS

Article 2.3.3.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with *Mycobacterium bovis* (*M. bovis*) infection in cattle (*Bos taurus*, *Bos indicus*, *Bos grunniens* and *Bubalus bubalis*).

When authorising import or transit of the following *commodities*, *Veterinary Administrations* should comply with the requirements prescribed in this Chapter relevant to **bovine tuberculosis** in the exporting country, zone or compartment:

a) live animals

b) semen, ova and *in vivo* derived embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

c) *meat* and *meat products*

d) *milk* and *milk products*;

e) hides and skins

Standards for diagnostic tests are described in the *Terrestrial Manual.*

Article 2.3.3.2.

Country or zone or compartment free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a country or zone or compartment should satisfy the following requirements:

1. Bovine tuberculosis is a *notifiable disease* in the country;

2. Regular and periodic testing of all cattle herds has shown that at least 99.8% of the herds and 99.9% of the animals in the country, zone or compartment have been found free from bovine tuberculosis for 3 consecutive years.

3. A surveillance programme should be in place to ensure the discovery of bovine tuberculosis in the country or zone or compartment, through monitoring at slaughter based on the inspection described in Article 2.3.3.9. In addition, a prescribed test can also be used for surveillance purposes. The *Veterinary Administration* should be able to trace and test the herd of origin of any reactor to a prescribed test or of any animal which discloses gross pathological lesions of tuberculosis in an abattoir or elsewhere disclosed after removal from the country, zone or compartment.

Appendix III (contd)

4. Cattle introduced into a country or zone or compartment free from bovine tuberculosis should be accompanied by a certificate from an *Official Veterinarian* attesting that they come from a country, zone, compartment or herd, free from bovine tuberculosis.

Article 2.3.3.3.

Herd free from bovine tuberculosis

To qualify as free from bovine tuberculosis, a herd of cattle should satisfy the following requirements:

1. the herd is in a country or zone or compartment free from bovine tuberculosis and is certified free by the *Veterinary Services*; or

2. all cattle in the herd:

   a) show no clinical sign of bovine tuberculosis;

   b) over 6 weeks of age, have shown a negative result to at least two tuberculin tests carried out at an interval of 6 months, the first test being performed at 6 months following the slaughter of the last affected animal;

   c) showed a negative result to an annual tuberculin test to ensure the continuing absence of bovine tuberculosis;

3. all cattle introduced into the herd come from a herd free from bovine tuberculosis. This condition may be waived for animals which have been isolated and which, prior to entry into the herd, were subjected to at least two tuberculin tests carried out at a 6 months interval with negative results.

Article 2.3.3.4.

Artificial insemination centre free from bovine tuberculosis

An *artificial insemination centre* free from bovine tuberculosis is one that fulfils the requirements of Article 2.3.3.3.

Article 2.3.3.5.

Veterinary Administrations of *importing countries* should require:

for cattle for breeding or rearing

the presentation of an *international veterinary certificate* attesting that the animals:

1. showed no clinical sign of bovine tuberculosis on the day of shipment;

2. originate from a herd free from bovine tuberculosis that is in a country or zone or compartment free from bovine tuberculosis; or

3. were subjected to the tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment and come from a herd free from bovine tuberculosis; or

4. were isolated for the 3 months prior to shipment and were subjected to the tuberculin test for bovine tuberculosis with negative results on two occasions, with an interval of not less than 60 days between each test.

Appendix III (contd)

Article 2.3.3.6.

Veterinary Administrations of *importing countries* should require:

for cattle for slaughter

the presentation of an *international veterinary certificate* attesting that the animals:

1. originated from a free herd or were subjected to a tuberculin test for bovine tuberculosis with negative results during the 30 days prior to shipment

2 were not being eliminated as part of an eradication programme against bovine tuberculosis

Article 2.3.3.7.

Veterinary Administrations of *importing countries* should require:

for semen of cattle

the presentation of an *international veterinary certificate* attesting that:

1. the donor animals:

   a) showed no clinical sign of bovine tuberculosis on the day of collection of the semen;

   b) were kept in an *artificial insemination* centre free from bovine tuberculosis in a country, zone or compartment free from bovine tuberculosis and which only accepts animals from free herds in a free country, zone or compartment OR

   c) showed negative results to tuberculin tests carried out at six months intervals and were kept in an *artificial insemination* centre free from bovine tuberculosis

2. the semen was collected, processed and stored in conformity with the provisions of Section 3.2.

Article 2.3.3.8.

Veterinary Administrations of *importing countries* should require:

for embryos/ova of cattle

the presentation of an *international veterinary certificate* attesting that:

1. the donor females:

   - and all other susceptible animals in the herd of origin showed no clinical sign of bovine tuberculosis during the 24 hours prior to departure to the *collection centre*;

   - originated from a herd free from bovine tuberculosis in a country, zone or compartment free from bovine tuberculosis ; OR

   - were kept in a herd free from bovine tuberculosis, were isolated in the *establishment* of origin for the 30 days prior to departure to the *collection centre* and were subjected to a tuberculin test for bovine tuberculosis with negative results.

2. the embryos/ova were collected, processed and stored in conformity with the provisions of Section 3.3.

Appendix III (contd)

Article 2.3.3.9.

Veterinary Administrations of *importing countries* should require:

for *fresh meat* of cattle

the presentation of an *international veterinary certificate* attesting that the entire consignment of meat comes from animals which have been subjected to ante-mortem and post-mortem inspections for bovine tuberculosis carried out by the *Veterinary Services* in an *approved abattoir* with favourable results.

Article 2.3.3.10

Veterinary Administrations of *importing countries* should require:

for *meat products*

the presentation of an *international veterinary certificate* attesting that:

1. the meat is derived from animals satisfying conditions mentioned in Article 2.3.3.9;

2. the necessary precautions were taken after processing to avoid contact of the entire meat products with any potential source of *M. bovis*;

Article 2.3.3.11

Veterinary Administrations of *importing countries* should require:

for *milk* and *milk products*

the presentation of an *international veterinary certificate* attesting that the consignment has been derived from animals in a herd free from bovine tuberculosis;

OR

The consignment was subjected to pasteurisation or a combination of control measures with equivalent performance in reducing *Mycobacterium bovis* in raw milk as described in the Codex Alimentarius Code of Hygienic practice for Milk and Milk products

Article 2.3.3.12

Veterinary Administrations of *importing countries* should require:

For hides and skins from cattle

the presentation of an *international veterinary certificate* attesting that:

1. the entire consignment comes from animals which have been subjected to ante-mortem and post-mortem inspections for bovine tuberculosis carried out by the *Veterinary Services* in an *approved abattoir* with favourable results.

2. the necessary precautions were taken after processing to avoid contact of the products with any potential source of *M. bovis.*

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November 2004

REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON AVIAN INFLUENZA SURVEILLANCE

Teramo (Italy), 11-13 November 2004

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The OIE Ad hoc Group on avian influenza (AI) surveillance met at the Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise 'G.Caporale' (OIE Collaborating Centre), Teramo, Italy from 11 to 13 November 2004.

