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February 2007

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

**Paris, 26 - 28 February 2007**

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A meeting of the OIE Scientific Commission for Animal Diseases was held at the OIE Headquarters in Paris, France, from 26 to 27 February 2007. Dr. Gideon Brückner, Head of the Scientific and Technical Department welcomed the participants on behalf of Dr Bernard Vallat, Director General of the OIE and introduced the agenda of the meeting.

The meeting was chaired by Prof. Vincenzo Caporale, President of the Scientific Commission and Dr. Preben Willeberg was rapporteur.

The Commission approved the Agenda after provision was made for discussion of the recommendations of the FMD mission to South America with a delegation from the countries concerned.

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

**1. Report of the meeting of the Scientific Commission: 30 January - 2 February 2007**

The Commission noted the report of the meeting of the Scientific Commission held from 30 January to 2 February 2007 at the OIE Headquarters.

**2. Reports of *ad hoc* Groups**

• ***Ad hoc* Group on vaccination strategies for avian influenza**

The Commission noted that work on the guidelines for vaccination strategies for avian influenza is in progress and will be finalized after consideration of the recommendations of the OIE/FAO/IZSVe international conference on vaccination in Verona, Italy in March 2007. The Commission confirmed its previous decision that following the Verona conference, the Director General will be requested to convene an *ad hoc* Group representing members from the Epidemiology and Newcastle disease *ad hoc* Groups to ensure consistency in the guidelines for vaccination and surveillance for avian influenza and Newcastle disease. The Commission took note that the existing document for guidelines on vaccination strategies for avian influenza is intended to be an information document for Member Countries and not intended for inclusion in the *Terrestrial Code*.

- ***Ad hoc* Group on Bovine Brucellosis**

The Commission noted that three issues in the proposed chapter were considered, namely: the question of whether the three species of *Brucella* should be covered by the chapter (Article 2.3.1.1); whether all herds or a sample of herds should be tested to determine statistical confidence of freedom at a specified design prevalence (Article 2.3.1.2[3]) and the presentation of an international veterinary certificate (Article 2.3.1.10). The Commission endorsed the recommendations by the *ad hoc* Group on all three issues (see [Appendix III](#)).

The comments from the *ad hoc* Group on the FAO Brucellosis programme for Tajikistan were reviewed and endorsed by the Commission.

- ***Ad hoc* Group on country evaluation for contagious bovine pleuropneumonia (CBPP) (electronic consultation)**

The Commission concluded that no recommendation can be submitted for adoption following the application of a Member Country for disease freedom as the opinions from the *ad hoc* Group members were incomplete. The application will be re-evaluated following the submission of additional information.

- ***Ad hoc* Group on country evaluation for bovine spongiform encephalopathy (BSE)**

The Commission endorsed the final report of which the recommendations were already endorsed during the previous meeting of the Commission. The report can be found at [Appendix IV](#).

- ***Ad hoc* Group on country evaluation for Rinderpest**

The Commission noted and approved the recommendation of the *ad hoc* Group that the proposed surveillance guidelines and the questionnaire be reviewed by the Epidemiology *ad hoc* Group. The application from one country was considered to be associated with some difficult issues, as described by the *ad hoc* Group. The recommendations of the *ad hoc* Group for the allocation of freedom of infection or disease for five Member Countries were reviewed and their recommendation to approve the application of three applicant countries and one of another country pending since the previous meeting of the Commission were endorsed, while two applications were referred back to the applicant countries due to non-compliance with the provisions of the *Terrestrial Code*. The report can be found at [Appendix V](#).

- ***Ad hoc* Group on Antigen and vaccine banks**

The discussion of this report has been postponed for the next meeting of the Commission.

- ***Ad hoc* Group on country evaluation for foot and mouth disease (FMD)**

The Commission noted the most important issues reflected in the report namely a discussion of the report of the OIE FMD mission to South America; recommendations on the application for freedom from FMD by five Member Countries and comments received from Member Countries on suggested changes to Chapter 2.2.10 (foot and mouth disease) – specifically as it relates to the introduction of a new concept of a *containment zone*.

The recommendations of the *ad hoc* Group on the applications of five Member Countries were reviewed and the recommendations in respect of four of the Member Countries (Botswana, Peru, Colombia and Brazil) were endorsed whilst the recommendation in respect of the application of Argentina for the reinstatement of their disease free status with vaccination and the enlargement of the disease free area without vaccination, were reserved pending the response of the Member Country to proposals by the Scientific Commission on the control of the disease in the frontier areas of the country. The report is attached as [Appendix VI](#).

Following the discussions on the findings of the OIE FMD mission to South America, the Commission recommends that the Biological Standards Commission be requested to reconsider the terms of reference of the *ad hoc* Group on NSP tests and to consider a closer working relationship of this Group with the *ad hoc* Group on Epidemiology to discuss the application problems from using emergency vaccination for foot and mouth disease in the field and to interpret the reactors to the various NSP-tests. The suggested combined *ad hoc* Group should also address the problem of finding the pockets of infected individuals in a vaccinated population at a very low prevalence with a random survey – alternative strategies should be considered on how to locate these reactors if and where they exist.

The comments of the Group on country comments on the suggested changes to Chapter 2.2.10 were endorsed by the Commission and will be forwarded to the Code Commission.

- ***Ad hoc* Group on Epidemiology**

The Commission noted and endorsed the report of the *ad hoc* Group and the draft guidelines for compartmentalisation prepared by the Group for further consideration by the Code Commission. The report can be found at [Appendix VII](#).

- ***Ad hoc* Group on Newcastle disease**

The Commission noted and endorsed the report of the *ad hoc* Group and the draft chapter prepared by the Group for further consideration by the Code Commission. The report can be found at [Appendix VIII](#).

### **3. Working Group on wildlife diseases**

The Commission invited Prof Marc Artois of the Working Group to present the main issues emanating from the last meeting of the Working Group. The Commission supported the request of the Group that the Director General be requested to consider enlarging the Group by the appointment of one representative from each of the Asian and South American regions to ensure a more even global representation. The Group also reiterated the importance that Member Countries who have not yet done so, should designate a focal point for wildlife diseases in their respective countries. The suggestion of the Group to incorporate wildlife surveillance data of the most relevant diseases as a third and separate section of WAHID was not supported by the Commission as it was considered more suitable to join disease data of wildlife to the existing WAHID system. The Commission however, supported the proposal that the Director General be requested to convene an *ad hoc* Group with the support of the Animal Health Information Department of the OIE to evaluate an extension of the WAHIS to incorporate diseases of wildlife. The Group was also advised to seek closer collaboration with the webmaster of the Central Bureau to improve the accessibility of the current page on the OIE website on wildlife diseases.

The work done by the Group and the draft proposals submitted on Managing significant emerging diseases involving wildlife and Preparedness for a response to trans-boundary animal diseases in wildlife were commended by the Commission who will refer the documents to the *ad hoc* Group on Epidemiology for further discussion and incorporation into their working program.

The Commission supported the intention of the Group to produce a paper for publication in the *OIE Scientific and Technical Review* on the role of waterfowl in outbreak of avian influenza in Europe.

The request of the Working Group for more structured training in wildlife diseases to Member Countries was supported by the Commission but the Group was requested to first establish a list or reference to available training opportunities and facilities in wildlife diseases.

### **4. Issues referred to the Scientific Commission by other Commissions**

- ***Terrestrial Animal Health Code Commission:***

- 1) *Scientific publication on hog casings for the inactivation of foot and mouth disease virus:* The Commission recommended that the request be referred to an OIE Reference Laboratory for a scientific opinion.

- 2) *Request from the Delegate of Zimbabwe on the inactivation of FMDV in matured meat*: The Commission was of the opinion that the request of the Member Country is already covered within the recommendations for virus inactivation in the *Terrestrial Code*.
- 3) *Review of Member Country comments on the draft chapter and surveillance guidelines for bluetongue*: The comments of the Commission were forwarded to Code Commission.
- 4) *Review of the comments by Member Countries on the suggested changes to Chapter 2.2.10 (Foot and mouth disease)*: The comments made by the *ad hoc* Group on Country Evaluation for foot and mouth disease in respect of this suggested changes were endorsed by the Commission and is attached to the report of the *ad hoc* Group.
- 5) *Revision of the guidelines for surveillance for avian influenza*: The Commission resolved that the Director General be requested to convene an *ad hoc* Group consisting of experts from the *ad hoc* Groups on avian influenza, Newcastle disease and Epidemiology to have discussions on this following the Verona Conference.
- 6) *Bluetongue chapter and surveillance guidelines*: The comments of the Commission were forwarded to Code Commission.
- 7) *AI surveillance appendix*: The comments of the Commission were forwarded to Code Commission.
- 8) *Chapter on tuberculosis*: The comments of the Commission were forwarded to Code Commission.
- 9) *Guidelines on compartmentalisation*: Included with the report of the *ad hoc* Group on Epidemiology.
- 10) *Newcastle disease revised chapter*: Included with report of *ad hoc* Group.
- 11) *Definitions for surveillance and monitoring*: Reflected in report of *ad hoc* Group on Epidemiology: not yet resolved.
- 12) *Compartmentalisation for foot and mouth disease*: Reflected in report of *ad hoc* Group on Epidemiology recommending the consideration of compartmentalisation for foot and mouth disease.

## 5. Discussion on the report of the OIE FMD mission to South America and discussions with a delegation from the South American countries

The response of the South American countries to the recommendations contained in the FMD mission report that was made available to the delegation during the last meeting of the Scientific Commission from 30 January to 2 February, was submitted to the Scientific Commission by the CVP (Comité Veterinario Permanente del Cono Sur) on 26 February 2007. The response of the CVP was evaluated against each of the recommendations in the FMD mission report and listed for easy reference of the CVP. The Commission noted with appreciation that the CVP had addressed most of the concerns and presented action plans for implementation of most of the recommendations. However, the Commission indicated that they would first need clarity on the response from the CVP on the following recommendations which were not fully covered within the CVP response:

- 1) The absence of an additional surveillance zone in all the affected countries in the areas adjacent to the proposed high surveillance zone of 15km along the frontier areas of each country.
- 2) The assurance of independent surveillance and outbreak investigation in collaboration with relevant OIE Reference Laboratories opposed to mere “auditing” as indicated in the report
- 3) Clarity on the time frame for the implementation of the coordinated regional approach to control foot and mouth disease in the frontier region
- 4) Agreement that the movement of susceptible animals and their products to and from the high surveillance frontier zone would be done in compliance with Articles 2.2.10.8 (slaughter); Article 2.2.10.11 (all susceptible animals); Article 2.2.10.15 (semen); Article 2.2.10.22 (fresh meat) and Article 2.2.10.23 (meat products) of the *Terrestrial Code*.

The delegation re-considered their proposals in view of the comments of the Commission and agreed to all the proposals suggested above. In discussions it was re-iterated that the area of 15km comprising an area of higher and intensive surveillance and control along the frontier areas of each country, would for the time being be excluded from the free zones of the countries concerned and that Paraguay and Argentina need to confirm that only the areas not included within higher surveillance zone of 15km, would be liable to be listed as zones free from disease with vaccination. These areas located outside the 15km areas would therefore, if approved by the International Committee of the OIE, be listed as zones and not countries free from foot and mouth disease with vaccination. The reinstatement of zones previously infected would be dependent on acceptance of this concept.

The delegation of the CVP were requested to carefully consider the proposed concept and to confirm their agreement in writing to the Director General. Letters of confirmation were subsequently received from Paraguay, Argentina and Brazil agreeing to sacrifice a small area of 15km along the common borders in the frontier areas of each of these three countries and to exclude these areas from the zones allocated as officially free by the OIE until such a time that the OIE can be requested to reconsider the situation. Such a request will depend on the epidemiological situation of the disease in the frontier areas of the three countries.

The acceptance of the proposal by all three countries subsequently justified the application of the mandate of the Scientific Commission to reinstate the previously infected area of Argentina to an area free of foot and mouth disease with exclusion for the time being, of the 15km high surveillance zone along the border with adjoining countries and to recommend to the International Committee, the enlargement of the current area free without vaccination.

The Commission would also recommend to the International Committee to accept the zone of Paraguay identified by the Delegate of Paraguay in letters to the Director General on 5 and 8 March 2007 as free from foot and mouth disease with vaccination.

The report of the OIE FMD mission to South America and the proposals of the CVP, are reflected in Appendices IX and X respectively.

## **6. Review of the working programme of the Scientific Commission for 2007 – schedule of dates**

The Commission agreed to at least three meetings for 2007/2008 and the scheduling of meeting of *ad hoc* Groups already as from June/July 2007 to avoid an overloaded program prior to the General Session in 2008. The following dates for meetings were tentatively identified:

- Meeting of the Bureau of the Commission: 6<sup>th</sup> June 2007 (telephonic conference)
- First Meeting of the Commission: 18 to 20 September 2007
- Second meeting of the Commission: 13 to 16 February 2008

## **7. Other matters discussed**

- *Foot and mouth disease OIE Foot and mouth disease Reference Laboratories Network*: The Commission were informed that the President of the Commission will conduct a visit to all OIE FMD Reference and potential OIE FMD Reference Laboratories to make proposals to the Director General on the policy and desired mechanisms for the implementation of OIE Reference Laboratories networks.
- *Request for a chapter in the Terrestrial Code on Trypanosoma evansi*: The Commission recommended a review an update of this issue by an *ad hoc* Group or by expert consultation but regarded it as low priority compared to other more important issues on the working program.
- *Report of FMD Reference Laboratories*: The Commission did not receive a final report for the year at the date of the meeting. This issue was identified for discussion at the next meeting of the Commission in September 2007.

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.../Appendices



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

**Paris, 26 – 28 February 2007**

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**Agenda**

- 1. Report of the meeting of the Scientific Commission: 30 January - 2 February 2007**
  - 2. Reports of *ad hoc* Groups**
    - *Ad hoc* Group on vaccination strategies for avian influenza
    - *Ad hoc* Group on Bovine Brucellosis
    - *Ad hoc* Group on country evaluation for contagious bovine pleuropneumonia (CBPP) (electronic consultation)
    - *Ad hoc* Group on country evaluation for bovine spongiform encephalopathy (BSE)
    - *Ad hoc* Group on country evaluation for Rinderpest
    - *Ad hoc* Group on Antigen and vaccine banks
    - *Ad hoc* Group on country evaluation for foot and mouth disease (FMD)
    - *Ad hoc* Group on Epidemiology
    - *Ad hoc* Group on Newcastle disease
  - 3. Working Group on wildlife diseases**
  - 4. Issues referred to the Scientific Commission by other Commissions**
    - Terrestrial Animal Health Code Commission:
  - 5. Discussion on the report of the OIE FMD mission to South America and discussions with a delegation from the South American countries**
  - 6. Review of the working programme of the Scientific Commission for 2007 – schedule of dates**
  - 7. Other matters discussed**
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**MEETING OF THE  
OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES**

**Paris, 26 – 28 February 2007**

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**List of participants**

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**REPORT OF THE MEETING  
OF THE OIE AD HOC GROUP ON BRUCELLOSIS  
Paris, 8 - 9 February 2007**

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A meeting of the OIE *Ad hoc* Group on Brucellosis was held at the OIE Headquarters in Paris, from 8 to 9 February 2007. Dr Gideon Brückner, 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 Appendix II.

Dr Klaus Nielsen was designated as Rapporteur. Prof. Vincenzo Caporale, President of the Scientific Commission attended the meeting temporarily.

**1. Review of Chapter 2.3.1 on Bovine Brucellosis in the OIE *Terrestrial Animal Health Code***

The *Ad hoc* Group was charged with reviewing and addressing Member Country comments on the revised Chapter 2.3.1 – Bovine brucellosis of the OIE *Terrestrial Animal Health Code*. The chapter was discussed at considerable length in its current format along with suggestions and comments made by reviewers from several countries with a view to offer expert opinions in order to revise and amend the chapter.

All references to diagnostic tests and vaccines are described in the OIE *Manual*.

**General comments:**

- According to the *Code*, brucellosis is a multispecies disease with respect to host species and causative agents. Hence the inclusion of *Brucella* species other than *B. abortus* as causative agents in cattle is acceptable and it was decided that there was sufficient evidence to include *B. melitensis* and *B. suis* as causative agents of bovine brucellosis.
- Freedom from brucellosis refers specifically to domestic animals at the exclusion of wild animal species.

**Specific comments:**

- While not common, *B. melitensis* does infect cattle. The incidence is increasing.
- *B. suis*, especially biotype 4 has been shown to infect cattle where there may be contact with wild cervids
- It is questionable if current cattle vaccines protect against infection with other *Brucella* sp. For example, does S19 protect against *B. melitensis* infection?
- It is suggested that transmission should be avoided by limiting exposure to other species of domestic/wild animals, contaminated water and feed stuffs etc.

- Exposure through placenta/fetuses remaining on grazing land after abortion/births should be avoided (both animal and human exposure)
- The definition of a 'herd' is somewhat debatable. Therefore, the AHG suggests that a herd be considered as 'All large domestic animals under common ownership or supervision that are grouped in one or more parts of a single premise'. Small ruminants constitute a 'flock'.
- The chapter covers large domestic ruminants, including cattle of all species, domestic bison and domestic buffalo.
- Testing for disease is confounded by the requirement for testing *all* animals in a country, zone or compartment in three consecutive years. This is an undue burden on some countries and it is suggested that a statistically significant number of randomly selected animals be tested each year, especially in the latter stages of control programs.
- Freedom from brucellosis is considered if a surveillance program has been in place throughout a country/zone/compartiment that demonstrates with 95% confidence limits for at least three years freedom from disease in 99.8% or more of herds tested.
- Vaccination must be done in accordance with the OIE *Terrestrial Manual*.
- A country/zone/compartiment can be free *with* vaccination as it is recognized that infection will be revealed by serological tests.
- It is possible for disease free, vaccination free zones/compartiments can exist within a vaccination program of a larger area.
- It is recognized that freedom from disease with vaccination is not equal to freedom without vaccination. It is, however, feasible to have a vaccinated population free from disease.
- It is also recognized that rules distinguishing freedom from disease with or without vaccination are necessary for trade purposes.
- Recertification of herds after a break in infection may be accomplished in six months, not 3 or 12 months as suggested.
- Movement from freedom with vaccination to freedom without vaccination can be accomplished in three years post vaccination.
- A number of other points are included in the revised Chapter.

## 2. Other matters

The *Ad hoc* Group was asked to provide scientific guidance to the FAO-Tajikistan brucellosis program. The considerations and recommendations are appended ([Appendix III](#)).

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.../Appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON BRUCELLOSIS**  
**Paris, 8–9 February 2007**

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**Agenda**

1. Review of Chapter 2.3.1. - Bovine Brucellosis in the OIE *Terrestrial Animal Health Code*
  2. Other matters
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**MEETING OF THE OIE AD HOC GROUP ON BRUCELLOSIS**  
**Paris, 8–9 February 2007**

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**List of Participants**

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Appendix III**BRUCELLOSIS PROGRAMME TAJIKISTAN***Comments of the ad hoc Group on Brucellosis 8-9 February, 2007*

- An introduction providing information on the current epidemiological situation is required
  - Vaccine and vaccination, as well as diagnostics should be in accordance with the recommendations of the *Manual of Diagnostics and Vaccines for Terrestrial Animals*
  - *Mass vaccination*: Only vaccination of young replacement animals is recommended. Vaccination of adult animals is scientifically and economically not recommended, especially in view of the brucellosis prevalence stated in the target area and the limited size of the population to be vaccinated. Consideration could be given to vaccination of adult animals on a very limited basis, under well defined epidemiological and logistic conditions. There is no need to vaccinate animals twice, considering the average life span of small ruminants and the long lasting protective immunity achieved by the vaccine. The Group concluded that it would be helpful to receive more scientific evidence of incidents or countries where the application of such a mass vaccination strategy actually achieved satisfactory results.
  - Marking of animals to recognize them as vaccinated is a critical prerequisite.
  - Quality of laboratory performance and personnel should be ensured. Education of field personnel and adequate information of farmers should also be ensured, in an integrated way through the veterinary services and human health services. Public education on risks of brucellosis should be encouraged to minimize human infections.
  - Inclusion of cattle in the vaccination programme: In general the section on brucellosis in cattle would need redrafting; addressing all the specific issues, as specified in the goat and sheep section. Emphasis should be given to a) *Brucella* species concerned; b) appropriate vaccination scheme, in compliance with the recommendations of the *Manual of Diagnostics and Vaccines for Terrestrial Animals*
  - A case definition of brucellosis for all hosts involved in the programme (including humans) is a prerequisite
  - A description of the planned surveillance system should be included. Elaborating the surveillance system, reference should be made to provisions of the *Terrestrial Animal Health Code*.
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**OIE AD HOC GROUP FOR EVALUATION OF COUNTRY STATUS  
FOR BOVINE SPONGIFORM ENCEPHALOPATHY IN ACCORDANCE  
WITH THE *TERRESTRIAL ANIMAL HEALTH CODE***

**Paris, 14–16 November 2006 and 9–11 January 2007**

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In two sessions, the meeting of the *Ad hoc* Group for evaluation of country submissions as complying with the 2006 bovine spongiform encephalopathy (BSE) Chapter of the *OIE Terrestrial Animal Health Code* (the *Terrestrial Code*) for recognition as ‘negligible BSE risk’ or ‘controlled BSE risk’ status was held at OIE headquarters from 14 to 16 November 2006 and 9 to 11 January 2007. The agenda and list of participants are provided as Appendices I and II, respectively. Prof. V. Caporale, President of the OIE Scientific Commission for Animal Diseases (SCAD), chaired the sessions and welcomed observers and members of the Group. Drs. M. Nunn (November 2006) and J. Kellar (January 2007) shared rapporteur responsibilities.