Dr Dewan Sibartie, Deputy-Head of the Scientific and Technical Department of the OIE welcomed members of the Group on behalf of the OIE Director General and thanked Professor V. Caporale for having kindly organised the meeting at the Istituto Zooprofilattico in Teramo, Italy. He explained the importance of developing guidelines for AI in order to assist OIE Member Countries in the surveillance of the disease and also in the interpretation of the amended Chapter on AI being proposed by the OIE Terrestrial Animal Health Standards Commission (the Code Commission) for inclusion in the OIE Terrestrial Animal Health Code (the *Terrestrial Code*). He thanked the Code Commission for providing a draft copy of the amended Chapter to serve as a basis for the development of surveillance guidelines.

Dr Sibartie pointed out that in accordance with standard practice, any Ad hoc Group functioning under the auspices of the Scientific Commission for Animal Diseases (Scientific commission) is chaired by a member of that commission. Prof. Caporale, Chairman of the Scientific Commission, was thus designated as Chairman of the meeting and Dr Cristóbal Zepeda Sein was nominated as Rapporteur.

The list of participants and the Agenda of the meeting are presented at Appendices I and II respectively.

1. Surveillance Guidelines

The members of the Group discussed the changes made to the proposed Code Chapter by the Ad hoc Group which met in Padova, Italy from 8 to 10 November 2004 and noted that the revised version emphasizes the difference between Highly Pathogenic Notifiable Avian Influenza (HPNAI) and Low Pathogenic Notifiable Avian influenza (LPNAI) and lays down guidelines for trade in poultry and poultry products in each case. The following aspects of the new AI Chapter were considered relevant in the development of AI guidelines:

- No trade of live birds or raw products is allowed from HPNAI infected countries, zones or compartments. The trade of products from birds affected with HPNAI is allowed only if these are treated to destroy the virus and measures taken to avoid re contamination.

- Live birds, day-old poultry and hatching eggs can be traded from Notifiable Avian Influenza (NAI) free country, zone or compartment. In the case of HPNAI free country, zone or compartment, trade can occur from NAI free establishments for day-old live poultry and hatching eggs.

- Meat or products for human consumption have to originate from NAI free country, zone or compartment.

- HPNAI free countries, zones or compartments can trade meat from NAI free establishments or if freedom from virus is demonstrated with appropriate virus detection methods 7-10 days prior to slaughter if the animals have been kept in an establishment since they were hatched or for the past 21 days and in which there has been no evidence of NAI in the past 21 days. This is due to potential contamination of the meat during processing by virus from the respiratory or gastrointestinal tract during the acute infectious phase.

- Trade of table eggs may take place from HPNAI free countries, zones or compartments if the eggs come from an NAI free establishment or have had their surfaces decontaminated and are transported in new, disposable packing material.

The Group then discussed the strategy to follow in drafting the specific AI surveillance guidelines. It was agreed to follow the OIE surveillance guidelines for foot and mouth disease as a template, incorporating where appropriate, elements specific to the epidemiology of NAI and deleting elements not relevant to AI.

The Group discussed the particular problem posed by the presence of AI virus in wild birds and agreed that in essence, no country can declare itself free from AI in wild birds and it would thus not be possible to declare countries or zones free from NAI although this possibility exists for compartments. The Group noted that the proposed definition of NAI in the *Terrestrial Code* Chapter refers only to the infection in 'poultry' which is defined as 'all birds reared or kept in captivity for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds'. This definition therefore excludes wild birds and allows for the recognition of countries and zones as free from NAI.

The Group agreed that demonstration of the absence of infection in absolute terms is scientifically impossible but the demonstration of the absence of virus circulation is feasible.

During discussions on the issue of declaring NAI free establishments, the Group noted that the proposed Code Chapter allows trade of meat and eggs for consumption from NAI free establishments within HPNAI free countries, zones or compartments. Alternatively meat trade is possible under certain conditions laid down in Article 2.7.12.21. This concept may prove helpful for trade of eggs for consumption or hatching eggs/day old poultry.

The Group noted that OIE-FAO-WHO has issued a joint statement in which surveillance in wild bird populations is considered in the overall control of AI. The Group recognizes that the risk posed by wild bird populations to domestic poultry is similar throughout the world with a possible exception for countries receiving or welcoming wild migratory birds where the risk may be seasonally higher. This has also been taken into account in the draft guidelines which are presented in Appendix III.

The Group also recommended that Chapter 2.1.14 of *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*) be reviewed to consider validation of tests for species other than chickens and also to include the current knowledge on avian influenza with references to both HPNAI and LPNAI.

2. Cognate matters

a) The chairman circulated a document prepared at his request on the application of compartmentalization and requested members of the Group to send their comments to the OIE Central Bureau within 10 days. He urged members to consider whether compartmentalisation should be included in the surveillance guidelines for individual diseases or be a separate Chapter of the *Terrestrial Code*. Given that compartmentalisation is heavily based on biosecurity and that most of the measures required are not disease-specific and may vary from country to country, the Group felt that it should be a separate section in the *Code*.

b) The Group expressed its gratitude to Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise 'G.Caporale'and to Prof. Caporale and his staff for the excellent organisation of the meeting and the generous hospitality offered to members.

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…/Appendices

Appendix I

REPORT OF THE MEETING OF THE OIE
AD HOC GROUP ON AVIAN INFLUENZA SURVEILLANCE

Teramo (Italy), 11-13 November 2004

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Agenda

1. Surveillance Guidelines
2. Cognate matters

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Appendix II

REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON AVIAN INFLUENZA SURVEILLANCE

Teramo (Italy), 11-13 November 2004

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APPENDIX 3.X.X

GUIDELINES FOR THE SURVEILLANCE REQUIRED TO SUPPORT A DECLARATION OF RECOGNITION AND RE-RECOGNITION OF FREEDOM FROM NOTIFIABLE AVIAN INFLUENZA IN A COUNTRY, ZONE OR COMPARTMENT

Article 3.x.x.1.

Introduction

This document defines the principles and provides a guide for the surveillance of notifiable avian influenza (NAI) in accordance with Chapter 1.3.6, applicable to countries declaring freedom from NAI, either with or without the use of vaccination. This may be for the entire country or a zone or a compartment within the country. Guidance for countries seeking reestablishment of freedom from NAI for the whole country or a zone or a compartment, either with or without vaccination, following an *outbreak*, as well as guidelines for the maintenance of NAI status are also provided. These guidelines are intended to expand on and explain the requirements of Chapter 2.7.12 of this *Terrestrial Code*.

The presence of NAI in wild birds creates a particular problem. In essence, no country can declare itself free from avian influenza (AI) in wild birds. However, the definition of NAI in the OIE code refers to the infection in poultry only. Poultry is defined as 'all birds reared or kept in captivity for the production of meat or eggs for consumption, for the production of other commercial products, for restocking supplies of game, or for breeding these categories of birds'. The guidelines for surveillance are developed under this definition.

The impact and epidemiology of NAI differs widely in different regions of the world and therefore it is impossible to provide specific guidelines for all potential situations. It is axiomatic that the surveillance strategies employed for demonstrating freedom from NAI at an acceptable level of confidence will need to be adapted to the local situation. Variables such as the frequency of contacts of poultry with wild birds, different biosecurity levels and production systems and the commingling of different susceptible species including domestic waterfowl require specific surveillance strategies to address each specific situation. It is incumbent upon the country to provide scientific data that explains the epidemiology of NAI in the region concerned and also demonstrates how all the risk factors are managed. There is therefore considerable latitude available to Member Countries to provide a well-reasoned argument to prove that absence of NAI virus (NAIV) infection is assured at an acceptable level of confidence.