The OIE Director General, Dr B. Vallat welcomed the Group and briefly outlined the background to OIE’s involvement in standards for BSE, particularly recent developments resulting in the European Commission and Parliament agreeing to cease the Geographical BSE Risk (GBR) process and adopt the OIE classification of BSE status. He stressed that this development would lead to a significant increase in work by OIE, which has contracted Dr L. Knopf to work specifically on recognition of disease status.

Dr Vallat noted that four countries had previously been assessed as meeting the *Code* requirements for a status of ‘BSE free’ in accordance with the 2004 *Terrestrial Code* and that this status was current until May 2008 (provided ongoing surveillance continues in each country and the disease situation in each country remains the same). He indicated that care was needed to manage the transition of these countries’ assessments to the assessment under the new BSE Chapter. He outlined the process whereby SCAD would consider and endorse the recommendations of this Group at its meeting at the end of February 2007, followed by 60 days for comment by Delegates of Member countries, and then comment and adoption by the International Committee at the General Session in May 2007.

Dr G. Brückner, Head of the OIE Scientific and Technical Department, welcomed the Group and stressed the need for consistency of approach in assessing dossiers submitted for evaluation of BSE status against the BSE Chapter of the 2006 *Terrestrial Code*. At the time of the November 2006 session, he noted that a delegation had arrived from Brazil and asked that the Group meet with it during the course of that session.

The Group explored in detail how it would evaluate dossiers against the new Chapter. With guidance from Prof. Caporale, it compared and contrasted all of the dossiers received before making formal evaluations against the BSE Chapter of the 2006 *Terrestrial Code*. Prof. Caporale stressed the need for strict confidentiality concerning the deliberations of the Group, noting that all dossiers remained confidential as did the discussions, the *Ad hoc* Group’s notes, and any preliminary evaluations and recommendations (which could not be finalised until after consideration by the Scientific Commission and final adoption by the International Committee at the General Session in May 2007, as Dr Vallat had outlined in his introduction).

During consideration of the dossiers, to avoid any actual or perceived conflict of interest, members whose own countries were being evaluated withdrew themselves from assessment of those respective submissions.

This report includes a section on technical comments, clearly differentiated from the evaluations made against the BSE chapter of the 2006 *Terrestrial Code*. The *Ad hoc* Group experienced challenges in evaluating the country dossiers. It agreed that this section is needed to highlight to the Scientific Commission (SCAD) and the International Committee a number of technical issues and concerns around which those challenges revolved.

## 1. Technical comments

### 1.1. Evaluation of BSE status in the context of broader considerations

The Group evaluated BSE status in the context of broader considerations, particularly the influence of other Chapters of the *Terrestrial Code*. It noted that in considering the recommendations of the Group's October 2005 meeting, SCAD had taken into account interpretations arising from other Chapters of the *Terrestrial Code*, in particular, the Chapters on surveillance, risk analysis, and evaluation of veterinary services.

The Group acknowledged that SCAD's consideration of this broader context (and related guidance to the Commission by the Director General) reflected the desire of SCAD for flexibility in interpretation of the Code and related documents — taking into account the experience, expertise and judgement of its own members and those of its *Ad hoc* Groups. As demonstrated by the interpretation of the SCAD of 2005 country submissions, this position reflects the complexity of the work undertaken and the inadequacy of following what would otherwise be an automatic 'checklist' approach.

The Group agreed that if the process detected an apparent inconsistency between any part of the *Terrestrial Code* Chapter on BSE, the risk assessment guidelines and the questionnaire on BSE status, the Chapter would rule. It was agreed that if any apparent inconsistency were detected, the Group would, through its chair, formally advise SCAD and propose a possible means to resolve the situation.

### 1.2. Dossier allocations among Group members

The Group noted that a system of allocating – electronically, in advance of the meeting — specific dossiers for detailed review and presentation by particular members of the Group worked quite well. If feasible, it is preferable that two members review each dossier in parallel, as each member brings different skills and experience that ensure a more thorough review and preliminary evaluation than if only one member were so assigned.

It was also noted that in some cases, particularly with any country that had provided abbreviated information for evaluation to confirm a BSE status that had previously been evaluated and endorsed, reference needed to be made to previous dossiers from that country. New members of the Group who had not been involved in evaluating the initial dossier from such a country did not always have information sufficient to support an evaluation to confirm a country's previously endorsed status.

There is thus a need for the OIE Secretariat to make available, for reference at each meeting of the Group, hard and electronic copies of previous dossiers and related correspondence for each country being evaluated. This need will be compounded as the number of countries submitting dossiers for evaluation of their BSE status increases.

### 1.3. Importance of ensuring that dossiers adhere to format of the BSE status questionnaire

The Group noted that the evaluation of BSE status against the requirements of the *Terrestrial Code* was greatly facilitated when dossiers presented information exactly as requested and in the format of the questionnaire. Dossiers received represented varying degrees of compliance with that standard. The fact that multiple countries adhered fully reflected the clarity of the guidance provided to submitters.

The Group cautioned that in some cases in which dossiers did not comply with the questionnaire format, submitters might be omitting information that would increase the likelihood of a favourable evaluation. The Group recommended that future correspondence stress to Delegates the importance of closely and fully following the template provided in the questionnaire.

#### 1.4. Importance of submitting dossiers electronically and on time

The Group echoed the concerns of its Chairman regarding evaluation inefficiencies caused by tardy submissions. The pre-meeting assignment of dossiers among members depends on both the scheduled arrival and receipt of dossiers in electronic format. The Group noted that the early distribution of dossiers before meetings helped to ensure that members were well prepared and that the face-to-face meetings were efficient. Having voluminous dossiers in electronic format (particularly as Adobe .pdf files) greatly facilitates their distribution to members. The Group encourages the OIE Secretariat to reiterate in future correspondence to Delegates that all components (reports and attachments) of dossiers be submitted on time in electronic form.

#### 1.5. Transition to the new evaluative process

Neither the Group nor submitters appeared challenged by the transition to BSE status evaluation based on the 2006 *Terrestrial Code* and the associated questionnaire template. Technical points raised in this report are considered administrative in nature as opposed to reflecting on the process itself. The greater definition and objectivity in terms of information sought regarding key BSE programme elements and the guidance received from SCAD since 2005 have facilitated the transition.

#### 1.6. Responding to incomplete dossiers

In the spirit of the flexibility that governs the current evaluative process, the Group sought additional information and clarification from submitters when dossiers were considered incomplete upon initial review. Where applicable, questions were directed in writing to Delegates, except for two occasions on which representatives were on hand to receive the enquiries directly. The latter approach proved inefficient and the Group endorses the Chairman's position that written correspondence be the norm for such exchanges.

As an adjunct to the above process, the Group agreed to accept other relevant information (e.g. from GBR, Eurostat, FAO) when available and advisable to supplement — but not replace — that included in otherwise incomplete dossiers. It also agreed that it should specifically cite the source of any additional information used and note this in its report to the relevant Delegate whenever this is done.

#### 1.7. The appropriate period for the risk assessment

The *Ad hoc* Group notes an apparent inconsistency between the risk assessment guidelines and the questionnaire on recognition of BSE status with regard to the period to be scrutinized for imports of both animals and meat-and-bone meal. Seven and eight years, respectively, are specified in the questionnaire but not in the risk assessment guidelines. The *Ad hoc* Group notes that the *Terrestrial Code* itself does not limit the period.

In deference to the *Terrestrial Code* and reflecting on the world experience in the demographics of animal and meat-and-bone meal movements from infected countries in the 1990s, the *Ad hoc* Group recommends that the period in the questionnaire be specified as a minimum of 14 years, reflecting about twice the 95th percentile of the estimated incubation period, about three times the average incubation period, and a reasonable average maximum lifetime for cattle.

The recommended modification does not negatively affect any of the submissions received.

#### 1.8. Assessment of feed ban effectiveness

The Group explored the interpretation of what constitutes an appropriate level of control and audit, especially in countries in which BSE had occurred. The Group approached this issue in the spirit of flexibility advocated by SCAD as alluded to earlier in this report. Within each submission, feed ban findings were judged on their own merit and in conjunction with those of the associated risk assessment and surveillance applications. To ensure consistency in evaluation among countries, the Group compared and contrasted summary information from all submissions. Although applauding the efforts undertaken by countries, the Group noted among submissions that feed-testing programmes predicated on detection of only elevated thresholds of contamination (0.5% or 1.0%), although sensitive to deliberate violations, are unlikely to detect inadvertent cross-contamination.

Since the inception of the BSE Chapter, risk assessment and surveillance results have served as the key points of reference in assessment of the underlying BSE prevalence of a country. The current assessment process marked the first time that detailed surveillance findings — on an age cohort basis facilitated by the BSurvE model — were reviewed in terms of the additional contribution that they might also make towards gauging the apparent effectiveness of a feed ban.

### 1.9. Assessment of surveillance adequacy

Assessment of several countries showed that they clearly merited an evaluation of better than ‘undetermined BSE risk’, although their surveillance programmes had not yet accumulated the target number of surveillance points formally required for designation as ‘controlled BSE risk’. In acknowledgement of the evolution in surveillance guidance in the *Terrestrial Code* over time, the Group approached this issue in the spirit of flexibility advocated by SCAD as alluded to earlier in this report. To encourage countries to strive to improve their surveillance and progress towards a higher BSE status, the Group developed the following draft paragraph. The Group recommends that it be included in evaluation reports provided to Delegates of countries that have not yet met the target number of surveillance points but that are clearly striving to implement surveillance and risk mitigation measures to improve their BSE status:

*A review of your dossier indicates that the trend in the number of surveillance points described is approaching the target number for designation as [Controlled BSE Risk OR Negligible BSE Risk] for the size of your country’s adult cattle population in accordance with the surveillance requirements specified in Appendix 3.8.4. Designation of your country as [Controlled BSE Risk OR Negligible BSE Risk] took into consideration this trend, in the light of the risk assessment and mitigation measures undertaken, despite the fact that you have not yet attained the target number of surveillance points formally required. For OIE to confirm this positive trend is continuing [OR that the target has been attained] you are reminded that you should ensure that your annual report includes specific details of your annual surveillance. These details should be provided in the format of Table 3.6 in Section 3 of the questionnaire on recognition of BSE status.*

### 1.10. Ongoing surveillance requirements

The Group examined Appendix 3.8.4 and the (unofficial draft) record of the last meeting of the *Ad hoc* Group on Epidemiology in relation to ongoing surveillance requirements. It considered and further interpreted this information to develop the following draft paragraph for inclusion, where relevant, in reports to Delegates:

*A review of your dossier indicates that your country has met the surveillance requirements for designation as [‘Controlled BSE Risk’ OR ‘Negligible BSE Risk’] for the size of your country’s adult cattle population in accordance with the surveillance requirements specified in Appendix 3.8.4. The retention of such status depends in part on the continuing accumulation of surveillance points.*

*To continue to designate the status of a country as ‘Negligible BSE Risk’, in reference to Appendix 3.8.4, the continuing surveillance requirement becomes that of level B. To continue to designate the status of a country as ‘Controlled BSE Risk’, in reference to Appendix 3.8.4, once seven years of surveillance has been undertaken at level A, the continuing surveillance requirement may be reduced to that required under level B (provided all other indicators remain positive).*

*In both instances, to continue to conform with the requirements of Appendix 3.8.4, ongoing annual surveillance must continue to include all clinical cases and at least three of the four prescribed subpopulations must continue to be sampled. It is expected that surveillance in each succeeding year will contribute no less than one-seventh of the number of surveillance points required for designation as [‘Negligible BSE Risk’, OR ‘Controlled BSE Risk’ with Surveillance Level B].*

## 2. Country Evaluations

### 2.1. Canada

The submission from Canada sought assessment against the requirements for recognition as complying with the 2006 *Terrestrial Code*. The *Ad hoc* group noted that the country dossier from Canada followed the format recommended by OIE in the guidelines circulated for countries wishing to make a formal submission for evaluation of their BSE status against the requirements of the 2006 *Terrestrial Code*. During its evaluation, additional information was sought on a number of points, and the *Ad hoc* group acknowledges the cooperation of the Delegate of Canada in providing the additional details sought.

Points specifically noted by the *Ad hoc* group are summarized in the following discussion.

#### a) *Section 1: Risk Assessment — Article 2.3.13.2 point 1*

The *Ad hoc* group considered that a robust and comprehensive risk assessment had been undertaken, taking into account all known pathways of BSE exposure in accordance with the criteria specified in Article 2.3.13.2 point 1.

- *Risk assessment for introduction of the BSE agent*

Taking into account the free trade until 2003 between Canada and the United States, one or more of the importations of cattle from the United Kingdom and other BSE-affected countries to North America may have introduced the first generation of BSE to Canada.

- *Risk of recycling and amplification of the BSE agent*

A ruminant to ruminant feed ban came into force in 1997. According to the information provided, the rendering standards will in 60% of the total production of meat-and-bone meal lead to a reduction in infectivity. The *Ad hoc* group considered that the conclusion of the release assessment was that the absence of a feed ban before 1997, the partial implemented feed ban since 1997, and the absence of a prohibition on the use of specified risk material for animal feed allow the risk of recycling and amplification of the BSE agent within the country.

#### b) *Surveillance according to Appendix 3.8.4*

The *Ad hoc* group noted that the surveillance undertaken meets the minimum requirements of the type A surveillance according Article 3.8.4.3 of the Appendix 3.8.4. on surveillance for BSE in the 2006 *Terrestrial Code*.

#### c) *Other requirements — Article 2.3.13.2 points 2–4*

- *Awareness programme*

The *Ad hoc* group concluded that the awareness programme meets the requirements of the 2006 *Terrestrial Code*.

- *Compulsory notification and identification*

The *Ad hoc* group noted that BSE has been declared as a notifiable disease under relevant legislation since 1990 and concluded that the system for compulsory notification and investigation meets the requirements of the 2006 *Terrestrial Code*.

- *Laboratory examination*

The *Ad hoc* group noted that the arrangements for laboratory examination meet the minimum requirements of the 2006 *Terrestrial Code*.

- *Appropriate level of control and audit of the feed ban*

The *Ad hoc* group noted that the control of the proper implementation of the feed ban focused on the visual inspection of the rendering facilities and feed mill, particularly on those establishments producing ruminant materials. Following the first case of BSE in 2003, additional resources have been made available to the feed inspection programme. Beginning in the summer of 2005, additional inspection staff was employed to facilitate an increase in the frequency of feed mill inspections. It is planned to move from an annual inspection programme to up to four times per year for facilities handling prohibited material, particularly those that also make ruminant feed.

Each inspection involves a rigorous onsite assessment of a number of feed ban related tasks depending on whether the mill handles both prohibited and non prohibited material and makes ruminant feed or not, or whether it is dedicated to handling non-prohibited material. Details were provided on the outcome of the control and audits.

**d) Compliance with conditions for ‘Controlled BSE Risk’ status — Article 2.3.13.4**

**e) Conclusions**

- *Recommended status*

Taking into account the outcome of the risk assessment and the information provided on other requirements, it is the recommendation of the *Ad hoc* Group that Canada be regarded as having met the requirements for recognition as complying with the 2006 BSE Chapter of *Terrestrial Code* as ‘Controlled BSE Risk’.

- *Comments to Member Country by Scientific Commission*

- Status

Taking into account the limited capacity of the rendering practices within Canada to reduce the infectivity, the ruminant to ruminant feed ban, the absence of sampling and testing in the framework of the control and audit of the feed ban, the proper implementation of the feed ban — documented in detail — will be a key factor in maintaining the ‘Controlled BSE Risk’ status of the country.

- Annual update — specific requirements

The Delegate of Canada is invited to provide updates on the control and audit of the feed ban provisions and the data on the surveillance efforts in 2006.

Despite some reasonable gains in compliance rates with the feed ban there is still room for improvement. Although increased inspections will assist in raising the level of compliance further, as long as potentially infective material continues to be rendered and enter the animal feed chain there remains the potential for cross-contamination.

The likelihood of such events can be eliminated by excluding specified risk material from the animal feed chain. From July 2007, all specified risk material will be banned from animal feed, pet food and fertilizer. It is recommended that Canada carefully consider sampling and testing within the framework of control and audit of the implementation of the feed ban rules.

- Specific comments with regard to the submitted dossier

The submitted dossier was according to the questionnaire and the information was sufficient to carry out the evaluation of the requirements for recognition as complying with the 2006 *Terrestrial Code*.

## 2.2. New Zealand

The submission from New Zealand sought assessment against the requirements for recognition as complying with the 2006 *Terrestrial Code*. The *Ad hoc* group noted that the country dossier from New Zealand generally followed the format recommended by OIE in the guidelines circulated for countries wishing to make a formal submission for evaluation of their BSE status against the requirements of the 2006 *Terrestrial Code*. During its evaluation, additional information was sought on a number of points, and the *Ad hoc* group acknowledges the cooperation of the Delegate of New Zealand in providing the additional details sought.

Points specifically noted by the *Ad hoc* group are summarised in the following discussion.

### a) *Section 1: Risk Assessment — Article 2.3.13.2 point 1*

The *Ad hoc* Group considered that a robust and comprehensive risk assessment had been undertaken, taking into account all known pathways of BSE exposure in accordance with the criteria specified in Article 2.3.13.2 point 1.

- *Risk assessment for introduction of the BSE agent*

Based on the information provided, the *Ad hoc* Group considered that the conclusion of the release assessment was that there is a negligible risk that the BSE agent could have entered the country.

- *Risk of recycling and amplification of the BSE agent*

Based on the information provided, the *Ad hoc* Group considered that the conclusion of the exposure assessment was that there is a risk of recycling and amplification of the BSE agent if it were present in the country's cattle population.

### b) *Surveillance according to Appendix 3.8.4*

Based on the information provided, the *Ad hoc* Group concluded that the number of animals examined and the resulting points meet the minimum requirements of the 2006 *Terrestrial Code*.

### c) *Other requirements — Article 2.3.13.2 points 2–4*

- *Awareness programme*

The *Ad hoc* Group concluded that the awareness programme meets the requirements of the 2006 *Terrestrial Code*.

- *Compulsory notification and identification*

The *Ad hoc* Group noted that BSE has been declared as a notifiable disease under relevant legislation since 1993 and concluded that the system for compulsory notification and investigation meets the requirements of the 2006 *Terrestrial Code*.

- *Laboratory examination*

The *Ad hoc* Group concluded that the arrangements for laboratory examination meet the requirements of the 2006 *Terrestrial Code*.

- *Appropriate level of control and audit of the feed ban*

The *Ad hoc* Group concluded that it could be demonstrated that for at least eight years no meat-and-bone meal or greaves had been fed to ruminants.

**d) Compliance with Conditions for 'BSE negligible risk' Status - Article 2.3.13.3**

Taking into account the outcome of the risk assessment, the surveillance and the information provided on other requirements, it is the recommendation of the *Ad hoc* Group that New Zealand be regarded as meeting the requirements for recognition as complying with the 2006 *Terrestrial Code* as 'negligible BSE risk'.

**e) Conclusions**

- *Recommended status*

The *Ad hoc* Group recommends that New Zealand be regarded as meeting the requirements for recognition as complying with the 2006 *Terrestrial Code* as 'Negligible BSE Risk'.

- *Comments to Member Country by Scientific Commission*

- Status

The *Ad hoc* Group recommends that New Zealand be regarded as meeting the requirements for recognition as complying with the 2006 *Terrestrial Code* as 'Negligible BSE Risk'.

- Annual update — specific requirements

Although the *Ad hoc* Group concluded that it could be demonstrated that for at least eight years no meat-and-bone meal or greaves had been fed to ruminants, the quality of the feed control could be optimised. Testing of feed to detect only a level of contamination of more than 1% can only detect deliberate violations and not contaminations due to cross-contamination. Therefore, in the annual update an enhanced feed control should be demonstrated.

- Specific comments with regard to the submitted dossier

The submitted dossier was according to the questionnaire and the information was sufficient to carry out the evaluation of the requirements for recognition as complying with the 2006 *Terrestrial Code*.

**2.3. Taipei-China**

The submission from Taipei-China sought assessment against the requirements for recognition as complying with the 2006 *Terrestrial Code*. The *Ad hoc* group noted that the country dossier from Taipei-China followed the format recommended by OIE in the guidelines circulated for countries wishing to make a formal submission for evaluation of their BSE status against the requirements of the 2006 *Terrestrial Code*. During its evaluation, additional information was sought on a number of points, and the *Ad hoc* group acknowledges the cooperation of the Delegate of Taipei-China in providing the additional details sought.

Points specifically noted by the *Ad hoc* group are summarised in the following discussion.

**a) Section 1: Risk Assessment — Article 2.3.13.2 point 1**

The abstract of the Quantitative Risk Assessment performed to assess the BSE status of Taipei-China as of 2004 was made available in one of OIE's official languages. Although the method used would appear standard and the findings suggest a low probability of BSE evolving, the *Ad hoc* Group had access to neither the full text of the paper nor the key assumptions on parameters from which the probability assessments derived. Documentation otherwise provided within the questionnaire from Taipei-China suggested that the study had considered all known pathways of BSE exposure in accordance with the criteria specified in Article 2.3.13.2 point 1.

- *Risk assessment for introduction of the BSE agent*

Based on the information provided regarding importation of considerable quantities of commodities from countries subsequently affected with BSE, the *Ad hoc* Group considered that the conclusion of the release assessment was that there is a risk that the BSE agent could have entered the country, notwithstanding the commendable efforts undertaken by Taipei-China to preclude that event.

- *Risk of recycling and amplification of the BSE agent*

Based on the information provided regarding the continued use of specified risk material in animal feed, the absence of evidence regarding reduction of contamination during the rendering process, the possibility of cross-contamination in some production lines, and the limited sensitivity threshold of sampling procedures applied to feed to detect such possibilities, the *Ad hoc* Group considered that the conclusion of the exposure assessment was that there was a decreasing risk of recycling and amplification of the BSE agent if it were present in the country's cattle population.

**b) *Surveillance according to Appendix 3.8.4.***

Based on the information provided, the *Ad hoc* Group concluded that the number of animals examined and the resulting points are progressing toward meeting the minimum requirements of the 2006 *Terrestrial Code*.

**c) *Other requirements — Article 2.3.13.2 points 2–4***

- *Awareness programme*

The *Ad hoc* Group concluded that the awareness programme meets the requirements of the 2006 *Terrestrial Code*.

- *Compulsory notification and identification*

The *Ad hoc* Group noted that BSE has been declared a notifiable disease under relevant legislation since 1990 and concluded that the system for compulsory notification and investigation meets the requirements of the 2006 *Terrestrial Code*.

- *Laboratory examination*

The *Ad hoc* Group concluded that the arrangements for laboratory examination meet the requirements of the 2006 *Terrestrial Code*.

- *Appropriate level of control and audit of the feed ban*

Although commending the efforts of Taipei-China in respect of considerable regulatory and operational progress achieved, the *Ad hoc* Group concluded that it could not be demonstrated that for at least eight years no meat-and-bone meal or greaves had been fed to ruminants.

**d) *Compliance with conditions for 'Controlled BSE Risk' status — Article 2.3.13.4***

Taking into account the outcome of the risk assessment, the surveillance and the information provided on other requirements, it is the recommendation of the *Ad hoc* Group that Taipei-China be regarded as meeting the requirements for recognition as complying with the 2006 *Terrestrial Code* as 'Controlled BSE Risk'.

**e) Conclusions**

▪ *Recommended status*

The *Ad hoc* Group recommends that Taipei-China be regarded as meeting the requirements for recognition as complying with the 2006 *Terrestrial Code* as 'Controlled BSE Risk'.

▪ *Comments to Member Country by Scientific Commission*

- Status

The *Ad hoc* Group recommends that Taipei-China be regarded as meeting the requirements for recognition as complying with the 2006 *Terrestrial Code* as 'Controlled BSE Risk'.

- Annual update — specific requirements

A review of the dossier indicates that the trend in the number of surveillance points described is approaching the target number for designation as 'Controlled BSE Risk' for the size of Taipei-China's adult cattle population in accordance with the surveillance requirements specified in Appendix 3.8.4. Designation of Taipei-China as 'Controlled BSE Risk' took into consideration this trend, in the light of the risk assessment and mitigation measures undertaken, despite the fact that the target number of surveillance points formally required has not been attained. For OIE to confirm this positive trend is continuing, the annual report should include specific surveillance details in the format of Table 3.6 in Section 3 of the questionnaire on recognition of BSE status.

- Specific comments with regard to the submitted dossier

The submitted dossier was according to the questionnaire and the information was sufficient to carry out the evaluation of the requirements for recognition as complying with the 2006 *Terrestrial Code*.

**2.4. United States**

The submission from the United States sought assessment against the requirements for recognition as complying with the 2006 *Terrestrial Code*. The *Ad hoc* group noted that the country dossier from the United States followed the format recommended by OIE in the guidelines circulated for countries wishing to make a formal submission for evaluation of their BSE status against the requirements of the 2006 *Terrestrial Code*. During its evaluation, additional information was sought on a number of points, and the *Ad hoc* group acknowledges the cooperation of the Delegate of the United States in providing the additional details sought.

Points specifically noted by the *Ad hoc* group are summarised in the following discussion.

**a) Section 1: Risk Assessment — Article 2.3.13.2 point 1**

The *Ad hoc* group considered that a robust and comprehensive risk assessment had been undertaken, taking into account all known pathways of BSE exposure in accordance with the criteria specified in Article 2.3.13.2 point 1.

▪ *Risk assessment for introduction of the BSE agent*

The ban on imported products from BSE-affected countries was not absolute. Taking into account the free trade until 2003 between the United States and Canada, one or more of the importations from cattle imported from the United Kingdom and other BSE-affected countries to North America may have introduced the first generation of BSE to the United States.

- *Risk of recycling and amplification of the BSE agent*

Since 1997, the United States prohibits the use of meat-and-bone meal (except poultry origin and pure porcine or equine meat-and-bone meal) in ruminant feed. The *Ad hoc* group considered that the conclusion of the release assessment was that the absence of a feed ban before 1997, the partial implemented feed ban since 1997 (potential cross-contamination, limited number of samples taken to control the implementation of the feed ban), and the absence of a prohibition on the use of specified risk material for animal feed allow the risk of recycling and amplification of the BSE agent within the country.

**b) *Surveillance according to Appendix 3.8.4***

The *Ad hoc* group noted that the surveillance undertaken meets the minimum requirements of the type A surveillance according Article 3.8.4.3 of the Appendix 3.8.4 on surveillance for BSE in the 2006 *Terrestrial Code*.

**c) *Other requirements — Article 2.3.13.2 points 2–4***

- *Awareness programme*

The *Ad hoc* group concluded that the awareness programme meets the requirements of the 2006 *Terrestrial Code*.

- *Compulsory notification and identification*

The *Ad hoc* group noted that BSE has been declared as a notifiable disease under relevant legislation since 1986 and concluded that the system for compulsory notification and investigation meets the requirements of the 2006 *Terrestrial Code*.

- *Laboratory examination*

The *Ad hoc* group noted that the arrangements for laboratory examination meet the minimum requirements of the 2006 *Terrestrial Code*.

- *Appropriate level of control and audit of the feed ban*

The *Ad hoc* group noted that the control of the proper implementation of the feed ban focused mainly on the visual inspection of the rendering facilities and feed mill focusing on those establishments producing ruminant materials and a feed testing programme. The feed testing programme for domestically produced product did not begin until 2004. Details were provided on the outcome of the control and audits.

**d) *Compliance with Conditions for ‘Controlled BSE Risk’ Status — Article 2.3.13.4***

**e) *Conclusions***

- *Recommended status*

Taking into account the outcome of the risk assessment and the information provided on other requirements, it is the recommendation of the *Ad hoc* Group that the United States be regarded as having met the requirements for recognition as complying with the 2006 BSE Chapter of *Terrestrial Code* as ‘Controlled BSE Risk’

- *Comments to Member Country by Scientific Commission*

- Status

Taking into account the ruminant to ruminant feed ban, the potential of cross-contamination, the use of specified risk material in animal feed, the limited sampling and testing in the framework of the control and audit of the feed ban since 2004, the proper implementation of the feed ban, documented in detail, will be a key factor in maintaining the ‘Controlled BSE Risk’ status of the country.

- Annual update — specific requirements

The Delegate of the United States is invited to provide updates on the control and audit of the feed ban provisions and the data on the surveillance efforts in 2006.

- Specific comments with regard to the submitted dossier

Despite some reasonable gains in compliance rates of the feed ban, there is still room for improvement. Although increased inspections will assist in raising the level of compliance further, as long as potentially infective material continues to be rendered and enter the animal feed chain the potential for cross-contamination is still present. The likelihood of such events can be eliminated by excluding specified risk material from the animal feed chain.

It is recommended that the United States carefully consider excluding specified risk material from use in animal feed.

## 2.5. Brazil

The submission from Brazil sought assessment against the requirements for recognition as complying with the 2006 *Terrestrial Code*. The *Ad hoc* group noted that the country dossier from Brazil did not follow the format recommended by OIE in the guidelines circulated for countries wishing to make a formal submission for evaluation of their BSE status against the requirements of the 2006 *Terrestrial Code*. However, most of the information that had been sought through these guidelines was provided in the country dossier and in responses to additional information sought on a number of points. The *Ad hoc* group acknowledges the cooperation of the Delegate of Brazil in providing the additional details sought.

Points specifically noted by the *Ad hoc* group are summarised in the following discussion.

### a) *Section 1: Risk Assessment — Article 2.3.13.2 point 1*

The *Ad hoc* Group noted that the country dossier included as an annex a risk assessment that examined the risk of recycling and amplification of the BSE agent in Brazilian production systems. Given the information in the dossier and this annex, the Group considered that a robust and comprehensive risk assessment had been undertaken, taking into account all known pathways of BSE exposure in accordance with the criteria specified in Article 2.3.13.2 point 1.

- *Risk assessment for introduction of the BSE agent*

Based on the information provided regarding importation of considerable quantities of risk commodities from countries subsequently affected with BSE, the *Ad hoc* Group considered that the conclusion of the release assessment was that there is a risk that the BSE agent could have entered the country.

- *Risk of recycling and amplification of the BSE agent*

Based on the information provided regarding the continued use of some specified risk material in animal feed, the absence of evidence regarding reduction of contamination during the rendering process, the possibility of cross-contamination in some production lines, and the limited sensitivity threshold of sampling procedures applied to feed to detect such possibilities, the *Ad hoc* Group considered that the conclusion of the exposure assessment was that there was a decreasing risk of recycling and amplification of the BSE agent if it were present in the country's cattle population.

### b) *Surveillance according to Appendix 3.8.4.*

Based on the information provided, the *Ad hoc* Group concluded that the number of animals examined and the resulting points did not meet (but was progressing toward meeting) the minimum requirements of the 2006 *Terrestrial Code*.

**c) Other requirements — Article 2.3.13.2 points 2–4**

▪ *Awareness programme*

The *Ad hoc* Group concluded that the awareness programme meets the requirements of the 2006 *Terrestrial Code*.

▪ *Compulsory notification and identification*

The *Ad hoc* Group noted that BSE has been declared a notifiable disease under relevant legislation since 1997 and concluded that the system for compulsory notification and investigation meets the requirements of the 2006 *Terrestrial Code*.

▪ *Laboratory examination*

The *Ad hoc* Group concluded that the arrangements for laboratory examination meet the requirements of the 2006 *Terrestrial Code*.

▪ *Appropriate level of control and audit of the feed ban*

Although commending the efforts of Brazil in respect of considerable regulatory and operational progress achieved, the *Ad hoc* Group concluded that it could not be demonstrated that for at least eight years no meat-and-bone meal or greaves had been fed to ruminants.

**d) Compliance with conditions for ‘Controlled BSE Risk’ status — Article 2.3.13.4**

Taking into account the outcome of the risk assessment, the surveillance and the information provided on other requirements, it is the recommendation of the *Ad hoc* Group that Brazil be regarded as meeting the requirements for recognition as complying with the 2006 *Terrestrial Code* as ‘Controlled BSE Risk’.

**e) Conclusions**

▪ *Recommended status*

The *Ad hoc* Group recommends that Brazil be regarded as meeting the requirements for recognition as complying with the 2006 *Terrestrial Code* as ‘Controlled BSE Risk’.

▪ *Comments to Member Country by Scientific Commission*

- Status

The *Ad hoc* Group recommends that Brazil be regarded as meeting the requirements for recognition as complying with the 2006 *Terrestrial Code* as ‘Controlled BSE Risk’.

- Annual update — specific requirements

A review of the dossier indicates that the trend in the number of surveillance points described does not meet (but was progressing toward meeting) the target number for designation as ‘Controlled BSE Risk’ for the size of Brazil’s adult cattle population in accordance with the surveillance requirements specified in Appendix 3.8.4. Designation of Brazil as ‘Controlled BSE Risk’ took into consideration this trend, in the light of the risk assessment and mitigation measures undertaken, despite the fact that the target number of surveillance points formally required has not been attained. For OIE to confirm this positive trend is continuing, the annual report should include specific surveillance details in the format of Table 3.6 in Section 3 of the questionnaire on recognition of BSE status.

- Specific comments with regard to the submitted dossier

The Delegate of Brazil is invited, in future annual updates to OIE, to follow closely the format recommended by OIE in the guidelines circulated for countries wishing to make a formal submission for evaluation of their BSE status against the requirements of the *Terrestrial Code 2006*.

## 2.6. Singapore

The submission from Singapore sought assessment against the requirements for recognition as complying with the 2006 *Terrestrial Code*. The *Ad hoc* group noted that the country dossier from Singapore followed the format recommended by OIE in the guidelines circulated for countries wishing to make a formal submission for evaluation of their BSE status against the requirements of the 2006 *Terrestrial Code*.

Points specifically noted by the *Ad hoc* group are summarised in the following discussion.

### a) *Section 1: Risk Assessment — Article 2.3.13.2 point 1*

The *Ad hoc* group considered that a robust and comprehensive risk assessment had been undertaken, taking into account all known pathways of BSE exposure in accordance with the criteria specified in Article 2.3.13.2 point 1.

- *Risk assessment for introduction of the BSE agent*

MBMs, BMs, MMs, greaves and ruminant offal are imported only for human consumption.

No pet food is sent for cattle feeding. No cattle were imported from countries that have identified indigenous cases of BSE since 1983.

- *Risk of recycling and amplification of the BSE agent*

Since 2000, no abattoir for cattle and no rendering industry have existed. All condemned material and animal waste were incinerated. The *Ad hoc* group noted no recycling and amplification of the BSE agent in the country.

### b) *Surveillance according to Appendix 3.8.4.*

Surveillance is based on detection of clinically affected animals through detection of neurological signs. This plan was put into effect in 2001, with no BSE detected.

### c) *Other requirements — Article 2.3.13.2 points 2–5*

- *Awareness programme*

The *Ad hoc* group concluded that the awareness programme meets the requirements of the 2006 *Terrestrial Animal Health Code*.

- *Compulsory notification and identification*

The *Ad hoc* group noted that BSE has been declared a notifiable disease under relevant legislation since 1994 and concluded that the system for compulsory notification and investigation meets the requirements of the 2006 *Terrestrial Animal Health Code*.

- *Laboratory examination*

The *Ad hoc* group noted that the arrangements for laboratory examination meet the minimum requirements of the 2006 *Terrestrial Animal Health Code*.

- *Appropriate level of control and audit of the feed ban*

The *Ad hoc* group noted the appropriate control of the mammalian protein feed ban, focused on visual inspection of feed and implemented in 1997.

**d) Compliance with Conditions for 'BSE negligible risk' Status - Article 2.3.13.3**

Taking into account the outcome of the risk assessment and the information provided on other requirements, it is the recommendation of the *Ad hoc* Group that Singapore be regarded as having met the requirements for recognition as complying with the 2006 BSE Chapter of *Terrestrial Animal Health Code* as "Negligible BSE risk".

**e) Conclusions**

- *recommended status*

The *Ad hoc* Group recommends that Singapore be regarded as having met the requirements for recognition as complying with the 2006 *Terrestrial Code* as "Negligible BSE risk".

- *Comments to Member Country by Scientific Commission*

- Status (no comments)
- annual update, specific requirements (no comments)
- specific comments with regard to the submitted dossier

The Group recalled information provided in a previous dossier, indicating that Singapore has a separate Free Trade Zone (FTZ) through which considerable amounts of MBM are traded. A potential consequence of this is that other countries' dossiers in future may show imports of MBM as being imported from Singapore but that they would in fact have originated from other countries (possibly from some that have recorded cases of BSE) and were merely transhipped through Singapore's FTZ.

**2.7. Switzerland**

The submission from Switzerland sought assessment against the requirements for recognition as complying with the 2006 *Terrestrial Code*. The *Ad hoc* group noted that the country dossier from Switzerland followed the format recommended by OIE in the guidelines circulated for countries wishing to make a formal submission for evaluation of their BSE status against the requirements of the 2006 *Terrestrial Code*.

Points specifically noted by the *Ad hoc* group are summarised in the following discussion.

**a) Section 1: Risk Assessment — Article 2.3.13.2 point 1**

The *Ad hoc* group considered that a robust and comprehensive risk assessment had been undertaken, taking into account all known pathways of BSE exposure in accordance with the criteria specified in Article 2.3.13.2 point 1.

- *Risk assessment for introduction of the BSE agent*

Introduction of cattle into Switzerland during the interval 1990 to 2006 was mainly from France for immediate slaughter, with lesser numbers from other members of the EC and beyond. Annual totals varied between two and seven thousand head. During the same interval, MBM importations in tonnes varied from one to four thousand, mainly from France and Germany, with lesser numbers from other members of the EC and beyond. MBM is used for pig, poultry, lamb meal, and pet food. Greaves were imported from Germany and France. Beef was imported from South Africa and Brazil at an annual rate of five to twelve thousand tonnes during the same period.

- *Risk of recycling and amplification of the BSE agent*

An official ban was imposed on the feeding of mammalian protein to ruminants December 1, 1990. From 1996 to 2000, MBM was directed only to non-ruminants and fertilizer. The feed ban was extended to include all farm animals January 1, 2001. The *Ad hoc* group noted the effectiveness of the 2001 ban.

**b) *Surveillance according to Appendix 3.8.4.***

The *Ad hoc* group noted that the surveillance undertaken meets the minimum requirements of type A surveillance according to Article 3.8.4.3. of Appendix 3.8.4. on surveillance for BSE in the 2006 *Terrestrial Animal Health Code*.

**c) *Other requirements — Article 2.3.13.2 points 2–5***

- *Awareness programme*

The *Ad hoc* group concluded that the awareness programme meets the requirements of the 2006 *Terrestrial Animal Health Code*.

- *Compulsory notification and identification*

The *Ad hoc* group noted that BSE has been declared a notifiable disease under relevant legislation since 1990 and concluded that the system for compulsory notification and investigation meets the requirements of the 2006 *Terrestrial Animal Health Code*.

- *Laboratory examination*

The *Ad hoc* group noted that the arrangements for laboratory examination meet the minimum requirements of the 2006 *Terrestrial Animal Health Code*.

- *Appropriate level of control and audit of the feed ban*

The *Ad hoc* group noted that the control of the proper implementation of the feed ban focused on the visual inspection of feed mills, focusing on those establishments producing materials for ruminants. Cross-contamination in feed mills has been checked since 1997. From a level of contamination of over 22% from 1997 to 1999, the proportion of positive samples detected had declined to zero in 2004 and 2005.

**d) *Compliance with Conditions for ‘BSE controlled risk’ Status - Article 2.3.13.4***

Taking into account the outcome of the risk assessment and the information provided on other requirements, it is the recommendation of the *Ad hoc* group that Switzerland be regarded as having met the requirements for recognition as complying with the 2006 BSE Chapter of the *Terrestrial Animal Health Code* as “controlled BSE risk”.

**e) *Conclusions***

- *recommended status*

The *Ad hoc* group recommends that Switzerland be regarded as having met the requirements for recognition as complying with the 2006 *Terrestrial Code* as “controlled BSE risk”.

- *Comments to Member Country by Scientific Commission*

- status (no comments)
- annual update, specific requirements (no comments)
- specific comments with regard to the submitted dossier (no comments)

## 2.8. Uruguay

The submission from Uruguay sought assessment against the requirements for recognition as complying with the 2006 *Terrestrial Code*. The *Ad hoc* group noted that the country dossier from Uruguay closely followed the format recommended by OIE in the guidelines circulated for countries wishing to make a formal submission for evaluation of their BSE status against the requirements of the 2006 *Terrestrial Code*. The information provided was complete and clear.

Points specifically noted by the *Ad hoc* Group are summarised in the following discussion.

### a) *Section 1: Risk Assessment — Article 2.3.13.2 point 1*

The *Ad hoc* group considered that a robust and comprehensive risk assessment had been undertaken, taking into account the criteria specified in Article 2.3.13.2 point 1.

- *Risk assessment for introduction of the BSE agent*

No MBM and greaves were imported for the purpose of feeding ruminants, swine or poultry. Only 28 cattle were imported into Uruguay. They were from countries with very few cases: 24 from Canada (1999) and 4 from the U.S. (2001).

- *Risk of recycling and amplification of the BSE agent*

According to the information provided about the measures adopted, only two of the 28 imported animals could have entered the feed chain. Taking this and other measures into account, along with the fact that the use of mammalian protein for ruminants was banned in 1996, the *Ad hoc* group concluded that the risk of recycling and amplification of the BSE agent is negligible.

### b) *Surveillance according to Appendix 3.8.4.*

The *Ad hoc* group noted that the surveillance undertaken complies (Surveillance points 1999-2005: 204,476 points) with type B surveillance in accordance with Article 3.8.4.3. of Appendix 3.8.4. on surveillance for BSE in the 2006 *Terrestrial Animal Health Code*.

### c) *Other requirements — Article 2.3.13.2 points 2–4*

- *Awareness programme*

The *Ad hoc* group concluded that the awareness programme meets the requirements of the 2006 *Terrestrial Animal Health Code*.

- *Compulsory notification and identification*

The *Ad hoc* group noted that BSE has been declared a notifiable disease under relevant legislation since 1994 and concluded that the system for compulsory notification and investigation meets the requirements of the 2006 *Terrestrial Animal Health Code*.

- *Laboratory examination*

The *Ad hoc* group noted that the arrangements for laboratory examination meet the minimum requirements of the 2006 *Terrestrial Animal Health Code*.

- *Appropriate level of control and audit of the feed ban*

The *Ad hoc* group noted that the control and audit of the proper implementation of the feed ban demonstrates that neither meat and bone meal nor greaves derived from ruminants have been fed to ruminants

**d) Compliance with Conditions for 'BSE negligible risk' Status - Article 2.3.13.3**

Taking into account the outcome of the risk assessment and the information provided on other requirements, it is the recommendation of the *Ad hoc* Group that Uruguay be regarded as having met the requirements for recognition as complying with the 2006 BSE Chapter of the *Terrestrial Animal Health Code* as 'Negligible BSE risk'.

**e) Conclusions**

- *recommended status*

The *Ad hoc* Group recommends that Uruguay be regarded as having met the requirements for recognition as complying with the 2006 *Terrestrial Code* as 'Negligible BSE risk'.

- *Comments to Member Country by Scientific Commission*

- Status

The *Ad hoc* Group recommends that Uruguay be regarded as meeting the requirements for recognition as complying with the 2006 *Terrestrial Code* as 'negligible BSE risk'.