Surveillance for NAI should be in the form of a continuing programme designed to establish that the whole territory or part of it, for which application is made, is free from NAIV infection.

For the purpose of the surveillance programme the definitions of infection, case and outbreak of NAI will be the ones in Chapters 1.1.1, 1.3.6 and 2.7.12 of this *Terrestrial Code*.

Article 3.x.x.2.

General conditions and methods

1) A surveillance system (Chapter 1.3.6 of this Terrestrial Code) should be under the responsibility of the *Veterinary Services* (Chapter 1.3.3. of this *Terrestrial Code*) with expertise in NAI. In particular:

   - NAI should be notifiable in the country, zone or compartment,
   - A formal and ongoing system for detecting and investigating outbreaks of disease should be in place
   - A procedure should be in place for the rapid collection and transport of samples from suspect cases of NAI to a laboratory suitably equipped and staffed to perform tests appropriate for NAI diagnosis as described in the *Terrestrial Manual*.
   - A system for recording, managing and analysing diagnostic and surveillance data should be in place.

Appendix III (contd)

2) The NAI surveillance programme should:

a) include an early warning system throughout the production, marketing and processing chain for reporting suspicious cases. Farmers and workers, who have day-to-day contact with poultry, as well as diagnosticians, should be encouraged to report promptly any suspicion of NAI. They should be supported directly or indirectly (e.g. through private veterinarians or *Veterinary Para-professionals*) by government information programmes and the *Veterinary Administration*. All suspected cases of NAI should be investigated immediately. Where suspicion cannot be resolved by epidemiological and clinical investigation, as is frequently the case with LPNAI infections, samples should be taken and submitted to an approved laboratory. This requires that sampling kits and other equipment are available for those responsible for surveillance. Personnel responsible for surveillance should be able to call for assistance from a team with expertise in NAI diagnosis and control. In cases where potential public health implications are suspected, notification to the appropriate public health authorities is essential;

b) implement, when relevant, regular and frequent clinical inspection, serological and virological testing of high-risk groups of animals, such as those adjacent to an NAI infected country, zone or compartments, places where birds and poultry of different origins are mixed, such as live bird markets, poultry in close proximity to waterfowl or other sources of NAIV.

An effective surveillance system will periodically identify suspicious cases that require follow up and investigation to confirm or exclude that the cause of the condition is NAIV. The rate at which such suspicious cases are likely to occur will differ between epidemiological situations and cannot therefore be predicted reliably. Applications for freedom from NAIV infection should, in consequence, provide details of the occurrence of suspicious cases and how they were investigated and dealt with. This should include the results of laboratory testing and the control measures to which the animals concerned were subjected during the investigation (quarantine, movement stand-still orders, etc.).

During investigation into suspected *outbreaks* of NAI it is necessary to apply measures that will confine the infection to its original locality until such time as the diagnosis is confirmed or refuted, e.g. through application of quarantine measures. The details of actions that need to be applied in such situations are not covered by this guide.

Surveillance strategies

The target population for surveillance aimed at identification of disease and infection should cover all the susceptible poultry species as defined in these guidelines within the country, zone or compartment to be recognised as free from NAIV infection. Active and passive surveillance for NAI should be ongoing. The frequency of active surveillance should be at least every six months within a country, zone or compartment. Surveillance should be composed of random and targeted approaches using virological, serological and clinical methods.

The strategy employed may be based on randomised sampling requiring surveillance consistent with demonstrating the absence of NAIV infection at an acceptable level of statistical confidence. The frequency of sampling should be dependent on the epidemiological situation. Random surveillance is conducted using serological tests described in the *Terrestrial Manual*. Positive serological results should be followed up with virological methods.

Targeted surveillance (e.g. based on the increased likelihood of infection in particular localities or species) may be an appropriate strategy. Virological and serological methods should be used concurrently to define the NAI status of high risk populations.

A country should justify the surveillance strategy chosen as adequate to detect the presence of NAIV infection in accordance with Chapter 1.3.6 and the prevailing epidemiological situation. It may, for example, be appropriate to target clinical surveillance at particular species likely to exhibit clear clinical signs (e.g. chickens). Similarly, virological and serological testing could be targeted to species that may not show clinical signs (e.g. ducks).

If a Member Country wishes to declare freedom in a specific zone/region within the country as being free from NAIV infection, the design of the survey and the basis for the sampling process would need to be aimed at the population within the zone/region.

Appendix III (contd)

For random surveys, the design of the sampling strategy will need to incorporate epidemiologically appropriate design prevalence. The sample size selected for testing will need to be large enough to detect infection if it were to occur at a predetermined minimum rate. The sample size and expected disease prevalence determine the level of confidence in the results of the survey. The applicant country must justify the choice of design prevalence and confidence level based on the objectives of surveillance and the epidemiological situation, in accordance with Chapter 1.3.6. Selection of the design prevalence in particular clearly needs to be based on the prevailing or historical epidemiological situation.

Irrespective of the survey approach selected, the sensitivity and specificity of the diagnostic tests employed are key factors in the design, sample size determination and interpretation of the results obtained. Ideally, the sensitivity and specificity of the tests used should be validated for the vaccination/infection history and the different species in the target population.

Irrespective of the testing system employed, surveillance system design should anticipate the occurrence of false positive reactions. If the characteristics of the testing system are known, the rate at which these false positives are likely to occur can be calculated in advance. There needs to be an effective procedure for following up positives to ultimately determine with a high level of confidence, whether they are indicative of infection or not. This should involve both supplementary tests (see below) and further field (follow-up) investigation (see below) to collect diagnostic material from the original sampling unit as well as flocks which may be epidemiologically linked to it.

The principles involved in surveillance for disease/infection are technically well defined. The design of surveillance programmes to prove the absence of NAIV infection/circulation needs to be carefully followed to avoid producing results that are either insufficiently reliable to be accepted by the OIE or international trading partners, or excessively costly and logistically complicated. The design of any surveillance programme, therefore, requires inputs from professionals competent and experienced in this field.

Clinical surveillance

Clinical surveillance aims at the detection of clinical signs of NAI at the flock level. Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated. Monitoring of production parameters such as increased mortality, reduced feed and water consumption, presence of clinical signs of a respiratory disease or a drop in egg production, is important for the early detection of NAIV and should trigger an investigation. In particular, for some LPNAIV the only indication of infection may be a drop in feed consumption or egg production.

Clinical surveillance and laboratory testing should always be applied in series to clarify the status of NAI suspects detected by either of these complementary diagnostic approaches. Laboratory testing may confirm clinical suspicion, while clinical surveillance may contribute to confirmation of positive serology. Any sampling unit within which suspicious animals are detected should be classified as infected until evidence to the contrary is produced.

Identification of suspect flocks is vital to identify sources NAIV and to enable the molecular, antigenic and other biological characteristics of the virus to be established. It is essential that NAIV isolates are sent regularly to the regional reference laboratory for genetic and antigenic characterization.