- annual update, specific requirements

Uruguay is invited to provide updates on the control and audit of the feed ban provisions and data on surveillance.

- specific comments with regard to the submitted dossier

The submitted dossier was according to the questionnaire and the information was sufficient to carry out the evaluation of the requirements for recognition as complying with the 2006 *Terrestrial Code*. The *Ad hoc* group notes the effort undertaken in order to present a very clear dossier.

**2.9. Chile**

The submission from Chile sought assessment against the requirements for recognition as complying with the 2006 *Terrestrial Code*. The *Ad hoc* group noted that the country dossier from Chile followed the format recommended by OIE in the guidelines circulated for countries wishing to make a formal submission for evaluation of their BSE status against the requirements of the 2006 *Terrestrial Code*. During its evaluation, additional information was sought on a number of points, and the *Ad hoc* group acknowledges the cooperation of Chile in providing the additional details sought.

Points specifically noted by the *Ad hoc* Group are summarised in the following discussion.

**a) Section 1: Risk Assessment — Article 2.3.13.2 point 1**

The *Ad hoc* group considered that a robust and comprehensive risk assessment had been undertaken, taking into account all known pathways of BSE exposure in accordance with the criteria specified in Article 2.3.13.2 point 1.

- *Risk assessment for introduction of the BSE agent*

In the last seven years only 9 live cattle have been imported (from U.S.) but they do not represent any risk since they have been quarantined. Meat and bone meal has been imported from Canada, Denmark and the U.S.

- *Risk of recycling and amplification of the BSE agent*

Taking into account the exposure assessment conducted on the disposition of imported meat and bone meal, the *Ad hoc* Group stated that the risk of recycling and amplification of the BSE agent within the country can be considered negligible.

**b) Surveillance according to Appendix 3.8.4.**

The *Ad hoc* group noted that the surveillance undertaken does not yet meet the minimum requirements of type A surveillance according to Article 3.8.4.3. of Appendix 3.8.4. on surveillance for BSE in the 2006 *Terrestrial Animal Health Code*. In recent years there has been significant improvement.

**c) Other requirements — Article 2.3.13.2 points 2–4**

- *Awareness programme*

The *Ad hoc* group concluded that the awareness programme meets the requirements of the 2006 *Terrestrial Animal Health Code*.

- *Compulsory notification and identification*

The *Ad hoc* group noted that BSE has been declared a notifiable disease under relevant legislation since 1996 and concluded that the system for compulsory notification and investigation meets the requirements of the 2006 *Terrestrial Animal Health Code*.

- *Laboratory examination*

The *Ad hoc* group noted that the arrangements for laboratory examination meet the minimum requirements of the 2006 *Terrestrial Animal Health Code*.

- *Appropriate level of control and audit of the feed ban*

The *Ad hoc* group noted that control of the proper implementation of the feed ban had been improved in 2005, reaching an appropriate level since that time.

**d) Compliance with Conditions for ‘BSE controlled risk’ Status - Article 2.3.13.4**

Taking into account the outcome of the risk assessment and the information provided on other requirements, it is the recommendation of the *Ad hoc* Group that Chile be regarded as having met the requirements for recognition as complying with the 2006 BSE Chapter of *Terrestrial Animal Health Code* as ‘controlled BSE risk’.

**e) Conclusions**

- *recommended status*

The *Ad hoc* Group recommends that Chile be regarded as having met the requirements for recognition as complying with the 2006 *Terrestrial Code* as ‘controlled BSE risk’.

- *Comments to Member Country by Scientific Commission*

- Status

Taking into account the fact that the use of MBM for ruminants was banned only in December 2000 and that surveillance has not met the minimum requirements of type A surveillance despite improvements in recent years, Chile meets the requirements of ‘controlled BSE risk’ status.

- Annual update, specific requirements

Chile is invited to provide updates on the control and audit of feed ban provisions and data on continuing surveillance efforts.

If improvements in these areas continue, Chile will reach “negligible BSE risk” status in the next two years.

- Specific comments with regard to the submitted dossier

The submitted dossier was in accordance with the questionnaire and the information was sufficient to carry out the evaluation of the requirements for recognition as complying with the 2006 *Terrestrial Code*.

## 2.10 Argentina

The second submission from Argentina sought assessment against the requirements for recognition as complying with the 2006 *Terrestrial Code* for negligible risk. The *Ad hoc* group noted that the country dossier from Argentina followed the format recommended by OIE in the guidelines circulated for countries wishing to make a formal submission for evaluation of their BSE status against the requirements of the 2006 *Terrestrial Code*.

Points specifically noted by the *Ad hoc* Group are summarised in the following discussion.

### a) *Section 1: Risk Assessment — Article 2.3.13.2 point 1*

- *Risk assessment for introduction of the BSE agent*

The *Ad hoc* Group considered that a robust and comprehensive risk assessment had been undertaken, taking into account all known pathways of BSE exposure in accordance with the criteria specified in Article 2.3.13.2 point 1.

Based on the information provided, the *Ad hoc* Group considered that the conclusion of the release assessment was that there is a negligible risk that the BSE agent could have entered the country.

- *Risk of recycling and amplification of the BSE agent*

Based on the information provided, the *Ad hoc* Group considered that the conclusion of the exposure assessment was that there is a negligible risk of recycling and amplification of the BSE agent if it were present in the country's cattle population.

### b) *Surveillance according to Appendix 3.8.4.*

Based on the information provided, the *Ad hoc* Group concluded that the number of animals examined and the resulting points meet the minimum requirements of the 2006 *Terrestrial Code*.

### c) *Other requirements — Article 2.3.13.2 points 2–5*

- *Awareness programme*

The *Ad hoc* Group concluded that the awareness programme meets the requirements of the 2006 *Terrestrial Code*.

- *Compulsory notification and identification*

The *Ad hoc* Group noted that BSE is a notifiable disease under relevant legislation. Based on the information provided, it is not clear when the disease became notifiable. Apparently it happened in 2003, under Resolution No. 10/03, but a Contingency Manual was established in 1998, laboratory testing of clinically suspect animals started in 1992 and the number of clinically suspected animals tested annually has stabilized at around 200-250 since 1997. Therefore, the Group concluded that the system for compulsory notification and investigation meets the requirements of the 2006 *Terrestrial Code*.

- *BSE monitoring and surveillance system*

The *Ad hoc* group noted that the monitoring and surveillance system meets the minimum requirements of the 2006 *Terrestrial Code*.

- *Laboratory examination*

The *Ad hoc* group noted that the arrangements for laboratory examination meet the minimum requirements of the 2006 *Terrestrial Code*.

- *Appropriate level of control and audit of the feed ban*

The *Ad hoc* Group concluded that it could be demonstrated that there has been a feed ban since 1995 (no MBM or greaves can be fed to ruminants); since 2002 there has been an official control programme, including inspection of feed mills and targeted monitoring to detect violations of the feed ban and possible cross-contamination with feed destined for non-ruminants.

**d) *Compliance with Conditions for 'BSE negligible risk' Status - Article 2.3.13.3***

Taking into account the outcome of the risk assessment and the information provided on other requirements, it is the recommendation of the *Ad hoc* group that Argentina be regarded as having met the requirements for recognition as complying with the 2006 BSE Chapter of the *Terrestrial Animal Health Code* as 'negligible BSE risk'.

**e) *Conclusions***

- *recommended status*

The *Ad hoc* Group recommends that Argentina be regarded as meeting the requirements for recognition as complying with the 2006 *Terrestrial Code* as 'negligible BSE risk'.

- *Comments to Member Country by Scientific Commission*

- status

The *Ad hoc* Group recommends that Argentina be regarded as meeting the requirements for recognition as complying with the 2006 *Terrestrial Code* as 'negligible BSE risk'.

- annual update, specific requirements

Argentina is invited to provide updates on the continuing control and audit of the feed ban provisions and the data on the surveillance efforts in 2006.

- specific comments with regard to the submitted dossier

The submitted dossier was according to the questionnaire and the information was sufficient to carry out the evaluation of the requirements for recognition as complying with the 2006 *Terrestrial Code*.

## **2.11. Australia**

The submission from Australia sought assessment against the requirements for recognition as complying with the 2006 *Terrestrial Code*. The *Ad hoc* group noted that the country dossier from Australia generally followed the format recommended by OIE in the guidelines circulated for countries wishing to make a formal submission for evaluation of their BSE status against the requirements of the 2006 *Terrestrial Code*. The dossier was well structured.

Points specifically noted by the *Ad hoc* group are summarised in the following discussion:

**a) *Section 1: Risk Assessment — Article 2.3.13.2 point 1***

The *Ad hoc* Group considered that a robust and comprehensive risk assessment had been undertaken, taking into account all known pathways of BSE exposure in accordance with the criteria specified in Article 2.3.13.2 point 1.

- *Risk assessment for introduction of the BSE agent*

Based on the information provided, the *Ad hoc* Group considered that the conclusion of the release assessment was that there is a negligible risk that the BSE agent could have entered the country.

- *Risk of recycling and amplification of the BSE agent*

Based on the information provided, the *Ad hoc* Group considered that the conclusion of the exposure assessment was that there is a risk of recycling and amplification of the BSE agent if it were present in the country's cattle population.

**b) *Surveillance according to Appendix 3.8.4***

Based on the information provided, the *Ad hoc* Group concluded that the number of animals examined and the resulting points meet the minimum requirements of the 2006 *Terrestrial Code*.

**c) *Other requirements — Article 2.3.13.2 points 2–4***

- *Awareness programme*

The *Ad hoc* Group concluded that the awareness programme conducted since 1994 meets the requirements of the 2006 *Terrestrial Code*.

- *Compulsory notification and identification*

The *Ad hoc* Group noted that BSE has been declared as a notifiable disease under relevant legislation since 1997 and concluded that the system for compulsory notification and investigation meets the requirements of the 2006 *Terrestrial Code*.

- *Laboratory examination*

The *Ad hoc* Group concluded that the arrangements for laboratory examination meet the requirements of the 2006 *Terrestrial Code*.

- *Appropriate level of control and audit of the feed ban*

The *Ad hoc* Group concluded that it could be demonstrated that for at least eight years no meat-and-bone meal or greaves had been fed to ruminants.

**d) *Compliance with Conditions for 'BSE negligible risk' Status - Article 2.3.13.3***

Taking into account the outcome of the risk assessment, the surveillance and the information provided on other requirements, it is the recommendation of the *Ad hoc* Group that Australia be regarded as meeting the requirements for recognition as complying with the 2006 *Terrestrial Code* as 'negligible BSE risk'.

**e) *Conclusions***

- *Recommended status*

The *Ad hoc* Group recommends that Australia be regarded as meeting the requirements for recognition as complying with the 2006 *Terrestrial Code* as 'Negligible BSE Risk'.

- *Comments to Member Country by Scientific Commission*

- Status

The *Ad hoc* Group recommends that Australia be regarded as meeting the requirements for recognition as complying with the 2006 *Terrestrial Code* as 'Negligible BSE Risk'.

- Annual update — specific requirements

No comments

- Specific comments with regard to the submitted dossier

The submitted dossier was according to the questionnaire and the information was clear and sufficient to carry out the evaluation of the requirements for recognition as complying with the 2006 *Terrestrial Code*.

## 2.12. Sweden

The participating experts of the *Ad hoc* Group concluded that the evaluation of Sweden's application could only be partly done due to relevant information not presented in chronological format and they resolved that it would result in deductions being made on assumptions of members of the Group. This would inevitably increase the likelihood of unjustified misinterpretation as the documentation provided by Sweden left too much room for different interpretations, making it very difficult to find the conclusive information for a definite BSE risk classification.

The *Ad hoc* Group also noted that the dossier ostensibly followed the BSE questionnaire, but the information sought by the questions was not answered in a concise way. The experts had to repeatedly search and interpret information in annexed BSE-related risk assessments reports or their updated versions, such as the GBR documentation. The GBR risk assessment follows another basic structure, compared to the OIE BSE questionnaire and provisions of the *Terrestrial Animal Health Code*.

The main document referred obtusely to EEC norms, instead of listing clear statements, as required by the questionnaire. In consequence the evaluators had to cautiously guess the dates of their coming into force (including the norm's revisions), but also as to when Sweden actually joined the EEC ranks. Although OIE encourages countries to provide relevant national legislation related to BSE with their application for BSE status evaluation, applications need to be submitted in one of the three official languages of the OIE (English, Spanish or French). An English summary of an important Swedish legislation document might be helpful.

Based on the conclusions of the *Ad hoc* Group, the submitted dossier was rejected and Sweden was advised to submit a revised version of its BSE dossier.

### Summary recommendations on countries' status

<b>14-16 November 2006</b>	<b>recommended status</b>
Chile	controlled risk
New Zealand	negligible risk
Argentina (original dossier)	<i>considered with new dossier</i>
Brazil	controlled risk
Singapore	negligible risk
USA	controlled risk
Taipei-China	controlled risk
Australia	negligible risk
<b>09-11 January 2007</b>	<b>recommended status</b>
Canada	controlled risk
Argentina (new dossier)	negligible risk
Sweden	<i>dossier rejected</i>
Uruguay	negligible risk
Switzerland	controlled risk

Appendix I

**OIE AD HOC GROUP FOR EVALUATION OF COUNTRY STATUS  
FOR BOVINE SPONGIFORM ENCEPHALOPATHY  
Paris, 14 – 16 November 2006 and 09-11 January 2007**

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**Agenda**

1. Review of new Country Status Applications for Bovine Spongiform Encephalopathy

09-11 January 2007

- Canada
- Argentina (new dossier)
- Sweden
- Uruguay
- Switzerland

14-16 November 2006

- Chile
- New Zealand
- Argentina (original dossier)
- Brazil
- Singapore
- USA
- Taipei-China
- Australia

2. Review (09-11 January 2007) of responses to questions raised during the 14-16 November review of Country Status Applications for Bovine Spongiform Encephalopathy

- Chile
- New Zealand
- Argentina
- Brazil
- Taipei-China
- USA

3. Discussions on the differing interim arrangements for country categorization procedures according to the BSE risk, EU and OIE position

4. Other matters

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## Appendix II

**OIE AD HOC GROUP FOR EVALUATION OF COUNTRY STATUS  
FOR BOVINE SPONGIFORM ENCEPHALOPATHY**

**Paris, 14 – 16 November 2006 and 9-11 January 2007**

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**REPORT OF THE OIE *AD HOC* GROUP ON COUNTRY STATUS EVALUATION  
FOR FREEDOM FROM RINDERPEST**

**Paris, 13-15 February 2007**

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A meeting of the *Ad hoc* Group on rinderpest was held at the OIE headquarters from 13 to 15 February 2007. The members of the Group were welcomed by Dr Gideon Brückner, Head of the Scientific and Technical Department. He outlined the important aspects on the provisional agenda and indicated that the Group should attempt to finalise the applications of Member Countries for freedom from rinderpest and then to finalise the draft Appendix 3.8.2 (Surveillance for rinderpest). He expressed the appreciation of the OIE for the excellent work done by the Group during its previous meeting. He informed the Group of the decision taken by the Scientific Commission for Animal Diseases during its meeting from 30 January to 2 February 2007, that applications of Member Countries will not be recommended for adoption by the International Committee if country information cannot be substantiated by regular disease and animal disease reports to the OIE Central Bureau. Dr Brückner apologised for the absence of the President of the Scientific Commission who could not attend due to other commitments as well as for the absence of Dr Shimsony who was unable to attend. It was agreed that Dr Anderson would act as Chairman and Dr Roeder as rapporteur.

The provisional agenda was adopted after the sequence of agenda items were reprioritised to first attend to country applications and then the revisions of the surveillance guidelines for rinderpest. The Agenda and list of participants are presented as Appendices I and II, respectively.

**1. Evaluation of country status for rinderpest disease freedom**

▪ **Ethiopia:** freedom from disease

After the previous *ad hoc* Group meeting and a joint FAO/OIE/AU-IBAR workshop held in Ghana (November 2006), Ethiopia requested to withdraw its application for freedom from infection, endorsed at the former meeting, and replace it with a request to be recognised as free from disease. This was done in the interests of maintaining harmonised progress with verification of rinderpest freedom in the Horn of Africa by coordinating submissions from Ethiopia and Kenya together with a declaration from Somalia in accordance with the joint GREP/IBAR effort to eradicate Rinderpest from the Somali Ecosystem. In fact the replacement dossier was a further improvement on the earlier dossier which had itself been well received.

**Recommendation:** the Group recommended that the application be accepted.

▪ **Iran:** freedom from disease

Iran declared provisional freedom for the whole country in June 2003 at which time it ceased to use rinderpest vaccine in cattle and buffalos. The dossier presented a persuasive case for freedom from rinderpest disease. However, the dossier states that rinderpest vaccine continued to be used in small ruminants for control of peste des petits ruminants until September 2004. In accordance with the current requirements of the *Terrestrial Code*, Iran can not be considered as eligible for recognition of the status of freedom from disease until September 2007.

**Recommendation:** After consultation with the Central Bureau, the Group concluded that the application had to be rejected but requested OIE to advise Iran that the country should resubmit their dossier for consideration in September 2007 and remind the veterinary authority of their OIE reporting obligation [currently in default].

- **Kenya:** freedom from disease

The dossier was judged to have been very well presented and was considered to present a convincing case for freedom from rinderpest disease, supported by the application from Ethiopia and a declaration of provisional freedom received from the Official Delegate of Somalia in mid-January. However, in accordance with the current requirements of the *Terrestrial Code*, Kenya is not yet eligible to be regarded free from disease because, by an oversight, provisional freedom was not declared to OIE for the infected and surveillance zones recognised by OIE in 2005 even though the change of status was reported to AU IBAR in 2006. If pursuing the full OIE Pathway, as it now stands, Kenya needs to make immediately a declaration of provisional freedom for the zone not already recognised in 2005 as free from disease. Eligibility for application for recognition of freedom from disease would then arise in 2010 and for freedom from infection in 2012 i.e. beyond the deadline for the completion of the Global Rinderpest Eradication Programme. Alternatively, under the existing provisions of the 'five year rule', Kenya could be considered eligible to apply for recognition of *freedom from disease* in December 2008, seven years after the last case of rinderpest was recognised and five years after the last use of vaccine. Introducing the proposed new *Terrestrial Code* Chapter would accelerate progress considerably (for all of the countries comprising the Somali Ecosystem).

**Recommendation:** After consultation with the Central Bureau, the Group concluded that the application had to be rejected and requested that OIE should notify Kenya of the reason why and invite a declaration of zonal provisional freedom before re-submission for recognition of freedom from rinderpest disease for the whole country in 2008. Provided that appropriate supportive serosurveillance results could be provided for 2008 and 2009 then an application for recognition of freedom from infection could be made in 2009.

- **Tajikistan:** freedom from disease

Tajikistan was considered to be eligible for recognition of freedom from disease by application of the 'five year rule'.

**Recommendation:** Pending the verification of submission of disease reports to the OIE Central Bureau, the Group recommended that the application be accepted.

## 2. Evaluation of country status for rinderpest infection freedom

- **Mozambique:** freedom from infection

Mozambique was judged to be eligible for recognition as free from rinderpest infection on a historical basis given rinderpest absence for at least 100 years and that rinderpest vaccine has never been used.

**Recommendation:** The Group recommended that the application be accepted.

## 3. Self-declaration of provisional rinderpest freedom in Somalia

The Group welcomed the declaration of provisional freedom made by the Official Delegate of Somalia on 15 January 2007 and noted that it was made for the whole country with the active consent of the authorities in Somaliland and Puntland. This self-declaration by Somalia will now be published on the OIE website.

#### 4. Other matters

- *Regional progress in rinderpest accreditation in Central Asia (Tajikistan, Turkmenistan, Uzbekistan, and Kyrgyzstan)*

Dr Roeder requested to clarify the situation of the Central Asian states which are members of an FAO regional project which, *inter alia*, is assisting countries to achieve accreditation of their status of rinderpest freedom achieved more than 50 years ago.

The issues relating to an application made to OIE by Tajikistan in 2005, but not finalised, were largely resolved by acceptance of the dossier re-presented for recognition of disease freedom.

The Group took note that the declaration of provisional freedom with respect to Uzbekistan has been published by OIE.

Dr Roeder from GREP provided the Group with the original and translation of a letter sent to OIE by the Turkmen authorities in August 2005 asking that the country was certified free from rinderpest. An answer letter informed the Turkmen Delegate on the minimal requirements to declare provisional freedom from rinderpest. Since this letter of August 2005, OIE did not receive any letters that might be related to the status of rinderpest from Turkmenistan. The Turkmen Delegate will be contacted by OIE for further inquiries.

Kyrgyzstan reported through the FAO project that it had submitted to OIE a request to be declared as free from rinderpest infection on the grounds that it had never experienced rinderpest nor used rinderpest vaccine. Copies of the application were not available to FAO nor could OIE trace any such application.

- *China*

The Group was informed that China has already prepared an application in 2005 for submission to OIE but that it never materialised. The Group requested that the Director General discuss this during his negotiations with the veterinary administration of China.

- *The issue of OIE reporting compliance and its impact on accreditation of rinderpest freedom*

During the process of examining the dossiers submitted to support requests for accreditation of rinderpest freedom (disease or infection), and subsequently, there was considerable discussion of the constraint proposed by the fact that applications, however meritorious, would be rejected by OIE unless countries had complied with the requirements of Chapter 1.1.2 of the *Terrestrial Code* (Notification of diseases and epidemiological information). The Group recommended that before dossiers are submitted to the Group for evaluation, compliance of the country with reporting obligations should be assessed as satisfactory. In the event of non-compliance the Group recommended that OIE should be pro-active in notifying and assisting countries to become compliant at least to the minimum extent required for applications to become acceptable.

- *Confirmation from Pakistan that the epidemiological situation remains unchanged since application in September*

The Group was informed that Pakistan has been requested to submit information of their animal disease status for at least 2005 to enable the acceptance of a recommendation from the Group during its previous meeting for freedom from infection.

#### 5. Review of the rinderpest questionnaire

The proposed rinderpest questionnaire was reviewed and amendments suggested to bring it in line with the proposed new *Terrestrial Code* Chapter ([Appendix III](#)).

## 6. Review of Appendix 3.8.2 on surveillance for rinderpest

A proposed appendix drafted by a member of the Group to be compatible with the proposed revised *Terrestrial Code* Chapter was reviewed and redrafted resulting in a final proposed document from the Group.

Comments and changes of the *ad hoc* Group for the Biological Standards Commission were inserted in the draft Chapter 2.02.12. of the *Terrestrial Manual* 2008.

The draft Appendix 3.8.2 accounts for the progress made in global rinderpest eradication and the changing clinical manifestations of rinderpest. Intensified and diversified surveillance activities are necessary to detect the last hidden foci, if present at all. The Group in reviewing the draft Appendix, also considered the recommendations from the joint FAO/AU-IBAR/OIE workshop on rinderpest accreditation held in Accra, Ghana, November 2006.

The Group emphasised that it is essential that both the revised Chapter and Appendix on surveillance guidelines need to be considered for adoption simultaneously as they are inter-dependent and neither can be changed alone.

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.../Appendices

Appendix I

**MEETING OF THE  
OIE AD HOC GROUP FOR EVALUATION OF COUNTRY STATUS  
WITH RESPECT TO RINDERPEST**

**Paris, 13 - 15 February 2007**

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**Agenda**

- 1. Review of Appendix 3.8.2. on Surveillance Systems for rinderpest from the OIE *Terrestrial Animal Health Code***
- 2. Review of the rinderpest questionnaire**
- 3. Evaluation of country status for rinderpest disease**
  - Ethiopia
  - Iran
  - Kenya
  - Tajikistan (supplementary information)
- 4. Evaluation of country status for rinderpest infection**
  - Mozambique (based on historical reasons)
- 5. Self declaration of provisional rinderpest freedom Somalia**
- 6. Other matters**
  - Regional progress in rinderpest accreditation Central Asia (Tajikistan, Turkmenistan, Uzbekistan and Kyrgyzstan)

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Appendix II

**MEETING OF THE  
OIE AD HOC GROUP FOR EVALUATION OF COUNTRY STATUS  
WITH RESPECT TO RINDERPEST**

**Paris, 13 – 15 February 2007**

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**List of participants**

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## Appendix III

## RINDERPEST INFECTION FREE COUNTRY

Report of Country which applies for recognition of status, under Chapter 2.2.12 and Appendix 3.8.2 of the *Terrestrial Animal Health Code*, as a rinderpest infection free country

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

### 1. Introduction

- 1.1. Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to rinderpest dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of disease. Provide a map identifying the factors above.
- 1.2. Livestock industry. Provide a general description of the livestock industry in the country.

### 2. Veterinary system

- 2.1. Legislation. Provide a list and summary of all relevant veterinary legislation in relation to rinderpest.
- 2.2. *Veterinary Services*. Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 1.3.3. and 1.3.4. of the *Terrestrial Code* and I.1.2 of the *Terrestrial Manual* and describe how the veterinary services supervise and control all rinderpest related activities. Provide maps and tables wherever possible.
- 2.3. Role of farmers, industry and other relevant groups in rinderpest surveillance and control (include a description of training and awareness programs on rinderpest)
- 2.4. Role of private veterinary profession in rinderpest surveillance and control

### 3. Rinderpest eradication

- 3.1. History. Provide a description of the rinderpest history in the country, date of first detection, origin of infection, date of eradication, lineage(s) present.
- 3.2. Strategy. Describe how rinderpest was controlled and eradicated (e.g. stamping-out, modified stamping-out, zoning), provide timeframe for eradication
- 3.3. Vaccines and vaccination. Was rinderpest vaccine ever used? If so, when was the last vaccination carried out? What species were vaccinated? Has heterologous vaccine been used in cattle, buffalo or yak?
- 3.4. Legislation, organisation and implementation of the rinderpest eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.
- 3.5. Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls.

#### 4. Rinderpest diagnosis

Provide evidence that a system is in place for the rapid confirmation of a suspected outbreak i.e. documentary evidence that the provisions in Chapters I.1.2 and 2.2.12.4.2 of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- 4.1. Is rinderpest laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to.
- 4.2. Provide an overview of the rinderpest approved laboratories, in particular to address the following points:
  - 4.2.1. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO etc. that exist in, or planned for, the laboratory system.
  - 4.2.2. Give details of participation in inter-laboratory validation tests (ring tests).
  - 4.2.3. Is live virus handled?
  - 4.2.4. Biosecurity measures applied
  - 4.2.5. Details of the type of tests undertaken

#### 5. Rinderpest surveillance

Provide documentary evidence that surveillance for rinderpest in the country complies with the provisions of Appendix 3.8.2. of the *Terrestrial Code* and Chapter 2.2.12.4.2 of the *Terrestrial Manual*. In particular, the following points should be addressed:

- 5.1. Clinical suspicion. What are the criteria for raising a suspicion of rinderpest? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for rinderpest virus, species, type of sample, testing method(s) and results (including differential diagnosis). In particular, provide evidence of compliance with the provisions of point paragraph 3.5. of Appendix 3.8.2 of the *Terrestrial Code*.
- 5.2. Serological surveillance. Are serological surveys conducted? If so, provide detailed information on the survey design in accordance with point paragraph 3 to 5 of Appendix 3.8.2 of the *Terrestrial Code*, (annual sample sizes shall be sufficient to provide 95% probability of detecting evidence of rinderpest if present at a prevalence of 1% of herds or other sampling units and 5% within herds or other sampling units). How frequently are they conducted? Are wildlife susceptible species included in serological surveys? If not, explain the rationale. Provide a summary table indicating, for the past two years, the number of samples tested for rinderpest virus, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow up actions taken on all suspicious and positive results.
- 5.3. Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many herds, flocks, etc., of each susceptible species are in the country? How are they distributed (e.g., herd density, etc.)? Provide tables and maps as appropriate.
- 5.4. Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?
- 5.5. Slaughterhouses and markets. Where are the major livestock marketing or collection centers? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions.

## 6. Rinderpest prevention

6.1. Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries that should be taken into account (e.g., size, distance from adjacent border to affected herds or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries.

6.2. Import control procedures

From what countries or zones does the country authorize the import of susceptible animals or their products? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or zone of origin, species and volume.

6.2.1. Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central veterinary services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

~~6.2.2. Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.~~

6.2.3. Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow up of the following:

- a) animals
- b) genetic material (semen and embryos)
- c) animal products
- d) veterinary medicinal products (i.e. biologics)

6.2.4. Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

## 7. Control measures and contingency planning

7.1. Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of rinderpest.

7.2. Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases?

7.3. In the event of a rinderpest outbreak:

- 7.3.1 indicate the sampling and testing procedures used to identify and confirm presence of the causative agent.
- 7.3.2 describe the actions taken to control the disease situation in and around any holdings found to be infected with rinderpest,
- 7.3.3 indicate the control and/or eradication procedures (e.g. vaccination, stamping out, partial slaughter/vaccination etc) that would be taken,

- 7.3.4 describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking,
- 7.3.5 Give details of any compensation payments made available to farmers etc when animals are slaughtered for disease control/eradication purposes.

## 8. Compliance with the *Terrestrial Code*

8.1. ~~The Delegate of the country must submit~~ In addition to the documentary evidence ~~must be supplied~~ that the provisions of Article 2.2.12.2 ~~or 3.8.1.6 (historical freedom) have been~~ properly implemented and supervised, ~~the Delegate of the country must submit a declaration indicating:~~

~~8.1.1. for the past 10 years there has been no vaccination against rinderpest and no evidence of rinderpest disease or infection and both throughout that period and currently maintains an adequate disease reporting system.~~

OR

~~8.1.2. For countries which have either vaccinated against rinderpest within the last 10 years or have had clinical evidence of rinderpest:~~

~~8.1.2.1. the country has been declared free from rinderpest disease at least one year earlier, and continues to meet the requirements for this status;~~

~~8.1.2.2. there is an effective serosurveillance system in operation in accordance with appendix 3.8.2. for a period of at least 2 years, and the findings are consistent with freedom from infection.~~

## 9. Recovery of status

Countries applying for recovery of status should comply with the provisions of Article 2.2.12.2~~3~~ of the *Terrestrial Code* and provide detailed information as specified in sections 3.1, 3.2, 3.3 and 5.2 of this report. Information in relation to other sections need only be supplied if relevant.

## **RINDERPEST DISEASE FREE COUNTRY**

Report of Country which applies for recognition of status, under Chapter 2.2.12 and Appendix 3.8.2 of the *Terrestrial Animal Health Code*, as a rinderpest disease free country

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

### **1. — Introduction**

- 1.1. — ~~Geographical factors. Provide a general description of the country including physical, geographical and other factors that are relevant to rinderpest dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of disease. Provide a map identifying the factors above.~~
- 1.2. — ~~Livestock industry. Provide a general description of the livestock industry in the country.~~

### **2. — Veterinary system**

- 2.1. — ~~Legislation. Provide a list and summary of all relevant veterinary legislation in relation to rinderpest.~~
- 2.2. — ~~*Veterinary Services.* Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 1.3.3. and 1.3.4. of the *Terrestrial Code* and I.1.2 of the *Terrestrial Manual* and describe how the veterinary services supervise and control all rinderpest related activities. Provide maps and tables wherever possible.~~
- 2.3. — ~~Role of farmers, industry and other relevant groups in rinderpest surveillance and control (include a description of training and awareness programs on rinderpest)~~
- 2.4. — ~~Role of private veterinary profession in rinderpest surveillance and control~~

### **3. — Rinderpest eradication**

- 3.1. — ~~History. Provide a description of the rinderpest history in the country, date of first detection, origin of infection, date of eradication, lineage(s) present.~~
- 3.2. — ~~Strategy. Describe how rinderpest was controlled and eradicated (e.g. stamping out, modified stamping out, zoning), provide timeframe for eradication~~
- 3.3. — ~~Vaccines and vaccination. Was rinderpest vaccine ever used? If so, when was the last vaccination carried out? What species were vaccinated? Has heterologous vaccine been used in cattle, buffalo or yak?~~
- 3.4. — ~~Legislation, organisation and implementation of the rinderpest eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.~~
- 3.5. — ~~Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd registration and traceability. How are animal movements controlled in the country? Provide evidence on the effectiveness of animal identification and movement controls.~~

**4.—Rinderpest diagnosis**

Provide documentary evidence that the provisions in Chapters I.1.2 and 2.1.4. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- 4.1. Is rinderpest laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to.
- 4.2. Provide an overview of the rinderpest approved laboratories, in particular to address the following points:
  - 4.2.1. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO etc. that exist in, or planned for, the laboratory system.
  - 4.2.2. Give details of participation in inter-laboratory validation tests (ring tests).
  - 4.2.3. Is live virus handled?
  - 4.2.4. Biosecurity measures applied
  - 4.2.5. Details of the type of tests undertaken

**5.—Rinderpest surveillance**

Provide documentary evidence that surveillance for rinderpest in the country complies with the provisions of Appendix 3.8.2. of the *Terrestrial Code* and Chapter 2.1.4 of the *Terrestrial Manual*. In particular, the following points should be addressed:

- 5.1. Clinical suspicion. What are the criteria for raising a suspicion of rinderpest? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for rinderpest virus, species, type of sample, testing method(s) and results (including differential diagnosis). In particular, provide evidence of compliance with the provisions of point 4 c) of Appendix 3.8.2 of the *Terrestrial Code*.
- 5.2. Clinical surveillance. Are clinical surveys conducted? If so, provide detailed information on the survey design in accordance with points 3 and 4 of Appendix 3.8.2 of the *Terrestrial Code*, (annual sample sizes shall be sufficient to provide 95% probability of detecting evidence of rinderpest if present at a prevalence of 1% of herds). How frequently are they conducted? Are wildlife susceptible species included in clinical surveillance? If not, explain the rationale. Provide a summary table indicating, for the past two years, the number of samples tested for rinderpest virus, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow up actions taken on all suspicious and positive results.
- 5.3. Livestock demographics and economies. What is the susceptible animal population by species and production systems? How many herds, flocks, etc., of each susceptible species are in the country? How are they distributed (e.g., herd density, etc.)? Provide tables and maps as appropriate.
- 5.4. Wildlife demographics. What susceptible species are present in the country? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?
- 5.5. Slaughterhouses and markets. Where are the major livestock marketing or collection centers? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions.

**6. — Rinderpest prevention**

~~6.1. — Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries that should be taken into account (e.g., size, distance from adjacent border to affected herds or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries.~~

~~6.2. — Import control procedures~~

~~From what countries or zones does the country authorize the import of susceptible animals or their products? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or zone of origin, species and volume.~~

~~6.2.1. Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central veterinary services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.~~

~~6.2.2. Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.~~

~~6.2.3. Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow up of the following:~~

- ~~a) animals~~
- ~~b) genetic material (semen and embryos)~~
- ~~e) animal products~~
- ~~d) veterinary medicinal products (i.e. biologics)~~

~~6.2.4. Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.~~

**7. — Control measures and contingency planning**

~~7.1. Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of rinderpest.~~

~~7.2. Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases?~~

~~7.3. In the event of a rinderpest outbreak:~~

~~7.3.1. indicate the sampling and testing procedures used to identify and confirm presence of the causative agent.~~

~~7.3.2. describe the actions taken to control the disease situation in and around any holdings found to be infected with rinderpest,~~

~~7.3.3. indicate the control and/or eradication procedures (e.g. vaccination, stamping out, partial slaughter/vaccination etc) that would be taken,~~

~~7.3.4. describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking;~~

~~7.3.5. give details of any compensation payments made available to farmers etc when animals are slaughtered for disease control/eradication purposes.~~

#### **8. — Compliance with the *Terrestrial Code***

~~8.1. In addition to the documentary evidence that the provisions of Article 2.2.12.2 are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:~~

~~8.1.1. That for the past 5 years, there has been no vaccination against rinderpest and no evidence of rinderpest disease and both throughout that period and currently maintains an adequate disease reporting system~~

~~OR~~

~~8.1.2. For countries which have declared themselves as *provisionally free*:~~

~~8.1.2.1. no clinical rinderpest has been detected for at least five years;~~

~~8.1.2.2. no rinderpest vaccines have been used for at least 3 years in any susceptible species, and no heterologous vaccines against rinderpest have been used for at least 3 years in cattle, buffaloes or yaks;~~

~~8.1.2.3. the country operates both clinical surveillance and disease reporting systems for rinderpest adequate to detect clinical disease if it were present;~~

~~8.1.2.4. all clinical evidence suggestive of rinderpest is investigated by field and laboratory methods (including serological assessment) to refute a possible diagnosis of rinderpest;~~

~~8.1.2.5. there are effective measures in force to prevent the re-introduction of the disease.~~

#### **9. — Recovery of status**

~~Countries applying for recovery of status should comply with the provisions of Article 2.2.12.3 of the *Terrestrial Code* and provide detailed information as specified in sections 3.1, 3.2, 3.3 and 5.2 of this report. Information in relation to other sections need only be supplied if relevant.~~

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## **RINDERPEST DISEASE FREE ZONE**

Report of a Country which applies for recognition of status, under Chapter 2.2.12.3 and Appendix 3.8.2 of the *Terrestrial Animal Health Code*, for a rinderpest disease free zone

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

### **1. Introduction**

- 1.1. ~~Geographical factors. Provide a general description of the country and the zone including physical, geographical and other factors that are relevant to rinderpest dissemination, countries sharing common borders and other countries that although may not be adjacent share a link for the potential introduction of disease. The boundaries of the zone must be clearly defined, including a surveillance zone if applied. Provide either a digitalised map or a non-digitalised map with a precise description of the geographical boundaries of the zone.~~
- 1.2. ~~Livestock industry. Provide a general description of the livestock industry in the country and the zone.~~

### **2. Veterinary system**

- 2.1. ~~Legislation. Provide a list and summary of all relevant veterinary legislation in relation to rinderpest.~~
- 2.2. ~~*Veterinary Services.* Provide documentation on the compliance of the Veterinary Service of the country with the provisions of Chapters 1.3.3. and 1.3.4. of the *Terrestrial Code* and I.1.2 of the *Terrestrial Manual* and describe how the veterinary services supervise and control all rinderpest related activities in the country and the zone. Provide maps and tables wherever possible.~~
- 2.3. ~~Role of farmers, industry and other relevant groups in rinderpest surveillance and control (include a description of training and awareness programs on rinderpest)~~
- 2.4. ~~Role of private veterinary profession in rinderpest surveillance and control~~

### **3. Rinderpest eradication**

- 3.1. ~~History. Provide a description of the rinderpest history in the country and zone, date of first detection, origin of infection, date of eradication in the zone, lineage(s) present.~~
- 3.2. ~~Strategy. Describe how rinderpest was controlled and eradicated in the zone (e.g. stamping out, modified stamping out, zoning), provide timeframe for eradication~~
- 3.3. ~~Vaccines and vaccination. Was rinderpest vaccine ever used in the country and the zone? If so, when was the last vaccination carried out in the zone? What species were vaccinated? Has heterologous vaccine been used in cattle, buffalo or yak?~~
- 3.4. ~~Legislation, organisation and implementation of the rinderpest eradication campaign. Provide a description of the organizational structure at the different levels. Indicate if detailed operational guidelines exist and give a brief summary.~~
- 3.5. ~~Animal identification and movement control. Are susceptible animals identified (individually or at a group level)? Provide a description of the methods of animal identification, herd registration and traceability. How are animal movements controlled in or between zones of the same or different status? Provide evidence on the effectiveness of animal identification and movement controls.~~

**4. — Rinderpest diagnosis**

Provide documentary evidence that the provisions in Chapters 1.1.2 and 2.1.4. of the *Terrestrial Manual* are applied. In particular, the following points should be addressed:

- 4.1. Is rinderpest laboratory diagnosis carried out in the country? If so, provide a list of approved laboratories. If not, provide the name(s) of and the arrangements with the laboratory(ies) samples are sent to. Indicate the laboratorie(s) where samples originating from the zone are diagnosed.
- 4.2. Provide an overview of the rinderpest approved laboratories, in particular to address the following points:
  - 4.2.1. Procedures for the official accreditation of laboratories. Give details of internal quality management systems, e.g. Good Laboratory Practice, ISO etc. that exist in, or planned for, the laboratory system.
  - 4.2.2. Give details of participation in inter-laboratory validation tests (ring tests).
  - 4.2.3. Is live virus handled?
  - 4.2.4. Biosecurity measures applied
  - 4.2.5. Details of the type of tests undertaken

**5. — Rinderpest surveillance**

Provide documentary evidence that surveillance for rinderpest in the zone complies with the provisions of Appendix 3.8.2. of the *Terrestrial Code* and Chapter 2.1.4 of the *Terrestrial Manual*. In particular, the following points should be addressed:

- 5.1. Clinical suspicion. What are the criteria for raising a suspicion of rinderpest? What is the procedure to notify (by whom and to whom) and what penalties are involved for failure to report? Provide a summary table indicating, for the past two years, the number of suspect cases, the number of samples tested for rinderpest virus, species, type of sample, testing method(s) and results (including differential diagnosis). In particular, provide evidence of compliance with the provisions of point 4 e) of Appendix 3.8.2 of the *Terrestrial Code*.
- 5.2. Clinical surveillance. Are clinical surveys conducted? If so, provide detailed information on the survey design in accordance with points 3 and 4 of Appendix 3.8.2 of the *Terrestrial Code*, (annual sample sizes shall be sufficient to provide 95% probability of detecting evidence of rinderpest if present at a prevalence of 1% of herds). How frequently are they conducted? Are wildlife susceptible species included in clinical surveillance? If not, explain the rationale. Provide a summary table indicating, for the past two years, the number of samples tested for rinderpest virus, species, type of sample, testing method(s) and results (including differential diagnosis). Provide details on follow up actions taken on all suspicious and positive results.
- 5.3. Livestock demographics and economics. What is the susceptible animal population by species and production systems? How many herds, flocks, etc., of each susceptible species are in the country and zone? How are they distributed (e.g., herd density, etc.)? Provide tables and maps as appropriate.
- 5.4. Wildlife demographics. What susceptible species are present in the country and zone? Provide estimates of population sizes and geographic distribution. What are the measures in place to prevent contact between domestic and wildlife susceptible species?
- 5.5. Slaughterhouses and markets. Where are the major livestock marketing or collection centers? What are the patterns of livestock movement within the country? How are the animals transported and handled during these transactions.

**6. — Rinderpest prevention**

6.1. — Coordination with neighbouring countries. Are there any relevant factors about the adjacent countries or zones that should be taken into account (e.g., size, distance from adjacent border to affected herds or animals)? Describe coordination, collaboration and information sharing activities with neighbouring countries. If the rinderpest disease free zone is situated in a rinderpest infected country or borders an infected country or zone it must be separated by a surveillance zone or physical or geographical barrier. The applicant country must provide detailed description of the measures applied to preserve the health status of the disease free zone.

**6.2. — Import control procedures**

From what countries or zones does the country authorize the import of susceptible animals or their products into the disease free zone? What criteria are applied to approve such countries or zones? What controls are applied on entry of such animals and products, and subsequent internal movement? What import conditions and test procedures are required? Are imported animals of susceptible species required to undergo a quarantine or isolation period? If so, for how long and where? Are import permits and health certificates required? What other procedures are used? Provide summary statistics of imports of susceptible animals and their products for the past two years, specifying country or zone of origin, species and volume.