Virological surveillance

Virological surveillance aims at the virus/antigen/genome detection using tests described in the *Terrestrial Manual*. Virological surveillance should be conducted:

- for monitoring of at risk populations
- for confirmation of clinically suspect cases
- as a follow up of positive serological results
- to test “normal” daily mortality to ensure early detection of infection in the face of vaccination or in establishments epidemiologically linked to an outbreak

Appendix III (contd)

Serological surveillance

Serological surveillance aims at the detection of antibodies against NAIV. Positive NAIV antibody test results can have four possible causes:

a) natural infection with NAIV;

b) vaccination against NAI;

c) maternal antibodies derived from a vaccinated or infected parent flock are usually found in the yolk and can persist in progeny for up to 4 weeks;

d) positive results due to the lack of specificity of the test

It may be possible to use serum collected for other survey purposes for NAI surveillance. However, the principles of survey design described in these guidelines and the requirement for a statistically valid survey for the presence of NAIV should not be compromised.

The discovery of clusters of seropositive flocks may reflect any of a series of events, including but not limited to the demographics of the population sampled, vaccinal exposure or infection. As clustering may signal infection, the investigation of all instances must be incorporated in the survey design. Clustering of positive flocks is always epidemiologically significant and therefore should be investigated.

If vaccination cannot be excluded as the cause of positive serological reactions, diagnostic methods to differentiate antibodies due to infection or vaccination should be employed.

The results of random or targeted serological surveys are important in providing reliable evidence that no NAIV infection is present in a country, zone or compartment. It is therefore essential that the survey be thoroughly documented.

Virological and serological surveillance in vaccinated populations

The surveillance strategy is dependent on the type of vaccine used. The protection against AI is haemagglutinin subtype specific. Therefore two broad vaccination strategies exist: 1) inactivated whole AI viruses, and 2) haemagglutinin expression-based vaccines.

In the case of vaccinated populations, the surveillance strategy should be based on virological and/or serological methods and clinical surveillance. It may be appropriate to use sentinel birds for this purpose. These birds should be unvaccinated, AI virus antibody free birds and clearly and permanently identified. The interpretation of serological results in the presence of vaccination is described in 3.x.x.5.

Article 3.x.x.3.

Documentation of NAI or HPNAI free status

Countries declaring freedom from NAI or HPNAI for the entire country, or a zone or a compartment

In addition to the general conditions described in Chapter 2.7.12 of this *Terrestrial Code* a Member Country declaring freedom from NAI for the entire country, or a zone or a compartment should provide evidence for the existence of an effective surveillance programme. The strategy and design of the surveillance programme will depend on the prevailing epidemiological circumstances and should be planned and implemented according to general conditions and methods described in these Guidelines, to demonstrate absence of NAI virus infection, during the preceding 12 months in susceptible poultry populations (vaccinated and non-vaccinated). This requires the support of a national or other laboratory able to undertake identification of NAI virus infection through virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*. This surveillance may be targeted to poultry population at specific risks linked to the types of production, possible direct or indirect contact with wild birds, multi-age flocks, local trade patterns including live bird markets, use of possibly contaminated surface water, and the presence of more than one species on the holding and poor biosecurity measures in place.

Appendix III (contd)

Countries that cannot meet the conditions to declare freedom from NAI may declare freedom from HPNAI only under the condition that no NAI virus infection detected has been identified as HPNAI virus infection.

Additional requirements for countries, zones or compartments that practice vaccination

Reference to vaccination in this guide allows the option of vaccination as part of an official disease control programme under the supervision of the *Veterinary Administration* aimed at interrupting the transmission of HPNAI virus in the zone/compartment or country concerned. The level of flock immunity required to achieve interruption of transmission will depend on the flock size, composition (e.g. species) and density of the susceptible poultry population. It is therefore impossible to be prescriptive in this matter. The vaccine must also comply with the provisions stipulated for NAI vaccines in the *Terrestrial Manual*. Based on the epidemiology of NAI in the country, zone or compartment, it may be that a decision is reached to vaccinate only certain species or other subsets of the total susceptible poultry population.

In all vaccinated flocks there is a need to perform virological and serological tests to ensure the absence of virus circulation. The use of sentinel animals may provide further confidence of the absence of virus circulation. The tests have to be repeated at least every six months or at shorter intervals according to the risk in the country, zone or compartment.

Evidence to show the effectiveness of the vaccination programme should also be provided.

Article 3.x.X.4.

Countries, zones or compartment re-declaring freedom from NAI or HPNAI following an *outbreak*

In addition to the general conditions described in Chapter 2.7.12.of this *Terrestrial Code*, a country re-declaring for country, zone or compartment freedom from NAI or HPNAI virus infection should show evidence of an active surveillance programme depending on the epidemiological circumstances of the outbreak to demonstrate the absence of the infection. This will require surveillance incorporating virus/antigen/genome detection and antibody tests described in the *Terrestrial Manual*. The following strategies are recognised by the OIE to eradicate NAI/HPNAI virus infection following an *outbreak*:

1) in case of HPNAI virus infection, stamping out of all infected and in-contact poultry followed by disinfection of all establishments. The waiting period shall be 3 months provided that during this period, surveillance in accordance with these guidelines is applied to demonstrate the absence of HPNAI virus infection;

2) in case of LPNAI virus infection stamping out or slaughter of all infected and in-contact poultry followed by disinfection of all establishments; the waiting period shall be 3 months provided that during this period surveillance in accordance with these guidelines is applied to demonstrate the absence of LPNAI virus infection.

In all circumstances, a Member Country re-declaring freedom of country, zone or compartment from NAI or HPNAI (with or without vaccination) should report the results of an active surveillance programme in which the NAI or HPNAI susceptible poultry population undergoes regular clinical examination and active surveillance planned and implemented according to the general conditions and methods described in these guidelines. The surveillance should at least give the confidence that can be given by a randomized representative sample of the populations at risk.

Article 3.x.x.5

NAI free establishments within HPNAI free *compartments*

NAI free e*stablishments* within HPNAI free *compartments*, may trade low risk commodities. The declaration of NAI free establishments under these conditions requires the demonstration of absence of NAIV infection. Birds in these establishments should be randomly tested using virus detection or isolation tests and serological methods, following the general conditions of these guidelines. The frequency of testing should be based on the risk of infection and at a maximum interval of 21 days.

Appendix III (contd)

Article 3.x.x.6

The use and interpretation of serological and virus detection (virus isolation or nucleic acid detection) tests.

The recommended serological and virus detection tests for NAI surveillance are described in the *Terrestrial Manual*.

Animals infected with NAI virus produce antibodies to haemagglutinin (HA), neuraminidase (NA), non-structural (NSP), nucleoprotein/matrix (NP/M) and the polymerase complex proteins. Detection of antibodies against the polymerase complex proteins will not be covered in these guidelines. Tests for NP/M antibodies include direct and blocking ELISA, and agar gel immunodiffusion (AGID) tests. Tests for antibodies against NA include the neuraminidase inhibition (NI), indirect fluorescent antibody and direct ELISA tests. For the HA, antibodies are detected in haemagglutination inhibition (HI) and neutralization (SN) tests. The HI test is reliable in avian species but not in mammals. The SN test can be used to detect subtype specific antibodies to the haemagglutinin and is the preferred test for mammals and some avian species. The AGID test is reliable for detection of NP/M antibodies in chickens and turkeys, but not in other avian species. As an alternative, blocking ELISA tests have been developed to detect NP/M antibodies in all avian species.