6.2.1. Provide a map with the number and location of ports, airports and land crossings. Is the official service responsible for import controls part of the official services, or is it an independent body? If it is an independent body, describe its management structure, staffing levels and resources, and its accountability to the central veterinary services. Describe the communication systems between the central authorities and the border inspection posts, and between border inspection posts.

6.2.2. Provide a description on the methods used for the safe disposal of waste from international traffic, who is responsible and provide a summary, for the past two years, of the quantity disposed of.

6.2.3. Describe the regulations, procedures, type and frequency of checks at the point of entry into the country and/or their final destination, concerning the import and follow up of the following:

- a) animals
- b) genetic material (semen and embryos)
- c) animal products
- d) veterinary medicinal products (i.e. biologics)

6.2.4. Describe the action available under legislation, and actually taken, when an illegal import is detected. Provide information on detected illegal imports.

**7. — Control measures and contingency planning**

7.1. Give details of any written guidelines, including contingency plans, available to the official services for dealing with suspected or confirmed outbreaks of rinderpest.

7.2. Is quarantine imposed on premises with suspicious cases, pending final diagnosis? What other procedures are followed regarding suspicious cases?

7.3. In the event of a rinderpest outbreak:

7.3.1. indicate the sampling and testing procedures used to identify and confirm presence of the causative agent.

7.3.2. describe the actions taken to control the disease situation in and around any holdings found to be infected with rinderpest

- ~~7.3.3. indicate the control and/or eradication procedures (e.g. vaccination, stamping out, partial slaughter/vaccination etc) that would be taken;~~
- ~~7.3.4. describe the procedures used to confirm that an outbreak has been successfully controlled/eradicated, including any restrictions on restocking;~~
- ~~7.3.5. give details of any compensation payments made available to farmers etc when animals are slaughtered for disease control/eradication purposes.~~

#### **8. ~~Compliance with the Terrestrial Code~~**

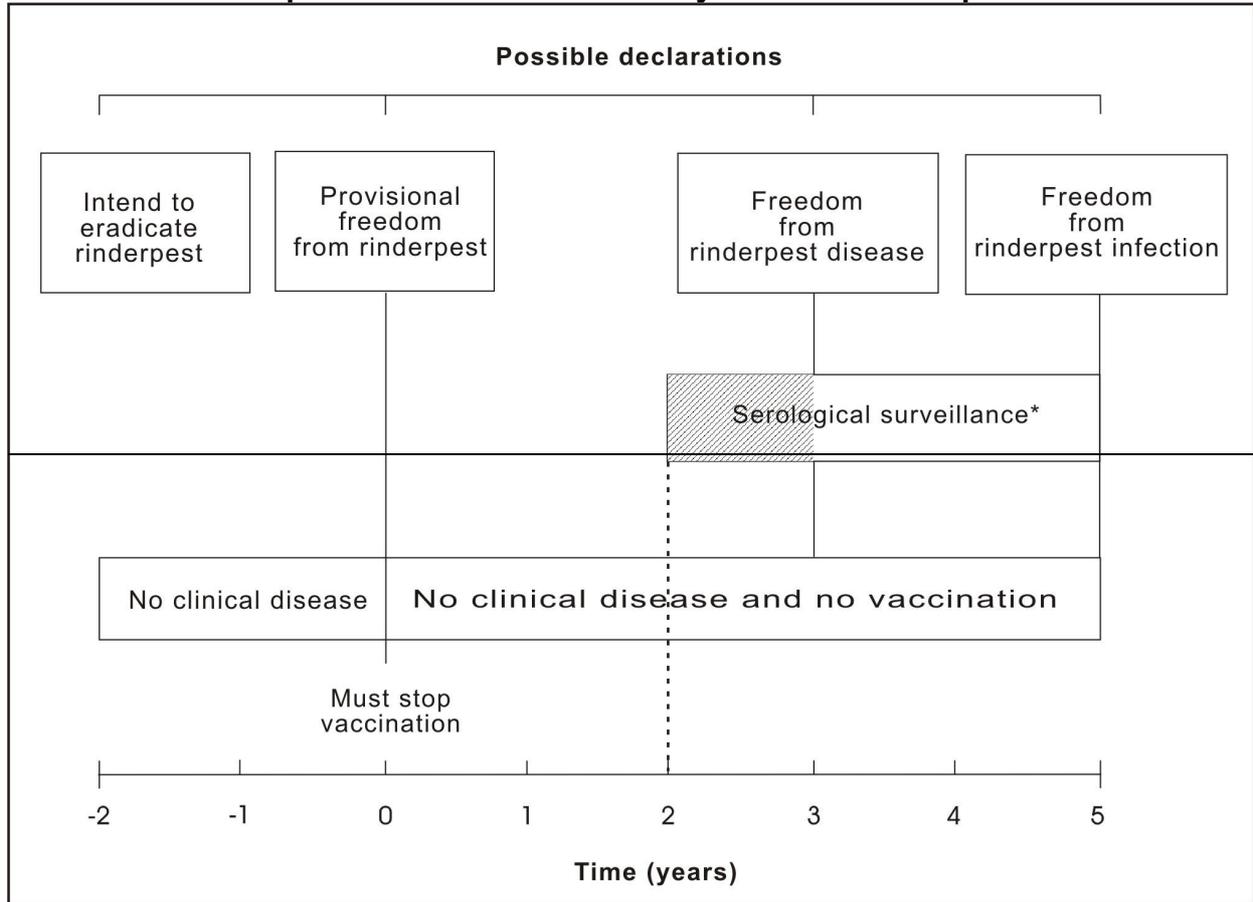
- ~~8.1. In addition to the documentary evidence that the provisions of Article 2.2.12.2 are properly implemented and supervised, the Delegate of the country must submit a declaration indicating:~~
  - ~~8.1.1. no clinical rinderpest has been detected within the zone for at least 5 years;~~
  - ~~8.1.2. no rinderpest vaccines have been used for at least 3 years in any susceptible species, and no heterologous vaccines against rinderpest have been used for at least 3 years in cattle, buffaloes or yaks;~~
  - ~~8.1.3. the country operates within the zone both clinical surveillance and disease reporting systems for rinderpest, adequate to detect clinical disease if it were present;~~
  - ~~8.1.4. all clinical evidence suggestive of rinderpest within the zone is investigated by field and laboratory methods (including serological assessment) to refute a possible diagnosis of rinderpest;~~
  - ~~8.1.5. there are effective measures in force to prevent the re introduction of the disease into the zone from the remainder of the country and from other countries.~~

#### **9. ~~Recovery of status~~**

~~Countries applying for recovery of status for the zone should comply with the provisions of Article 2.2.12.3 of the Terrestrial Code and provide detailed information as specified in sections 3.1, 3.2, 3.3 and 5.2 of this report. Information in relation to other sections need only be supplied if relevant.~~

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**Steps taken to declare a country free from Rinderpest**



\* If a country wants to be declared free from rinderpest infection at the end of year 4, serological surveillance of unvaccinated animals must be in operation at the end of year 2, in order to prove that there has been no seropositive case in the country for at least 2 years



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

**Paris, 22-23 February 2007**

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The meeting of the OIE *ad hoc* Group on the Evaluation of Country Status for Foot and mouth disease was held at OIE Headquarters, Paris from 22 to 23 February 2007.

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

**1. Opening and Agenda**

The meeting of the OIE *ad hoc* Group on the Evaluation of Country Status for Foot and mouth disease was held at OIE Headquarters, Paris from 22-23 February 2007. Dr Gideon Brückner, Head of the Scientific and Technical Department welcomed the Group on behalf of Dr Bernard Vallat, Director General of the OIE and explained the details of the agenda. Dr Alejandro Schudel chaired the *ad hoc* Group and Dr. Alf-Eckbert Füssel acted as rapporteur. The group endorsed the proposed agenda.

**2. Feedback on the OIE FMD mission to South America**

Dr Brückner explained the current state of discussion on the situation in the frontier area of the countries visited by an OIE mission in December 2006. During the previous meeting of the Scientific Commission a delegation of the countries concerned undertook to submit their comments on the report and a proposal how an OIE recognised status could be best secured by a regional approach to the control of foot and mouth disease in the region to best ensure the continuation of trade. The report will be submitted for discussion at the meeting of the Scientific Commission from 26 to 28 February 2007. The proposal and further approach to allocating free status for foot and mouth disease in any of the countries concerned will be determined by the outcome of the discussions on the proposal and comments of the southern cone Countries to be submitted to the OIE.

**3. Evaluation of Country applications for freedom from disease**

**3.1. Botswana**

Botswana requested the reinstatement of its disease free status it had lost as a consequence of outbreaks in 2006 in its south-eastern corner. In addition Botswana applied for the extension of its FMD-free zone without vaccination to include a previous surveillance zone separating the previously free zone without vaccination from the zone free with vaccination, which itself should be enlarged.

The group examined the well structured dossier provided by Botswana. There were 4 requests by the Official Delegate of Botswana:

- *Request 1: Reinstatement of previously infected zone with exclusion of zone 7*

The Group agreed that the conditions of the *Terrestrial Code* had been met to reinstate these zones as FMD free without vaccination. There was discussion on the adequacy of the separation of zone 6 and zone 3c and Zimbabwe because of the continuing risk of re-entry of FMD from that country into Botswana.

However the Botswana services had taken some additional measures along the border to mitigate this risk and the Group recommended the reinstatement of zones 3c, 4b, 5, 6, 8, 9, 10, 11, 12 and 13.

- *Request 2: Enlargement of the FMD free zone without vaccination*

The Group agreed that the conditions of the *Terrestrial Code* had been met to approve the addition of zones 3c and 4b into the FMD free zones without vaccination.

- *Request 3: Enlargement of the FMD free zones with vaccination through addition of zones 2a, 2b, 2c, 3b and 4a*

The Group concluded that as no surveillance to verify the absence of circulating virus had been carried out the requirements of the *Terrestrial Code* were not met. The group was concerned with the statement in the dossier that this had not been done due to the lack of purity of the vaccine produced at the BVI. The vaccine does not comply with the OIE requirements. The request was thus not recommended for approval.

- *Request 4: Allocating official OIE status to an infected zone*

This request to allocate official status to an infected zone was not within the mandate of the *Terrestrial Code* and was not further discussed.

Discussing the submission of Botswana, the Group noted that provision should possibly be made in the *Terrestrial Code* for an additional status category relating to a zone which is in the process to obtain a different status i.e. upgrading from FMD free with vaccination to FMD free without vaccination. The experience and observations are that certain Member Countries abandon vaccination already on its own initiative in an area listed as free with vaccination to reach a status of free from FMD without vaccination. The question was raised if it should be officially notified to OIE or should provision be made for a transitional period and what would be the surveillance requirements.

### 3.2. Colombia

Colombia requested the recognition of a new zone free from FMD with vaccination in the south-west region of the country.

The dossier presented by Colombia described the situation in that area and the measures taken to maintain the status of this area satisfactorily. Colombia has the intention to have this south-western zone recognised as a new zone, however once the status has been granted internal movement restrictions and the buffer zone between the northern and the south-western zone will be abandoned.

After detailed discussion of the dossier which was further complimented by additional information from a delegation from the Member Country, the Group concluded to recommend approval of the application of Colombia to establish a third zone free with vaccination in the south west of the country to be included into the two existing zones as one zone, as the zone complies with the requirements of the *Terrestrial Code*.

### 3.3. Peru

The Official Delegate applied for the recognition of the Amazonian zone as free from foot and mouth disease without vaccination.

After detailed discussion of the dossier, the Group concluded to recommend approval of the application of Peru to establish a zone free from FMD without vaccination in the Amazon region as indicate by the Official Delegate of Peru as the application complies with the requirements of the *Terrestrial Code*.

### 3.4. Argentina

An application was received from the Official Delegate of Argentina for the extension of the FMD free zone without vaccination to include the area of Patagonia B as outlined in the documentation provided by the Official Delegate.

After detailed discussion of the dossier which was further complimented by additional information from a delegation from the Member Country, the Group concluded that the application complies with the requirements of the *Terrestrial Code* and recommended the approval of the application of Argentina, to expand the existing zone free from FMD without vaccination to include the area of Patagonia B as indicated by the Official Delegate. The recommendation would however be subject to the final decision of the Scientific Commission on the application of Argentina on the reinstatement of the free status of the adjoining zone of Argentina previously listed as free with vaccination.

### 3.5. Brazil

#### 3.5.1. Santa Catarina

The Official Delegate submitted a dossier requesting the OIE to recognise the State of Santa Catarina as free from foot and mouth disease without vaccination.

After detailed discussion of the dossier which was further complimented by additional information from a delegation from the Member Country, the Group concluded that the application complies with the requirements of the *Terrestrial Code* and recommended the approval of the application of Brazil, to recognise the State of Santa Catarina of Brazil as free from FMD without vaccination.

#### 3.5.2. Middle- southern region of the State of Par , Brazil

Following a previous application by the Official Delegate of Brazil to recognise the middle-southern region of the State of Par  as a zone free from FMD with vaccination, the additional information supplied by Brazil in 2007 was evaluated and further complemented by information supplied verbally by an official delegation from Brazil.

The Group recommended approval of the application of the Official Delegate to recognise the middle-southern region of the State of Par  as indicated by the Official Delegate as a FMD free zone where vaccination is practised.

## 4. Discussions with a delegation from Argentina

The ad hoc Group held a meeting with a delegation from Argentina to discuss their request for the reinstatement of the status of FMD free with vaccination to the Northern zone of Argentina with regards to the recommendations of the OIE mission to the southern cone region in December 2006. The Group noted the satisfactory report of the OIE mission to South America with regard to the sanitary situation of Argentina and in particular with regard to the preventive measures implemented in the Northern border of the country. The Group agreed that the conditions established in the *Terrestrial Code* and requested by the Scientific Commission for recognizing the status in this zone have been fulfilled and recommended to the Scientific Commission the reinstatement of the free status with vaccination provided Argentina complies with the recommendations of the Scientific Commission for the control of foot and mouth disease in the frontier areas in the northern part of the zone.

It was concluded that a final decision on the implementations of the recommendations of the mission, should only be made after receiving the official response of the countries concerned on the FMD mission report to the Scientific Commission during their meeting from 26 to 28 February 2007.

**5. Comments on the FMD containment zone and *Terrestrial Code* chapter**

The Group discussed the comments of Member Countries on suggested changes to Chapter 2.2.10 of the *Terrestrial Code*, including the introduction of the new concept of a *containment zone* following the request to the Scientific Commission in terms of Resolution XXX at the 74th General Session of the OIE in May 2006.

**6. Request to evaluate the inactivation of foot and mouth disease virus in natural sausage casings**

The *ad hoc* Group concluded that more scientific information would be needed to enable the experts to analyse the described procedure under the provisions of the *Terrestrial Code*. A consideration of the new practical procedure then may be included in the Appendix 3.6.2. of the *Terrestrial Code*.

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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, 22 - 23 February 2007**

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**Agenda**

1. Feedback on the OIE FMD mission to South America
  2. Evaluation of requests from Member Countries for recognition of FMD free status
    - Botswana (recovery status)
    - Argentina
    - Colombia
    - Peru
    - Brazil (recovery status)
  3. Compartmentalization with regard to FMD
  4. Other matters
    - Discussion of country comments on suggested changes to chapter 2.2.10. (FMD)
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Appendix II

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

**Paris, 22 – 23 February 2007**

**List of participants**

**MEMBERS**

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**MEETING OF THE OIE AD HOC GROUP ON EPIDEMIOLOGY**  
**Paris, 7- 9 February 2007**

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The meeting of the OIE Ad hoc Group on Epidemiology of the Scientific Commission for Animal Diseases was held at OIE Headquarters, Paris from 7-9 February 2007.

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

Dr Gideon Brückner Head of the Scientific and Technical Department welcomed the Group to the OIE on behalf of Dr Bernard Vallat, Director General of the OIE. Dr Brückner emphasised the importance of their task especially in view of the urgency for the development of general guidelines for the *Terrestrial Code* on compartmentalisation. He advised the Group to use the revised Chapter 1.3.5 of the *Terrestrial Code* on *Zoning and compartmentalisation* as circulated recently to Member Countries and the concept paper on compartmentalisation as published in the *OIE Bulletin*, as reference documents to develop the general guidelines on compartmentalisation. Also included in the working documents are proposals for disease specific criteria for compartmentalisation for avian influenza and Newcastle disease developed by a consultant on request of the Terrestrial Animal Health Standards Commission. He reiterated the views expressed by the Director General that the same principle for general guidelines for compartmentalisation will be followed as were applied for developing general guidelines for animal disease surveillance i.e. the general guidelines for compartmentalisation would first be developed by the Group and then guidelines for specific diseases should the need arise. He discussed and finalised the provisional agenda for the meeting and requested the Group to consider the developments of guidelines for compartmentalisation as first priority and if time permits, to attend to other issues listed on the provisional agenda. He requested the Group that time should be allocated to finalise the priorities for the working program of the Group for 2007/2008. Several issues have been identified by the Scientific Commission that will be referred to the Group during the year. The most important of these being a revision of Appendix 3.8.5 (*Factors to consider for a risk assessment for bovine spongiform encephalopathy*) to ensure congruency of the Appendix with the current *Terrestrial Code* Chapter 2.3.13 on BSE and the questionnaire for evaluating country status for BSE; evaluating the proposals for surveillance guidelines for rinderpest and contagious bovine pleuropneumonia (CBPP); surveillance for wildlife diseases and guidelines for vector surveillance.

The meeting was chaired alternatively by Professor Arnon Shimsony and Professor Vincenzo Caporale, President of the Scientific Commission. Dr Cristobal Zepeda and Dr Howard Batho acted as rapporteurs.

**1. Draft Appendix on general guidelines for the application of compartmentalisation**

***General discussions on the concept of compartmentalisation***

- The Group agreed that the intention should be to formulate general guidelines for the implementation of compartmentalisation rather than for a particular disease as a first step. Specific disease Appendices could then be developed to take account of the epidemiology of that particular disease. This might be done by focusing on the type of spread of the disease agent e.g. insect vector borne diseases differ from a farm (i.e. compartment) free of Brucellosis which again is different from a disease which also affects wildlife such as avian influenza or classical swine fever. Specific additions to the disease Chapters could

be envisaged to add particular criteria not included in the general Chapter for compartmentalisation for particular diseases where necessary. It was also suggested that an automatic suspension of the compartment could be envisaged if suspicion (or other event warranted it) of disease occurred within a 1km radius as a precautionary measure. Any breakdown in the compartment would bring the system into disrepute. The group stressed the overriding importance of ensuring the integrity of the compartment and the need for a strong input and involvement by the *veterinary services* of a Member Country.

- It was also agreed to propose that consideration should be given to completely separate the two principles of zoning and compartmentalisation in Chapter 1.3.5.
- The President of the Terrestrial Animal Health Standards Commission, Dr. Alex Thiermann, in discussions with the Group indicated that if the draft was completed by the Group and accepted by the Scientific Commission, it would be possible to circulate it at or prior to the General Session in May 2007 for preliminary comments by Delegates prior to finalisation by the Group at its next meeting and then for possible adoption in May 2008. He emphasised that for the application of zoning high intensity input by the industry is not normally required while for compartmentalisation their input and co-operation would be essential.
- The group used the concept paper on compartmentalisation as the basis for the draft Appendix. It was agreed that it would be more user friendly to include the definition of compartmentalisation in the draft Appendix together with a short explanation of the concept highlighting the differences between zoning and compartmentalisation. It is recommended that the Scientific Commission request the Code Commission to discuss and endorse this approach.
- The Group agreed that there are two main needs for the use of compartmentalisation. Firstly before a disease outbreak occurs in a free country or zone or which is already infected. This would mean that in spite of disease incursion or ongoing outbreaks trade could continue to occur from authorised compartments. Secondly after a disease incursion in a free country or zone - but this could be more difficult in the event or during an outbreak as it may take longer to set up and agree with trading partners. There were in depth discussions on this situation as in the event of an unstable endemic situation, the maintenance of compartments could be jeopardised. In addition the situation of a free country or zone with an incursion of disease could also jeopardise the compartments. There was discussion over whether in these cases the compartment would be able to continue trading before the disease situation was known to stable. It would depend also on the disease in question and the bio-security involved. If trade was stopped due to a disease incursion in a country with no connection or some distance from an authorised compartment it would tend to nullify the need to apply compartmentalisation.
- It was resolved and emphasised that disease notifications to the OIE must also inform about the proximity of the outbreak to any authorised compartments.
- The group discussed the present definition of compartment as it really only refers to establishments which means premises on which animals are kept. However compartments may involve or contain slaughterhouses, feed mills, meat product plants, rendering plants and transport components etc. It was agreed that hatcheries did fall under the definition. All these establishments i.e. the components of the compartment must be under the bio-security plan.
- The Group had difficulties in trying to specify a complete list of prerequisites without omitting anything of significance such as the means of spread or introduction of disease - therefore it should be highlighted that any lists provided are not meant to be exhaustive.
- In addition there was considerable debate on the level of animal identification which is needed. However it was agreed that the principle should be that for compartments (which are of a high status and their *raison d'être* is to facilitate trade) then an individual animal identification system with a unique identifier should be required. However the group felt that some exceptions might be needed in particular (1) for broilers with an all-in-all-out policy (2) for day old chicks (DOC) (where individual identification was impractical) provided in all cases that sufficient guarantees could be given.