The HI and NI tests can be used to subtype AI viruses into 15 haemagglutinin and 9 neuraminidase subtypes. Such information is helpful for epidemiological investigations and in categorization of AI viruses.

Animals can be vaccinated with a variety of AI vaccines including inactivated whole AI virus vaccines, and haemagglutinin expression-based vaccines (currently under study by the OIE). Antibodies to the haemagglutinin confer subtype specific protection. Various strategies can be used to differentiate vaccinated from infected birds including serosurveillance in unvaccinated sentinel birds or specific serological tests in the vaccinated birds.

AI virus infection of unvaccinated birds including sentinels is detected by antibodies to the NP/M, subtype specific HA or NA proteins, or NSP. In birds vaccinated with haemagglutinin expression-based vaccines, antibodies are detected to the specific HA, but not any of the other AI viral proteins. Infection is evident by antibodies to the NP/M or NSP, or the specific NA protein of the field virus. Birds vaccinated with inactivated whole AI vaccines may develop low titres of antibodies to NSP, but the titre in infected animals will be markedly higher. Alternatively, usage of a vaccine strain with a different NA subtype than the field virus can allow differentiation of vaccinated from infected animals (DIVA) by detection of subtype specific NA antibodies of the field virus. Vaccines used should comply with the standards of the *Terrestrial Manual.*

All flocks with seropositive results should be investigated. Epidemiological and supplementary laboratory investigation results should document the status of NAI infection/circulation for each positive flock.

A confirmatory test should have a higher specificity than the screening test and sensitivity at least equivalent than that of the screening test.

Information should be provided on the performance characteristics and validation of tests used.

(i) The follow up procedure in case of positive test results if vaccination is used

In case of vaccinated populations one has to exclude that positive test results are indicative of virus circulation. To this end the following procedure should be followed in the investigation of positive serological test results derived from surveillance conducted on NAIV-vaccinated animals. The investigation should examine all evidence that might confirm or refute the hypothesis that the positive results to the serological tests employed in the initial survey were not due to virus circulation. All the epidemiological information should be substantiated and the results should be collated in the final report.

Appendix III (contd)

Knowledge of the type of vaccine used is crucial in developing a serological based strategy to differentiate infected from vaccinated animals.

a) Inactivated whole AI virus vaccines can use either homologous or heterologous neuraminidase subtypes between the vaccine and field strains. If birds in the population have antibodies to NP/M and were vaccinated with inactivated whole AI virus vaccine, the following strategies should be applied:

   i. Sentinel birds should remain NP/M antibody negative. If positive for NP/M antibodies, indicating AI virus infection, specific HI tests should be performed to identify H5 or H7 AI virus infection.

   ii. If vaccinated with inactivated whole AI virus vaccine containing homologous NA to field virus, presence of antibodies to NSP could be indicative of infection. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

   iii. If vaccinated with inactivated whole AI virus vaccine containing heterologous NA to field virus, presence of antibodies to the field virus NA or NSP would be indicative of infection. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

b) Hemagglutinin expression-based vaccines contain the HA protein or gene homologous to the HA of the field virus. Sentinel birds as described above can be used to detect AI infection. In vaccinated or sentinel birds, the presence of antibodies against NP/M, NSP or field virus NA is indicative of infection. Sampling should be initiated to exclude the presence of NAIV by either virus isolation or detection of virus specific genomic material or proteins.

(ii) The follow up procedure in case of positive test results indicative of infection for determination of infection due to HPNAI or LPNAI virus

The detection of antibodies indicative of a NAI virus infection as indicated in section (i) above will result in the initiation of epidemiological and virological investigations to determine if the infections are due to HPNAI or LPNAI viruses.

Virological sampling should be initiated for all antibody-positive and at risk populations of birds. The samples should be evaluated for the presence of AI virus, by virus isolation and identification, and/or detection of influenza A specific proteins or nucleic acids (Figure 2). Virus isolation is the gold standard for detecting infection by AI virus and the method is described in the Terrestrial Manual. All AI virus isolates should be tested to determine HA and NA subtypes, and *in vivo* tested in chickens and/or sequencing of HA proteolytic cleavage site of H5 and H7 subtypes for determination of classification as HPNAI, LPNAI or LPAI (not notifiable) viruses. As an alternative, nucleic acid detection tests have been developed and validated; these tests have the sensitivity of virus isolation, but with the advantage of providing results within a few hours. Samples with detection of H5 and H7 HA subtypes by nucleic acid detection methods should either be submitted for virus isolation, identification, and in vivo testing in chickens, or sequencing of nucleic acids for determination of proteolytic cleavage site as HPNAI or LPNAI viruses. The antigen detection systems, because of low sensitivity, are best suited for screening clinical field cases for infection by Type A influenza virus looking for NP/M proteins. NP/M positive samples should be submitted for virus isolation, identification and pathogenicity determination.

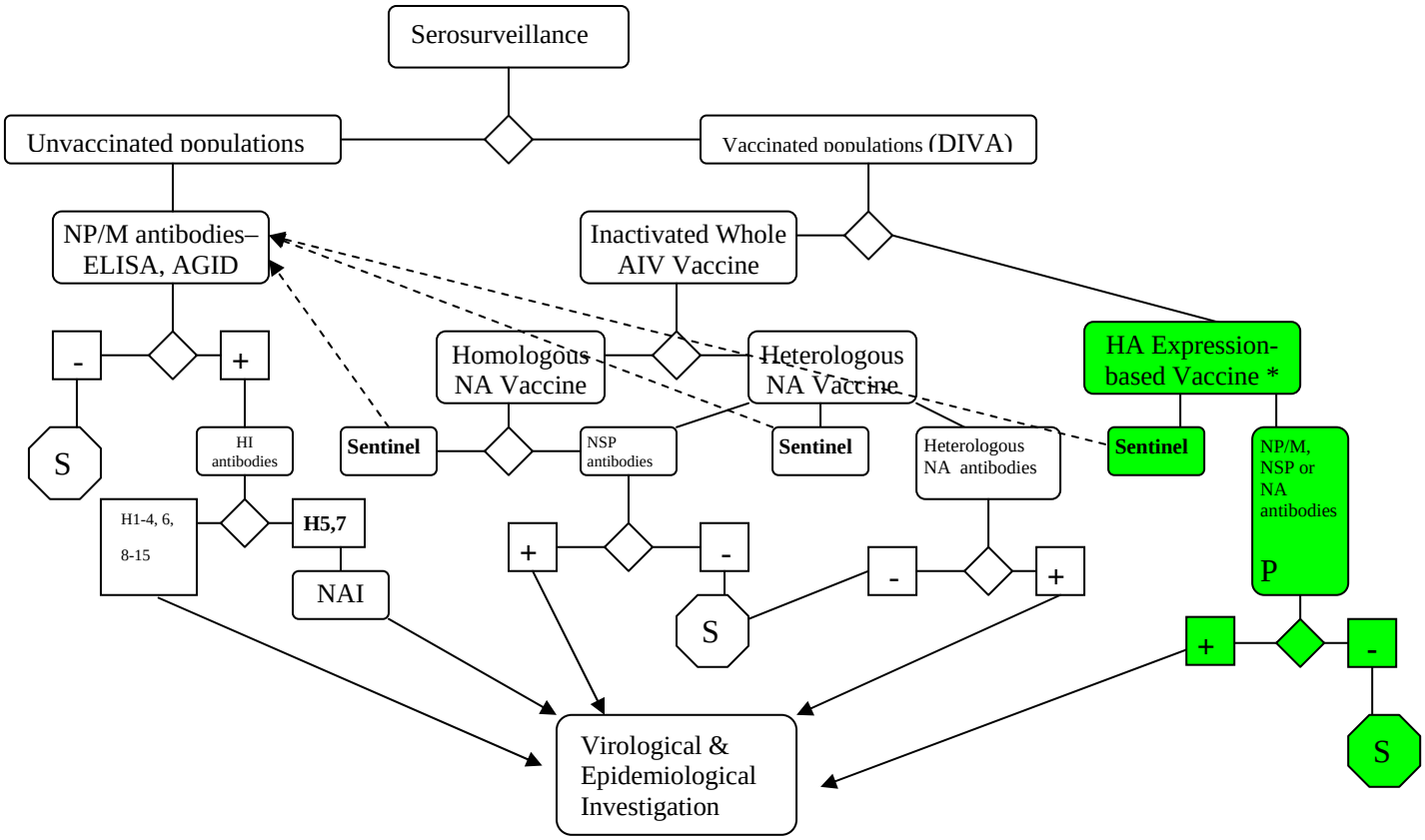
Appendix III (contd)

Laboratory results should be examined in the context of the epidemiological situation. Corollary information needed to complement the serological survey and assess the possibility of viral circulation includes but is not limited to:

a) characterization of the existing production systems;
b) results of clinical surveillance of the suspects and their cohorts;
c) quantification of vaccinations performed on the affected sites;
d) sanitary protocol and history of the affected establishments;
e) control of animal identification and movements;
f) other parameters of regional significance in historic NAIV transmission.

The entire investigative process should be documented as standard operating procedure within the epidemiological surveillance programme (system implementation).

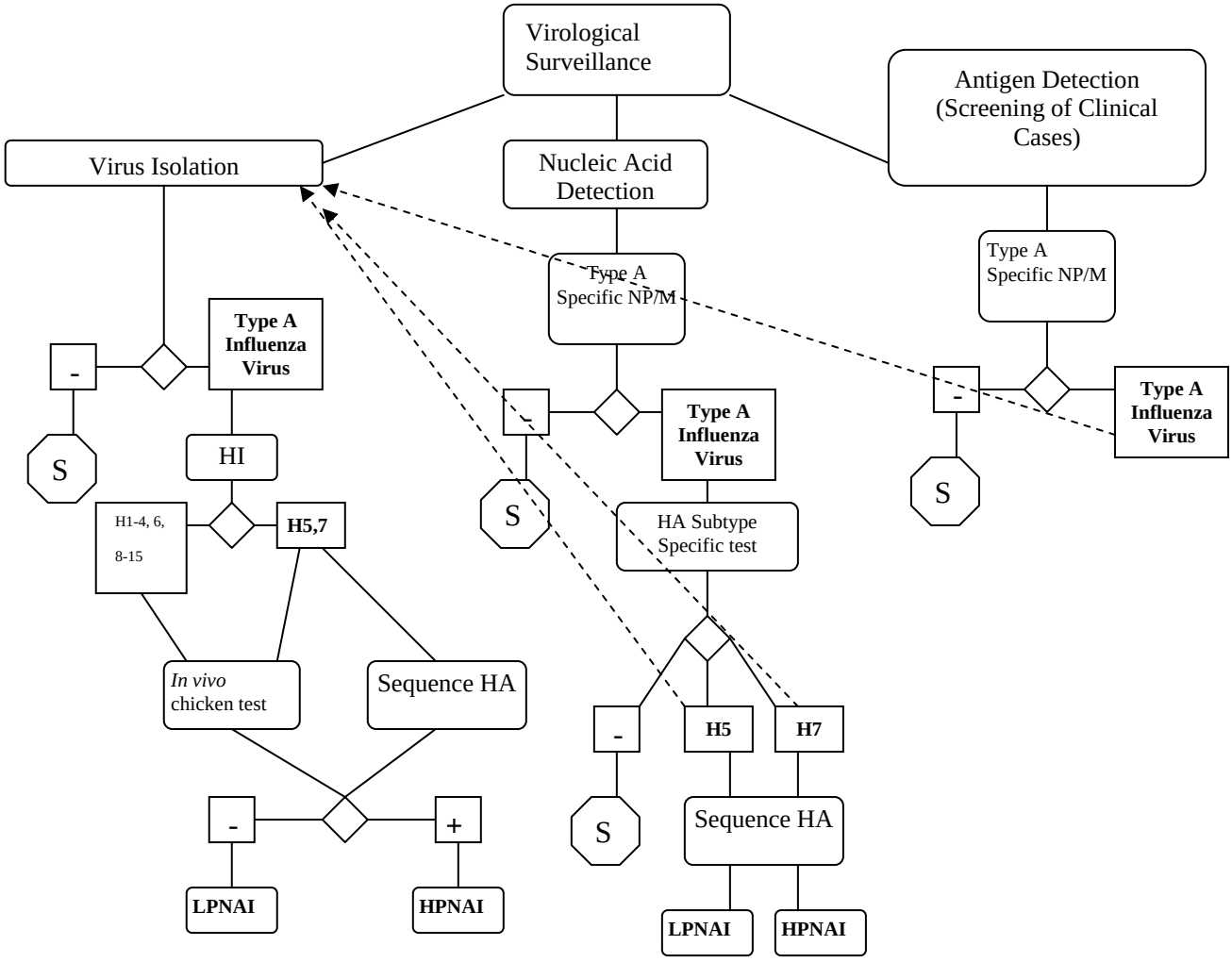
Figure 1 - ***Schematic representation of laboratory tests for determining evidence of NAI infection through or following serological surveys***



* under consideration in OIE

Appendix III (contd)

Figure 2. - ***Schematic representation of laboratory tests for determining evidence of NAI infection using virological methods***



The above diagrams indicates the tests which are recommended for use in the investigation of poultry flocks.

Key:

AGID	Agar gel immunodiffusion
DIVA	Differentiating infected from vaccinated animals
ELISA	Enzyme-linked immunosorbant assay
HA	Haemagglutinin
HI	Haemagglutination inhibition
NA	Neuraminidase
NI	Neuraminidase inhibition
NP/M	Nucleoprotein and matrix protein
NSP	Non-structural protein
SN	Serum neutralization

Appendix IV

73 SG/12 CS3B/AHG 9

Original: English
October 2004

REPORT OF THE OIE AD HOC GROUP ON COUNTRY STATUS EVALUATION FOR FREEDOM FROM RINDERPEST

Paris, 20-22 October 2004

A meeting of the OIE Ad hoc Group on country status evaluation for rinderpest was held at the OIE Headquarters, Paris from 20 to 22 October 2004. The first part of the meeting (surveillance guidelines and country status evaluations) was chaired by Professor Vincenzo Caporale, Chairman of the OIE Scientific Commission for Animal Diseases (Scientific Commission) and the remaining part of the meeting was chaired by Dr Arnon Shimshony. Dr Peter Roeder acted as rapporteur.