- The Group discussed the need to assess the situation in the compartment for diseases other than those for which the compartment has been defined as an incursion of disease could indicate a failure in the control procedures or management of the compartment. The question raised was would the compartment need to notify any disease case to the *veterinary administration*?. The OIE requires all listed diseases to be notified but this is variable depending on the country and the incidence of disease in the country. The Group concluded that there should be an onus on the compartment to report any OIE listed disease outbreak to the *veterinary administration*.
- The Group discussed at length the requirements for external surveillance and it was eventually agreed that the most intensive surveillance should be carried out in the compartment by the management of the compartment but still under the supervision of the Veterinary Administration. However, it was agreed that a certain level of surveillance, in particular passive surveillance, depending on (1) the disease and/or its incidence in the country or zone and (2) the foreseen risk, should be carried out by the *veterinary administration* outside the compartment as it would be important and obligatory for the *veterinary administration* to have a satisfactory level of knowledge of the disease situation in the country. Concentration on risk based surveillance i.e. active surveillance for those areas with a possible link with the compartment should nevertheless be foreseen.
- There Group discussed the notification of diseases in particular concerning the OIE Reference Laboratories. The Group agreed that in view of the importance of rapid and transparent notification of serious disease occurrences in a compartment, that specific requirements for notifying results to the OIE Central Bureau should be incorporated in the Appendix. However in the Mandate for OIE Reference Laboratories it is clearly stated that *in the case of results that are confirmed positive for diseases that are reportable to the OIE, the Reference Laboratory should immediately inform the OIE delegate of the Member Country from which the sample originated as well as the OIE Central Bureau*. It was agreed that the *veterinary services* must notify any case of suspicion of the disease in question and any OIE listed disease which had not been recently reported as this would indicate a breakdown in the integrity and biosecurity of the compartment. Furthermore any samples taken from suspect animals in an authorised compartment sent to an OIE Reference Laboratory must be labelled as coming from an authorised compartment in order that the results can be copied to the OIE. Any failure in immediate notification of suspicion of disease by the compartment will compromise the status of that compartment.
- The Group discussed the need for the compartment to react proactively on suspicion of such diseases to both assure and protect its trading partners. The onus should be shared between the management of the authorised compartment and the *veterinary administration* to suspend trade as a precautionary measure, to inform the trade partner(s) of the suspicion and of all consignments which may be affected, and take all necessary measures to re-establish the biosecurity. All confirmed cases must be notified in the usual way according to the OIE disease reporting procedures and the *veterinary administration* of the trading partners must also be notified directly of negative or positive results. However it was agreed that the responsibility for suspending certification and notification must remain with the *veterinary administration*.
- The Group discussed the need to try to demonstrate a baseline level of “usually” occurring or background level of all OIE listed diseases in the animals in the compartment. This should be used to monitor the biosecurity of the compartment as any change or deviation in the baseline level could indicate a breach of the biosecurity.
- The Group discussed the need to lay down additional disease specific guidelines for compartmentalisation but felt that the general guidelines gave enough flexibility and if it was thought necessary such criteria could be included in the relevant disease chapter.

## **2. Review of the revised Chapter 1.3.5 of the *Terrestrial Code* on *Zoning and compartmentalisation***

The review was postponed until the next meeting due to lack of sufficient time.

**3. Review the definitions of the Terrestrial Code on surveillance and monitoring**

The review was postponed until the next meeting due to lack of sufficient time

**4. Consistency between the time frames for BSE surveillance in the BSE questionnaire and the Terrestrial Code Chapter and appendices**

The review was postponed until the next meeting due to lack of sufficient time

**5. The feasibility of applying the concept of compartmentalisation to foot and mouth disease (FMD)**

The Group was in favour of applying the concept of compartmentalisation to FMD in view of the discussions on general guidelines for compartmentalisation. However, it was understood that some countries could have reservations which would need to be addressed.

**6. Future working program of the ad hoc Group**

- *The schedule of meeting agreed by the Group for 2007/2008 will be as follows:*

1. 7 to 8 June 2007 (combined with AI and NCD experts for consistency in surveillance guidelines)
2. 12 to 15 June 2007
3. 4 to 7 September 2007
4. 12 to 15 February 2008

- *Priority issues tentatively identified for the Group for 2007/2008*

1. Review of country comments on guidelines for compartmentalisation
2. Review of surveillance guidelines for BSE, Chapter 3.8.5 (risk assessment for BSE) and BSE questionnaire
3. Guidelines for Animal disease control
4. Guidelines for contingency planning for disease outbreaks
5. Manual on Animal Disease Surveillance
6. Review of questionnaire and surveillance guidelines for CBPP and rinderpest
7. Wildlife disease surveillance (with Wildlife Working Group)
8. Vector surveillance

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.../Appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON EPIDEMIOLOGY  
Paris, 7 – 9 February 2007**

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**Agenda**

1. Guidelines on compartmentalization for the *Terrestrial Code*
  2. Review of comments on the chapter 1.3.5. zoning and compartmentalisation, revised version
  3. Definition of the terms “surveillance” and “monitoring”
  4. Consistency of time frames for BSE surveillance in the questionnaire and the disease specific *Code* chapter and Appendices
  5. Review of the revisions on the Chapter, surveillance guidelines and questionnaire for the evaluation of country status for CBPP
  5. Feasibility of compartmentalization with regard to FMD
  6. Future working programme
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Appendix II**MEETING OF THE OIE AD HOC GROUP ON EPIDEMIOLOGY****Paris, 7 – 9 February 2007**

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**List of participants****MEMBERS**

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**MEETING OF THE  
OIE AD HOC GROUP ON NEWCASTLE DISEASE SURVEILLANCE  
Paris, 29 and 30 January 2007**

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Dr Brückner, Head of the Scientific and Technical Department, welcomed the group on behalf of the Director General and thanked all the participants for their continuous support to the OIE. He thanked the group for the excellent work of the previous meeting on the chapter and emphasized the need for surveillance guidelines for Newcastle disease. Dr Brückner explained again that the aim of the *Terrestrial Animal Health Code* is primarily to assure sanitary safety of international trade of animals and animal products as well as providing guidelines how to perform surveillance. After the Newcastle disease chapter had been updated in the last meeting, the group started working on the surveillance appendix which was not finalized yet. The new standards and surveillance guidelines should be developed in parallel with the avian influenza standards and guidelines and this new chapter and appendix are included in the documents to be used as example and format. Dr Brückner also explained that the OIE would like to have the opinion of the group on the paper “the application of compartmentalisation for avian influenza and Newcastle disease” The *Terrestrial Code* has a chapter on compartmentalisation and the document discusses the practical implementation of the concept for avian influenza and Newcastle disease.

Dr Jack King was chair and Dr Paul Selleck acted as rapporteur. The Agenda and list of participants are presented as Appendices I and II, respectively. After introduction of the participants, the group proceeded with the discussions on the surveillance guidelines. The Appendix 3.8.9 of the *Terrestrial Code* (Guidelines for the surveillance of avian influenza) provided a basis for comparison in the discussion and was used as a template by the participants in developing the newly proposed guidelines.

**Article 3.8.9.1:** The group is concerned about the lack of definition of confidence levels for surveillance. The term “acceptable” seems to be too vague and the group would like the SCAD to consider include defined confidence levels.

**Article 3.8.9.2:** zone and compartment were deleted as, under the OIE definition, these only refer to uninfected populations

**Article: 3.8.9.3 Introduction:** “Susceptible species” was replaced with “poultry” to ensure that vaccinated sub-populations and species of differing susceptibilities to clinical presentation of disease are included in any surveillance.

In the second paragraph sero-surveillance is removed since this will be dealt with later in the document.

There are apparent inconsistencies between the times listed for demonstration of freedom between different OIE documents dealing with freedom after eradication versus freedom from infection, i.e. 3 months, 6 months and 1 year. Two rounds of testing (6 monthly) are recommended before declaration of freedom to demonstrate an effective surveillance system and effective disease control.

**Article 3.8.9.3, Clinical Surveillance:** The group included the requirement of sending the viruses to an OIE reference laboratory as we feel that this is vital to monitoring global disease trends and evolution of viruses.

The paragraph in the Article specifying the requirement of sending isolates to an OIE reference laboratory is possibly relevant to other diseases.

**Article 3.8.9.3: Sentinel Poultry:** The section on sentinel poultry may also be applicable to the AI Appendix

The Article 3.8.9.5 was edited and incorporated as item #3 in Article 3.8.9.4. All articles from 3.8.9.6 on have been deleted since they are not relevant to ND.

The group made some comments on the document “The application of compartmentalisation for avian influenza and Newcastle disease”. Due to time restrictions it was not possible to go in detail. The group proposed a separate meeting to work further on this concept.

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.../Appendices

Appendix I

**MEETING OF THE  
OIE AD HOC GROUP ON NEWCASTLE DISEASE SURVEILLANCE**

**Paris, 29 – 30 January 2007**

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**Agenda**

1. Welcome and Introduction of participants
2. Development of surveillance guidelines for Newcastle Disease

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Appendix II

**MEETING OF THE  
OIE AD HOC GROUP ON NEWCASTLE DISEASE SURVEILLANCE  
Paris, 29 – 30 January 2007**

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**OIE MISSION  
TO  
ARGENTINA, BRAZIL AND PARAGUAY  
TO EVALUATE THE CONTROL MEASURES FOR  
FOOT AND MOUTH DISEASE**

**6 to 13 December 2006**



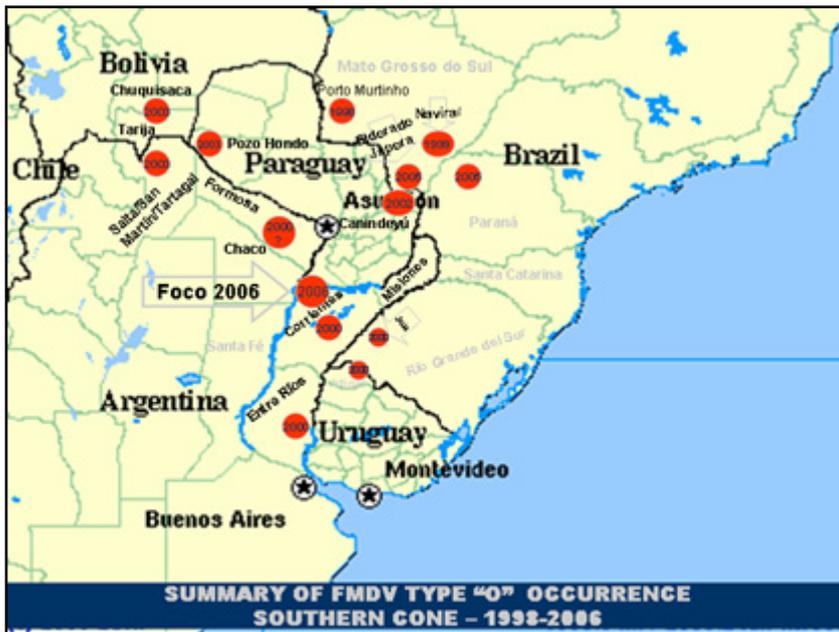
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## CHAPTER 1

### FMD Situation in Parts of South America

#### 1. Introduction

Following an evaluation of the foot-and-mouth disease (FMD) situation in Southern America by the Scientific Commission for Animal Diseases during its meeting in March 2006, the Commission recommended to the Director General of the OIE, that due to the apparent complex nature of the epidemiology of recent outbreaks in the region, an on-site evaluation by an OIE mission to the region would greatly assist the Commission to make an informed decision on country applications from the region for the recognition for freedom from disease.



**Figure 1: Map showing FMD type “O” outbreaks 1998-2006**

The request of the Commission was conveyed to the Delegates of the countries concerned who subsequently met with the Director General and the President of the Commission prior to the 74<sup>th</sup> General Session of the OIE in May 2006 and confirmed that they would welcome an on-site evaluation by a team constituted by the Director General.

Later in 2006 the Delegate of Argentina to the OIE submitted complete dossiers on the successful control of the February 2006 outbreak of foot-and-mouth disease (FMD) caused by virus type O on the farm San Juan in the Department of San Luis del Palmar, Corrientes Province, and the details of a project to

strengthen the control measures for foot and mouth disease in the Northern A and Northern B areas comprising approximately a 25 km frontier zone along the borders of Argentina with Bolivia, Paraguay and Brazil.

The dossier was evaluated by the Scientific Commission for Animal Diseases during its meeting in September 2006, but it was resolved that before a recommendation could be made to the International Committee to carry out a fact finding mission into the area in order to understand the situation and to avoid the continuation of repeated withdrawals of the status for countries or parts of the territory of countries in that area due to recurrent outbreaks of FMD along international borders in Argentina, Bolivia, Brazil and Paraguay that were detected over the past 5 years and suggest a common regional animal health problem.

#### 2. Mission objectives

- ⇒ Assess the epidemiological situation of FMD in the region
- ⇒ Assess the implementation of the control measures for FMD in the areas along international borders and the neighbouring countries as a whole, notably relating to early outbreak detection, outbreak investigation, disease control measures, vaccination and movement controls;
- ⇒ Assess the level of surveillance in the risk areas and within the countries as a whole

- ⇒ Assess if the measures applied to maintain or regain the FMD-free status with vaccination of the zone officially recognised by the OIE, are sufficient to recommend the re-instatement or maintenance of the FMD free status of the zone with vaccination, to the International Committee of the OIE.

### 3. Teams and principal itinerary

In order to meet the objectives of the mission the entire team had an introductory briefing in Florianopolis, Brazil, on 5 December 2006 and a final meeting in Rio de Janeiro on 12 December 2006. Due to time constraints and the urgency of the matter, it was decided to divide the mission into three teams:

- Team A Argentina and border with Paraguay and Bolivia, Paraguay veterinary Headquarters  
Team B Brazil (Mato Grosso do Sul), border area in Paraguay to Brazil  
Team C National Laboratories for vaccine control in Argentina, Brazil and Paraguay.

### 4. Pre-mission briefing (Florianopolis, Santa Catarina, Brazil)

- PANAFTOSA presented information to the participants on the FMD situation in Argentina, Bolivia, Brazil and Paraguay. Copies of the presentations are attached to this report.
- The participants agreed that, unlike FMDV-type A, FMDV-type O causes in recognised free areas in the four countries and in particular, in their border areas recurrent outbreaks of clinical FMD, which is indicative of contact of FMDV-type O with receptive animals.
- The type O isolates recovered from such outbreaks are clearly distinct from the vaccine strain O-Campos and are of the same lineage with little genetic variation, thus suggesting a stable but endemic situation.
- The vaccines currently in use include *inter alia* O-Campos that has a satisfactory match with the field virus and should, if properly applied, convey sufficient protective immunity and thus prevent clinical expression of the disease.
- It was therefore deemed necessary to consider a number of factors that would, alone or in conjunction, support the hypothesis of an endemic nature of the disease in this particular area.

### 5. Acknowledgment

The teams were accompanied throughout the mission by officials of the competent authorities of Argentina, Brazil and Paraguay respectively and wish to acknowledge their highly appreciated support for the successful accomplishment of the mission.

**CHAPTER 2**  
**Report Team A**  
**Mission to Argentina and Paraguay**

**1. Mission team objectives**

Following the submission of complete dossiers by the Delegate of Argentina to the OIE on the successful control of an outbreak of FMDV type O on the farm San Juan in the Department of San Luis del Palmar, Corrientes Province, in February 2006, and the details of a project to strengthen the control measures for foot and mouth disease in the Northern A and Northern B areas comprising approximately a 25 km frontier zone along the borders of Argentina with Bolivia, Paraguay and Brazil, the OIE team consisting of Drs Howard Batho, Gideon Brückner and Victor Saraiva, visited the frontier zone to:

- a) Assess the implementation of the control measures for foot and mouth disease outlined in the project proposal for Northern areas A and B;
- b) Assess if the progress with the application of these measures since officially mandated in September 2006, are such that it would render acceptable sanitary guarantees to reasonably mitigate the risk for the introduction, spread and early detection of FMDV into Argentina from outside its borders.
- c) Assess if the measures applied to maintain the foot and mouth disease free status with vaccination of the zone officially recognised by the OIE, are sufficient to recommend the re-instatement of the FMD free status of the zone with vaccination, to the International Committee of the OIE.

Throughout the mission the team was accompanied by officials of the competent authority in Argentina and wishes to acknowledge their highly appreciated support for the successful accomplishment of the mission including provision of excellent interpretation.

**2. Team A Itinerary**

<b>Date</b>	<b>Subject</b>
5.12.2006	Pre-mission briefing, Florianopolis, Santa Catarina, BRAZIL
6. 12.2006	<b>ARGENTINA</b> Initial meeting local SENASA office, Tartagal, Province SALTA
7.12.2006	Visit to Municipal slaughterhouse Tartagal,
	Visit to road check point border Aguaray - Northern zone A
	Visit to local SENASA office, Salvador Mazza in Northern zone A
	Visit to International border control point Prof Salvador Mazza (Argentina/Bolivia border) and meeting with BOLIVIAN veterinary services
	Farm visits within 25 Km Northern zone A
	Local SENASA office, Tartagal
8.12.2006	Farm visits within 25 km Northern zone A
	Visit to local SENASA office, Tartagal
	Farm visit outside 25 km zone
	Initial meeting local SENASA office, Corrientes, Province of CORRIENTES
9.12.2006	Visit Corrientes road transit check point
	Visit Corrientes river crossing check point
	Visit to vaccination office, Corrientes, Foundation for Animal Health (FUCOSA)
	Visit to Corrientes Province local office, CORRIENTES
	Visit to FMD outbreak farm in Northern zone B (owner Ronero Feris) Feb 2006 Province of CORRIENTES

Date	Subject
	Visit to SENASA local office, San Luis del Palmar in Northern zone B
10.12.2006	Visit to SENASA local office, Bermejo, in Northern zone B Province of CHACO
	Visit to SENASA local office, Northern zone B, Clorinda, Province of FORMOSA, ARGENTINA and meeting with SENACSA, veterinary services PARAGUAY
11.12.2006	Informal lunch with SENACSA president and staff, Asuncion, PARAGUAY
12.12.2006	Debriefing meeting at PANAFTOSA, Rio de Janeiro, BRAZIL
13.12.2006	Departure

### 3. Main findings and observations

SENASA (Argentinean Animal Health Authority) has taken preventive measures along the border with Bolivia and Paraguay (through Resolution No. 403/04 approving the “FRAMEWORK PROJECT FOR BORDER PROTECTION”) with a “SUBPROJECT FOR NORTHERN “A” BORDER” approved by SENASA Resolution No 748 dated on October 22, 2004. However following the two outbreaks of FMD in February 2006 which affected the Province of Corrientes, Department San Luis del Palmar, in the 25 Km from the border area, the measures were quickly extended to the remaining border lines with Paraguay and part of Brazil, in the Provinces of Chaco, Corrientes and Misiones, by “SUBPROJECT FOR NORTHERN “B” BORDER”.

#### a) ARGENTINA - Zoning (FMD “control” Northern zone A and B) and vaccination

The findings and observations supported the information as described in the submissions to the OIE. In the FMD control zones Northern A and B there is an increased vaccination, surveillance and controls. Therefore in general in these zones to the North of the country adjacent to Bolivia to the North West and Paraguay to the North East all species susceptible to FMD are vaccinated twice per year and tagged on initial vaccination in one ear and then again in the other ear for the second round. All age groups of animals are vaccinated during the vaccination campaigns lasting about 3 months during February to April and October to December.



**Figure 2: Map showing border areas (FMD control “Northern zone “A” and “B”)**

Calves are usually only vaccinated if the navel is dry. There are some local differences whereby in 3 western departments of Formosa the whole department is included in the control zone i.e. greater than 25 km and in certain departments to the East the cost of the vaccine for the bovines is paid by the farmer however as stated before vaccination of all the other animals of the susceptible species is carried out free of charge by SENASA as well as the ear tagging in **all** species. The team learned that during vaccination 1ml of vaccine is given to small animals including calves and 2 ml to other bovines.

In the Salta and Formosa provinces, vaccination is carried out by personnel contracted by SENASA for 6 months who are trained to ensure the cold chain and in carrying out vaccination. The whole of 3 departments in Formosa are included in the FMD control zone because of the farm structure, (an indigenous population with a lot of small farms and the poor economic situation). In Corrientes the vaccination is carried out by FUCOSA (an NGO see below) and similarly in Chaco by an NGO under supervision. Oil vaccine contains 4 strains A<sub>Cruzerio</sub>, A<sub>Argentina2001</sub>, O<sub>1 Campos</sub>, and C<sub>3 Indaial</sub>. Vaccine bottles, storage fridges, freezer bags, syringes, ear tagging equipment, individual numbered ear tags and records

were seen and checked. Ear tagging is carried out in the 25 km zones at the time of vaccination so it is easy to see if the animals have been vaccinated once or twice. In the submission to the OIE it is stated that non vaccinated calves are vaccinated in between vaccination periods; this does not appear to be the case although they would have to be vaccinated twice if they had to be moved to another holding.

Nationally, (i.e. outside zones A and B) there are about 362 non-governmental (NGO) sanitary bodies or entities charged with carrying out vaccination of bovine animals. These bodies are run by committee involving SENASA and farmers. They carry out the vaccination programme. The farmers are charged for the cost of vaccination and an administration fee to cover the overall vaccination costs. It is a non profit making organisation. Vaccination centres were visited where the records and cold chain were checked. Each vaccinator has a given area in which to carry out the two vaccination campaigns. Bovine animals are not marked when vaccinated except in the zones A and B as described above. Thus the vaccinators are fully occupied for about 6 months but at other times will have less work although they are involved in vaccinating animals which need to be vaccinated before moving if they have not been vaccinated twice i.e. all bovine animals must be vaccinated twice before being allowed to move to another holding.

**b) Animal identification, holding registration and SENASA animal health management database**

Brand marks and ear notching are compulsory and are recorded and issued by the national authorities. This is checked by the provincial police authority. In ARGENTINA the brand is on the left rump but in PARAGUAY the brand is on the right. Each owner (owner ID) and holding (RENSPA number) is registered and where necessary each production unit on the holding (i.e. where there are a more than one animal owner on the same holding) are further identified in the Sanitary Animal Health Information System (SGS).