The agenda and list of participants are presented as Appendices I and II, respectively.

1. Matters arising from and follow-up on the report of previous meeting of the OIE Ad hoc Group for evaluation of country status with respect to rinderpest, 7-8 January 2004

Two issues relating to the *Terrestrial Animal Health Code* (the *Terrestrial Code*) Chapter for Rinderpest had been identified for attention at the present meeting. These concerned incorporation of changes relating to the use of rinderpest vaccine in international movement of livestock and combining the disease and infection free stages of the OIE Pathway into a single status of freedom from rinderpest. As agreed at the first Ad hoc Group Meeting in January, this was to be addressed by consideration of a proposal drafted by Dr Roeder for the meeting.

Another issue concerned recognition of infection free status for Bhutan. Contact with the Bhutanese authorities had elicited an application for recognition of freedom from rinderpest infection which was to be evaluated at the present meeting.

2. Implications of the i-ELISA serological test for screening for rinderpest

Consideration was given to the statement included in Chapter 2.1.4 of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (The *Terrestrial Manual*) 2004 that "*An indirect ELISA method has been developed and might be useful for rinderpest surveillance programmes, especially in areas in which lineage II rinderpest virus could be present. However, the performance characteristics of the test indicate a problem with specificity and therefore its use will require confirmatory testing*." The Ad hoc Group concluded that in aiming for global eradication and accreditation of freedom recommending a test for which performance

criteria are not freely available is not acceptable. It considered that the paragraph is ambiguous and several issues relating to test performance are unclear. For example, which version of 'the indirect ELISA test' is under consideration – the formulation based on anti-IgG conjugate or alternatively that employing Protein G conjugate; how is the test is to be performed including the positive-negative threshold value recommended; what is the test performance using the recommended formulation? Retaining the recommendation could place OIE in an invidious position if dossiers in application for recognition of freedom from rinderpest are presented to OIE containing data generated solely from the use of the indirect ELISA. The Ad hoc Group requested the Biological Standards Commission to establish whether or not the paragraph constitutes a recommendation for use of the test recommended.

3. Evaluation of country status for rinderpest

3.1. Rinderpest disease

3.1.1. Ethiopia

The application was recommended for approval.

3.1.2. Sudan

The application was recommended for approval.

3.1.3. Tanzania

The application was recommended for approval.

3.1.4. Lebanon

A late application was received from Lebanon. This was recommended for approval. In communicating this result to the country it was recommended that the attention of the country be drawn to the first paragraph of Appendix 3.8.2 item 3 (c) of the *Terrestrial Code* which states conditions for a country to be recognised as free from rinderpest infection. The fact that Lebanon could apply for recognition of freedom from infection under the '10 year rule' should be drawn to the country's attention.

3.2 Rinderpest infection

3.2.1. Bhutan

The application was recommended for approval.

3.2.2. Turkey

The application was evaluated but was considered to present insufficient detail for the application to be considered credible. Turkey should be requested to provide the additional detail and resubmit its application. More details of the analysis of disaggregated serological data with an indication of geographical distribution of the seropositive animals and action taken to follow-up.

4. Proposed amendments to the Chapter/Appendix on rinderpest in the OIE *Terrestrial Animal Health Code*

The Members of the Group examined a text that had been prepared by Dr Roeder on proposed amendments to chapter 1.3.14 and Appendix 3.8.2 of the *Terrestrial Code*. The document was discussed at length.

Finally, the President of the Ad hoc Group, who is also the President of the OIE Scientific Commission for Animal Diseases, took the decision to ask the OIE Director General to form an Ad hoc Group of the experts concerned charged with the task of drawing up a new draft chapter.

5. Cognate matters

The Ad hoc Group noted that some Member Countries are understood to be at an advanced stage of preparing dossiers for application to OIE for recognition of disease or infection freedom but that these have not yet reached the OIE Central Bureau. It was recommended that if these applications are received by the OIE before 15 November 2004, they should be distributed electronically to the members of the Ad hoc Group and that if consensus is reached their adoption be recommended to the Scientific Commission at its meeting in January 2005.

6. Follow-up of the meeting

As a follow-up to section 5, the Group evaluated the dossiers received electronically from the following countries: Benin, Eritrea, Mongolia, Nigeria, Senegal, Togo, Turkey and Uganda. The Group recommended that the Scientific Commission consider recommending to the International Committee that Benin, Eritrea, Mongolia, Senegal, Togo and Turkey be recognised as free from rinderpest infection and that Nigeria be recognised as free from rinderpest disease. As regards Uganda, the Group recommended that the application be deferred and the Ugandan authorities be asked to provide the following information:

- Description of the methodology applied for the random clinical surveillance,
- A list of incidents of rinderpest-compatible disease events for the past five years and the results of the investigations conducted,
- The serological surveys and results tabulated for 2003 and 2004 with an explanation of the seropositivity encountered.

…/Appendices

Appendix I

REPORT OF THE OIE AD HOC GROUP ON COUNTRY STATUS EVALUATION FOR FREEDOM FROM RINDERPEST

Paris, 20-22 October 2004

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Agenda

1. Matters arising from and follow-up on the report of previous meeting of the OIE Ad hoc Group for Evaluation of Country Status with respect to rinderpest, 7-8 January 2004

2. Implications of the i-ELISA serological test for screening for rinderpest

3. Evaluation of country status for rinderpest

    3.1. Rinderpest disease

        3.1.1. Ethiopia
        3.1.2. Sudan
        3.1.3. Tanzania
        3.1.4. Lebanon

    3.2. Rinderpest infection

        3.2.1. Bhutan
        3.2.2. Turkey

4. Proposed amendments to the Chapter/Appendix on rinderpest in the OIE *Terrestrial Animal Health Code*

5. Cognate matters

6. Follow-up of the meeting

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Appendix II

REPORT OF THE OIE AD HOC GROUP ON COUNTRY STATUS EVALUATION FOR FREEDOM FROM RINDERPEST

Paris, 20-22 October 2004

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Special OIE/FAO meeting on Contagious Bovine Pleuropneumonia situation in SADC countries: OIE Headquarters: Paris, France, 24 May 2004

A special meeting was convened on 24 May 2004 by OIE and FAO during the 72nd General Session of the OIE in Paris, France to discuss the current situation of Contagious Bovine Pleuropneumonia (CBPP) in SADC countries with special reference to the emerging situation of the disease in Zambia. The meeting was co-chaired by Dr F Thiaucourt of CIRAD-EMVT-representing the OIE and Dr W Amanfu of FAO. Dr G.K. Brückner acted as rapporteur. The meeting was attended by the delegates of Zimbabwe, Zambia, Tanzania, Angola, Botswana, Swaziland, South Africa and a representative from FAO.

In attendance:

Dr Thiaucourt –OIE/CIRAD-Co-Chairman
Dr Amanfu-FAO/Co-Chairman

Angola: Dr Simao and Visesse
Botswana, Dr Chimbombi
Namibia: Dr Norval
Republic of South Africa: Dr Brückner (Rapporteur)
Swaziland: Dr Thwala
Tanzania: Dr Kimaryo and Bahari
Zambia: Dr Mangani
Zimbabwe: Dr Hargreaves
FAO: Dr Domenech

AVIS-UK: Dr Mark Rweyemamu

Background

Dr Thiaucourt introduced the discussions indicating that the recent identification of CBPP in the south-west regions of Zambia that had never been affected so far has raised major concerns. The south-west corner of Zambia borders the adjoining countries of Botswana, Namibia and Zimbabwe.. He reiterated the concerns that the disease might spread further east with the probable consequence that CBPP could become endemic in Zambia posing a potential danger of further spread to countries such as Botswana, Zimbabwe and possibly Mozambique and South Africa. He mentioned that Zambia and Angola have requested the assistance of the OIE to define CBPP control strategies and possibly access to support from the international community. The purpose of the meeting therefore was to get an overview of the disease situation in Zambia in particular and the SADC region in general, assess the ability of the countries to contain CBPP disease outbreaks and to formulate a plan of action to address the disease situation in Zambia.

Dr Amanfu outlined the involvement and commitment of FAO to assist with resolving the situation. He shared the information gained during a recent technical mission to Zambia with the meeting emphasizing that:

- the objectives of assistance to Zambia were to support the control programmes to prevent further outbreaks of livestock diseases especially CBPP in western Zambia resulting from the influx of refugee cattle from Angola;
- despite project interventions for the control of TADs, CBPP outbreaks in particular, continued to occur in the country;
- outbreaks of the disease were detected in north-western province in February 2003, specifically in Mufumbwe district in Kashima area and in Kaoma district in June 2003;.
- the outbreak in Katima-East Caprivi district of Namibia (October 2003) is thought to have originated from south-western Zambia;

- further outbreaks of CBPP were reported in Luampungu in Sesheke district in August 2003 and in Mulobezi in February 2004. Outbreaks continued to occur in March 2004 in Sesheke, Kazungula and Livingstone districts.
- the disease situation specifically related to Zambia, has a potential to spread from the western border of the country in a southerly direction towards Botswana and Zimbabwe and further to the eastern border towards Tanzania while there is also a potential threat of the disease spreading from northern and western Tanzania to the eastern areas of Zambia. The situation is further aggravated by possible transboundary movements into and from adjoining countries.

Dr Amanfu further mentioned that the Chief Veterinary Officers of SADC countries met in August 2003 under the auspices of an FAO TCP in Pretoria, South Africa where they opted for a regionally coordinated approach to the control of TADs (CBPP and FMD) within the framework of the joint FAO/OIE initiative Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADs). The meeting in Pretoria was facilitated by TCP/RAF/2809 prioritising CBPP and FMD as requiring urgent internationally coordinated and financially supported initiatives. Donor appeal was launched in Gaborone, Botswana in October-2003, by SADC and FAO. An EU appraisal mission on FMD control in SADC is currently in progress.

He expressed the wish to delegates that the meeting now convened by OIE/FAO could be the beginning of such an initiative at which coordinated efforts in addressing technical, economic analysis, policy and institutional dimensions confronting the control of CBPP within the region, are addressed. He emphasised that donor support as well as collective national efforts are needed to halt the spread of CBPP to countries that have been free of the disease for nearly a century and to control the disease in chronically affected countries.

Disease status in surrounding SADC countries

Brief country reports were presented by the CVOs or their accredited representatives present at the meeting. Botswana, Mozambique, South Africa and Zimbabwe indicated that the disease was absent in their respective countries while infected foci are present in Angola, Tanzania, Namibia and Zambia. Namibia experienced an outbreak in 2003 in the Eastern Caprivi strip bordering southern Zambia with occasional low intensity flare-ups still experienced, while Botswana reported that it eradicated the disease in 1995 through mass slaughter of 320 000 cattle. Vigilant disease surveillance and movement control is still maintained by Botswana on the northern boundary with Namibia and Zambia. Angola indicated that they are aware of cross-border movement of cattle between Angola and Zambia while vaccination, surveillance and movement control in Kuanda Kubango is not possible due to the presence of landmines. Tanzania indicated that there are few cattle in the south-eastern zone of the country bordering Mozambique with only one limited outbreak diagnosed. In the rest of the area of 20 districts, 19 are infected. Vaccinations in these areas are of variable success as each district is responsible for its own finances and logistical support. Zambia has donor support with 1 million doses of CBPP vaccine available mainly for preventative disease control on its western and north-western borders. The entire area is subjected to disease surveillance. Infected cattle and a limited number of in-contact cattle are sent for slaughter at local abattoirs. No vaccinations have yet been done in the southern (Livingstone) area bordering Zimbabwe and surveillance data was also found lacking. The delegate from Zambia indicated that vaccine would be needed for approximately 150 000 cattle in the south-western area and that provision should also be made for booster vaccination of the cattle population at risk after 3 months.

In discussing and evaluating the information submitted by delegates, the meeting was unanimously of the opinion that the disease situation in Zambia needs to be urgently characterised and described in detail to enable an informed decision on the way forward to be made. It was also regarded as critically important, that Zambia should urgently mobilise logistical and other means of support to commence vaccination of cattle as soon possible in the southern area (Livingstone) bordering Zimbabwe, Namibia and Botswana.

Resolutions taken to control the disease within the region

CONSIDERING

- the potential serious implications should the disease be allowed to spread uncontrolled from Zambia to neighbouring countries;

- the limited resources available in almost all of the potentially affected countries and countries at risk;

- the difficulty of rapid containment of the disease due to variable immune response elicited by current available vaccines;

- the serious socio-economic impact of the disease on affected farmers in the areas at risk;

THE DELEGATES RESOLVED

- that Zambia should urgently try to mobilise the resources and logistical support to commence with vaccinating cattle in the south-western area bordering Zimbabwe, Botswana and Namibia;

- the Director-General of the OIE in collaboration with the FAO, mandates an urgent detailed epidemiological investigation and characterisation of the outbreak of CBPP in Zambia and Zimbabwe by a designated expert mission;

- the designated expert mission should

  i) evaluate the immediate needs to establish a reliable surveillance system in Northern and Southern Zimbabwe and prepare an emergency plan of action should they be confronted by an outbreak of CBPP;

  ii) evaluate the needs for an emergency CBPP vaccination campaign in Southern Zambia, and possibly South West Angola, in order to diminish the CBPP risk of spread to the SADC countries which are still disease free;

  iii) establish the true CBPP distribution in Zambia and conduct detailed economic, livestock policy and institutional analysis of dimensions confronting CBPP control dynamics in Zambia in order to lay the grounds for a longer term plan of CBPP control and eradication;

- that a regional consultation be organized by the OIE, FAO and SADC in order to define a long term plan of action for the eradication of CBPP in the sub-region and the means to gain donor support for this activity.