The SGS has been operation since 1996 and has been updated regularly since then. The functionality of SGS was explained and seen in operation at the offices visited and appears to be quite detailed although at the moment ear tags are not recorded.

There will be a new national individual animal identification (ID) system introduced on 1 January 2007. From this time, all animals that are moved (except direct to slaughter), all animals born in 2006 and all imported bovines will have to be double ear tagged. This system will apply to the whole of Argentina but in Zone A and B this will be in addition to the rose coloured button vaccination tags. It will obviously take some time nationally before all cattle are identified by the new system which involves the use of colour coded ear tags covering national tags for vaccinated and non-vaccinated animals, lost tags and imported animals (see annex). The data capture for this system is being integrated into the existing SGS and will include the new CUIG number (forming the basis for the individual animal number) which will be allocated to each holding. The new animal ID system will record the ear tags issued to or used by each farm. Extensive information on the new system was given to the team although detailed instructions to field staff have still to be provided.

**c) Movement controls**

Animals need a movement permit (DTA) issued by the local office before any movement can take place. The DTA costs 1 Peso for the permit plus 90 cents for each bovine and less for small stock. The owner has to go to the local office to obtain this, is given a serially numbered seal and must seal the transport after loading the animals. In certain cases where the animals are destined to export approved slaughterhouse (SH) the seal is applied by SENASA staff. The seal must be intact at destination and is checked by the veterinarian at the slaughterhouse. The seal number is included on the DTA. The DTA is printed after carrying out a check on the SGS. This ensures the animals are eligible to move and an e-mail or fax notification to the local office of destination is sent. There is a pre-movement check at destination that animals can be received (no objection to moment) and a return receipt that animals have in fact arrived. In addition, within 48 hours of movement the farmer is obliged to go to the SENASA office with the DTA and this enables a check and an update of the SGS.

There are numerous road transit checks some permanent some mobile (which are changed monthly). SENASA staff checks the movement documentation of live animals (the DTA, the lorry seal and the cleansing and disinfection (C&D) document). Records were seen and in one check point it was stated that since operations began in 2001 there had been about 800 animals seized and killed at the local

slaughterhouse as there were no DTAs available. Most infringements relate now to the expiry of the C&D document which normally lasts 72 hours. Animal transport vehicles must have a C&D document to move if empty. This document is issued at the slaughterhouse, at an approved C&D point (maybe at a petrol station) or in certain cases the farmer is authorised.

#### **d) International border controls and International agreements**

Extensive controls are carried out at the International border with all luggage searched and/or subjected to scanning. All domestic animals and meat, meat products, milk, milk products and eggs etc are prohibited to be brought in by travellers. Figures for seizures are available and indicate plant material is the largest amount seized with very low figures for meat. The team observed some seizures of plants and vegetables on-site. There appeared to be no imports of livestock. There are problems with smuggling of drugs and also other goods including cigarettes in parts of the border area which tends to make enforcement of animal health controls more difficult. In addition at certain times of the year drought may contribute to illegal movements.

Animal Health Border Agreements have existed in the sub-region since the 70's. During the period of the River Plate Basin Project they were strengthened and were the basis for harmonized border activities.

The occurrence of FMD in the Tripartite border area (ARG/BOL/PAR) in 2003 re-emphasised the need for joint operations to control and prevent the disease in a region lacking definite geographical boundaries, low economic standards and known transhumance problems. This means that parts of the border are permeable and it is impossible to prevent some animal movements and transhumance across some the border areas. In other places wide rivers flowing all year round act as natural boundaries and those parts of the country can be considered at a much lower risk.

The Mission planned to visit the following local offices of SENASA: Salvador and Santa Victoria Este in the Province of SALTA and Clorinda in the Province of FORMOSA. Due to flooding after extensive rain, the road to Santa Victoria was impassable on the day of intended travel and the team could thus not visit this border area. However, the Mission was able to visit some farms at random and the local office to assess vaccination procedures.

In 2004 Argentina, Bolivia and Paraguay developed, with the aid of PAHO, a Third Country Cooperation program to set the basis for a common effort for controlling foot and mouth disease in the Chaco Americano region. SENASA has implemented the Northern Border A project and then Northern B Project in at least a 25 km zone south of the border with additional resources to increase disease awareness and control. In September 2006 an international meeting with the participation of PANAFTOSA/PAHO was convened to program activities for the next two years and to procure additional sources of funds.

During the visit to the Department of Salvador Mazza SALTA, the team was informed of the activities carried out by Argentina and Bolivia in the zone. The zone included varies from a minimum of 25 to 40 km on both sides of the border line. The farm registry has been updated by joint on the spot visits along the border area and the SGS is operational. Vaccine is bought by the governments and either applied by SENASA and SENASAG (Bolivian Animal Health Authority) The Bolivians stated that new local office near the border being built. There is a similar database with an individual file for each farm with GPS information, records on vaccination and movement being computerised. New software has been developed for movement controls since 1 January 2006. Bolivia is using some sentinel animals for FMD with serological surveillance for virus circulation and immunity levels.

As stated before, all susceptible species (bovine, sheep, goats and swine) in the area covered by the agreement are vaccinated twice a year and ear tagged and Bolivia use yellow button tag with a piece sticking out and a black button tag. Young animals receive the first ear tag when vaccinated for the first time and a second six months later. Therefore visual identification of vaccinated animals is possible. Slight variations to this rule were observed in Corrientes, Chaco and Formosa, where commercial farms included in the 25 km area are also subjected to official ear tagging and vaccination of all susceptible species, but the cost of vaccination of bovines is borne by the owners. Special attention is given to indigenous communities that have traditional ties on both sides of the border and where transhumance is known to take place and cannot be prevented.

Intense animal transit control is carried out in the zone with communication between offices about the transit of animals. All trucks carrying animals to slaughter or other destinations are sealed at the origin, as a national rule, which is enforced at road blocks and international border controls.

The Argentinean/Paraguayan border has 300 km of common land since the Pilcomayo River was diverted to serve dry zones on both sides. The zone has been subjected to the same program of activities as seen in the Northern A zone, such as farm registration, vaccination, transit control and co-ordinated surveillance.

Nevertheless, in the Paraguayan side of the border some differences in the operations are applied in the Department of Boqueron (PARAGUAY) which is a mixture of resource-poor communities consisting of indigenous people and well organised Mennonite farming communities. Livestock Committees are in charge of vaccination and the costs are borne by them and the commercial type farmers are charged 68 cents per vaccine dose but the indigenous farmers (small holdings) are not charged for the vaccine. The cost of ear tagging is borne by SENACSA (Paraguayan Animal Health Authority) and ear tags are white button type. In the adjoining Department of Presidente Hayes (PARAGUAY) which is more economically affluent, the entire operation is in the hands of the farmers but SENACSA has 127 vaccine supervisors to monitor if vaccinations are done according to SENACSA protocols. In this Department ear tagging is substituted by branding (V on the left mid dorsal area) of animals once on the first vaccination. Farmers prefer to use their own individual herd ear tags. In all cases, only bovines are vaccinated twice a year, and the vaccination cycles are not harmonized with the Argentinean side. The rationale for excluding small stock was that they could act as sentinels. When indicated to the Paraguay delegation that small stock are poor sentinels as they elicit insignificant or no symptoms of disease, they agreed that they would reconsider the issue. This was later reiterated by the official Delegate of Paraguay during an informal lunch in Asuncion.

#### **4. Conclusions and observations on Argentina and Paraguay**

- (1) The team had complete access to all records and to verify the implementation of the vaccination, movement and other risk mitigation policies, by means of on-site visits to farms and control points. These indicated that the Argentineans are applying more stringent and updated control measures to minimise the risk for the introduction of FMDV into the territory to assist early detection and rapid response to an incursion of the virus. Extra resources and logistical support has been provided by SENASA but it is imperative that this commitment is maintained.
- (2) The overall vaccination system used in Argentina appears to be very effective and ensures very high vaccine coverage. The team suggested that the system could be even further intensified by employing the services of vaccinators and Animal Health Committees (COPROSA) during the non-vaccination periods i.e. more frequent visits and inspections of farms not necessarily related to vaccinations to further complement the surveillance activities outside of the vaccination periods. The SENASA officials reacted positively to this suggestion.
- (3) The RENSPA database offers sufficient opportunities to incorporate the new ID system that will be implemented as from 1 January 2007. It was suggested that the facility already available on the system to allocate and record individual animal numbers should also be used to record individual animal numbers for serological surveys to facilitate follow-up and trace-back in the event of serological reactors.
- (4) The new individual animal ID system appears to be very promising and will further complement and strengthen movement controls and traceability systems but it needs to be well communicated both within and without SENASA to ensure that it will be well understood and properly applied.
- (5) There might occur some short term initial problems with supply of ear tags for the new animal ID system because only 3 manufacturers have been authorised due to the high quality demanded for the ear tag but the introduction of individual animal identification with double ear tags will bring considerable advantages.
- (6) Surveillance is carried out at slaughterhouses with particular check on hooves and mouth for FMD lesions, serological surveillance is carried out for measuring immunity and for NSP. The latter two are carried out according to a national plan from SENASA headquarters.

- (7) Additional sources of funds should be negotiated to finance the activities where existing budgets do not fully satisfy the demands.
- (8) Training of personnel assigned to the border area should be maintained and continuously updated.
- (9) The application of the 25km intensified FMD control zone acts as a buffer with an intensified surveillance zone *within* the free zone with vaccination. It could be reasoned that this zone should be excluded from the free zone. However, the team considered the advantages and disadvantages of possible exclusion of this 25km control area from the free zone, and concluded that it would be more advantageous to maintain the *status quo*. However, the inclusion or exclusion of the 25km zone from the free zone should be harmonised between adjoining countries.
- (10) The mission visited the main farm involved in the February 2006 outbreaks but it remains a complete mystery as to the origin of the infection and impossible to understand the epidemiology although intensive investigations were pursued. However not all animals were examined and not all animals sampled on both farms involved. In the mission's view more intensive and complete epidemiological investigations in the event of an outbreak (in particular the first few outbreaks) should be carried out.
- (11) The bi- and tri- national border agreements seem to be the best operational solution for the perceived past lack of preventive activities in the border zones. The system was perfected from the River Plate Basin Project and today covers key risk areas along the international borders. Nevertheless, certain important differences in the structure and application of processes of disease control and prevention were noted between ARGENTINA and the adjoining countries.
- (12) PANAFTOSA/OPS as the regional reference institution should be even more involved in the programming, developing and synchronising of activities in the zone.

## ANNEX

## Ear tags for new system



Yellow = FMD vaccinated; green = non-vaccinated; red = imported; blue = replacement tag



Front of primary tag: AR = Country of origin (Argentina), JC 432 = CUIG number; A345 = serial number, and -8 = verification number.

Back of primary tag: 06 MARCA = Production number, 01.080.0.03485/03 = RENSPA number, 00158 = printing number, 01/07 = date of printing, A200A399 = printing range.



Front of secondary tag: JC 432 = CUIG number; A345 = serial number, and -8 = verification number

**CHAPTER 3**  
**Report Team B**  
**Mission to Brazil and Paraguay**

**1. Composition and itinerary of Team B**

The mission team consisted of Drs V.P. Caporale (team leader), C. Zepeda, G.C. Darsi and A.-E. Füssel.

Date	Subject
5.12.2006	Introductory briefing, Florianopolis, Santa Catarina
6.12.2006	Campo Grande, Mato Grosso do Sul (MGS), meeting in Ministry of Agriculture
7.12.2006	Flight to Eldorado (MGS)
	IAGRO, local veterinary unit Eldorado
	Visit to the outbreak area
	Visit to Fazenda Jangada (outbreak)
8.12.2006	IAGRO, local veterinary unit Japora
	Visit to outbreak area
	Visit to green border with Paraguay
	Visit to Fazenda Itaipu (outbreak)
9.12.2006	SENACSA Region Nord Nr.2 Department Canindeyú, Zona XIV District Salto del Guaira, Paraguay
	Visit to SENACSA Control Post at Cruce Carolina Andrea
	Visit to Animal Health Commission La Paloma, Department of Canindeyú
	Drive along the border with Brazil
10.12.2006	Discussion with SENACSA on Surveillance
	Drive to Londrina (Parana, Brazil)
11.12.2006	Meeting at PANAFTOSA
12.12.2006	Debriefing at PANAFTOSA
13.12.2006	Departure

**2. Main findings and observations****2.1. Visit to Brazil (Mato Grosso do Sul (MGS))***2.1.1. Veterinary services*

The authorities provided a copy of their introductory presentation detailing the complex administrative structure of the veterinary services in Brazil, which includes 27 federal units, 5.561 municipalities and 3.378 communes. The presentation is attached to this report.

In the veterinary field, the federal responsibility is with the department for animal health. In each state, there is a secretariat for agriculture, and a varying number of regional offices. In Brazil, there are 1,563 local veterinary units. Some local veterinary units serve more than one municipality, in some municipalities there are several veterinary units. The local veterinary units report to the state. Not all local veterinary units have necessarily a veterinarian, but they have at least a para-veterinarian.

A superintendent ensures vertical coordination between the Federation and the individual state. There are various superintendents for different subjects and if coordinated action between veterinary and other services, such as police or customs controls, is necessary, a high level of personal collaboration or coordination from the federation is required. The superintendent supervises all activities of the secretariat for agriculture in the states, the regional offices and of the local veterinary units.

The state veterinary services are responsible for executing animal health control measures, notably surveillance, promotion and inspection of vaccination, sales of vaccines, outbreak control and investigation, animal identification and holding registration, animal movement control and training and education.

#### 2.1.2. *Animal identification and movement controls*

In MGS all livestock holdings are recorded and entered with their GPS data in a database. The database assigns an owner's number and a farm number to accommodate for properties that own more than one farm. The livestock numbers recorded for such holdings are based on owners' declarations in their vaccination records and movement documents. From this information the database calculates for a particular point of time the age and sex groups supposed to be on the holding, and warns if there is a mismatch between the calculated number of animals and the vaccination record. However, such warnings are frequently not sufficiently followed up. It appears accepted that owners do not report the introduction of animals between two subsequent updates of the database in the context of a report on the completion of the vaccination or an application for movement documents, for which information on the available livestock on the holding of dispatch is required.

As a rule, animals have only an approved property brand and there is no other official mark on the animals, unless animals are marked or tagged during vaccination to avoid double vaccination or for particular surveillance purposes.

Details about inspections on farm to verify the livestock numbers for fiscal reasons are in the presentation. As a rule 10% of farms are checked per year. If there are discrepancies between declared and existing livestock figures, the case is transferred to an attorney. IAGRO, the state agency for the protection of livestock and crops, recorded for MGS 2173 infractions for missing or wrong movement documents and 21 for false declaration of livestock in 2005, and 682 and 105 respectively in 2006. However, the team was informed that after the outbreak in 2005, cattle breeders in MGS received a state amnesty in order to encourage them to declare their real livestock figures. It was also mentioned that the control measures during the outbreak did disturb certain unauthorised cross-border activities and affected people reacted aggressively against the officials.

IAGRO explained that during 1997 to 2006 about 12 million head of cattle are moved annually within MGS and less than 2 million head are moved to other states in Brazil. Most of the movements concern animals for breeding and rearing. Movements for slaughter within the state are about 3.8 million in 2005, and less than 1 million to other states.



**Figure 3: Green border between Brazil and Paraguay**

Until the outbreak in 2005 prices farmers could realise for their livestock were higher in Brazil than in Paraguay, after the event this situation has reversed.

The team also visited the green border to Paraguay which does not effectively separate the animal populations of the neighbouring countries.

The team was informed that in at least one outbreak in Brazil,

Brazilian resident animals were killed and the animals in the part of the farm on Paraguayan territory animals were vaccinated by the Paraguayan authorities, although labour was moving regularly between the two farms.

The team also met veterinarians of a temporary control post next to the border, manned by state employed officials, which are frequently changed to ensure impartiality.

### 2.1.3. Disease notification and control measures



Figure 4: 2005 outbreaks in Mato Grosso do Sul

In 2005 outbreaks occurred in the three south-eastern most municipalities of MGS. The mission team visited two of them, notably the municipalities of Eldorado (index case) and Japora at the border with Paraguay. During the 2005 outbreak 628 clinically ill animals were observed out of a total of 17.806 animals investigated, i.e. on average 3.5 % of the animals showed clear clinical signs in spite of vaccination. In many cases the disease was reported very late and in some herds there were up to 20% of the animals showing clinical signs despite reinforced surveillance in the

protection and surveillance zone. The official veterinarians explained to the team that mouth lesions are the typical clinical signs and that foot lesions have not been observed on the inspected animals.

The outbreaks in Parana and the suspicions in Sao Paulo have been detected either through notification or denouncement by owners or in result of tracing from MGS.

Farms stamped-out for FMD receive compensation. 70% of that compensation comes from the Federation and 30 % from a fund supported by slaughter taxes and GIA fees. These federal expenses include also compensation for collateral damages, and consequential unemployment or loss of income.

### 2.1.4. Vaccination

Vaccination is the responsibility of each individual state and inspectors control vaccination through random audits.

In MGS vaccination is carried out as follows:

- Plano Alto two vaccinations, in May all animals, in November only cattle up to 24 months,
- Pantanal one vaccination of all animals in May or November.

Note: The FMD situation in the Pantanal is so much different from the situation in the highland of MGS that it is not part of this assessment.

Vaccination coverage in the highland of MGS is stated to be well above 95% percent. However this coverage is calculated from purchased vaccines and registered animals and based on declaration by the owner. While such high coverage may superficially appear satisfactory, in reality it means that hundreds of thousands of cattle are unvaccinated or under-vaccinated. Until 2005 vaccination was carried out 3 times a year (Feb-May-Nov), but since 2005 only two vaccinations are carried out. Moreover, due to the outbreak in 2005 there was no vaccination in the affected municipalities in November 2005 until the vaccination in May 2006.

Only in a small proportion of holdings vaccination is either carried out officially or monitored by officials whereas in the majority of cases vaccination is carried out by the owner and then declared to the authorities together with the submission of the invoice for the vaccines.

The interpretation by local veterinarians of EITB positive results in animals without clinical signs of previous infection as a consequence of illegal vaccination casts doubts on the controls over vaccines in the country.

#### 2.1.5. *Surveillance*

In general serological surveillance is not used for outbreak investigations but for the reinstatement of status and lifting of restrictions.

Samples are taken preferably from herds that keep certain age groups (between 6 and 24 months), in order to minimise the interference of repeat vaccinations with the specificity of the test used for the detection of antibodies against NSP. It is not clear to what extent this selection, which is a compensation for impurities in the used vaccines, impairs on the randomisation of the sampling protocol and thereby on the validity of surveillance results.



**Figure 5: The surveillance map of Japora shows outbreak holdings in red, sampled holdings in green and NSP positives in yellow**

In the case of Japora municipality where 21 of the 22 outbreaks occurred between 10 October and 21 November, the last outbreak was discovered on 12 April 2006 in the framework of a survey including 170 farms from which 2995 samples were taken. 28 properties were EITB positive; but because in 27 of them the officials did not see any clinical signs of previous or current FMD, it was concluded that the owners had carried out illegal vaccination. During the clinical inspection on one farm old lesions were detected in a cow with high EITB titre and 22 more animals on the farm were positive to EITB and the herd was declared an outbreak.

In Mundo Novo municipality a farm was included in the survey, and one animal was positive for antibodies to NSP, and upon retesting 32 animals had seroconverted, which was attributed to unrecorded/illegal vaccination. Although these findings would comply with the definition of an outbreak in the Code and yet it was not reported as such.

## 2.2. **Visit to Paraguay (District Salto del Guairá)**

### 2.2.1. *Veterinary services*

The mission had a meeting at the Regional office of SENACSA Region Nord Nr.2, Department Canindeyú Zona XIV District Salto del Guairá where the central authorities presented the veterinary services in the country. The presentation is attached to this report.

Paraguay has 406,752 km<sup>2</sup>, with 260,000 km<sup>2</sup> agricultural land, and 5.7 million inhabitants with 5 million east of the river Paraguay and the rest in the Chaco part of the country.

In Paraguay there are 9.5 to 10 million cattle in 4,040 holdings with 2.6 animals/ha on average. They also have 300,000 sheep and 1.5 million pigs.

They country is divided in 7 sanitary regions, 4 east of the river and 3 in the Chaco area.

More than 1000 officials work in SENACSA, not all are veterinarians, about half of them are occupied with animal movement and quarantine. SENACSA works closely together with the Animal Health Commission which is a private, industry driven organisation set up by law and in charge of certain disease control measures, such as FMD vaccination. There are 8 such commissions, notably for FMD, bovine tuberculosis and brucellosis, rabies, equine infectious anaemia, BSE, Newcastle disease, swine fever and improvement of disease control. The only operational one is the Commission for FMD. The structures of the Commission are divided into zones and there are 3 such zones in the Chaco and 14 in the rest of the country. The president is from SENACSA and there is a board in charge of animal health, quality, technical resources, laboratories and administration.

They also have set up an animal health fund for the compensation of outbreak farms fed by fees on certification and slaughter, and used also for the improvement of the database, better equipment for laboratories and other measures necessary to maintain animal health. The importance of the current OIE recognised FMD status is illustrated by the substantial increase in meat exports both in quantity and value since 2003.

### 2.2.2. *Animal identification and movement controls*

All cattle holdings are recorded in a database and they report also other livestock kept on their premises. Farms keeping only sheep and goats are not recorded and need therefore no documents if they intend to move these animals. Pig holdings with more than 50 pigs are usually commercial and require registration as they need to move animals. To move horses a fee has to be paid and such movements are therefore subjected to the checks at control posts, this also avoids hidden transport of other larger animals in horse transports.

Usually cattle leave the holding of birth for the rearing units at the age of 12 months. In 2005 Paraguay recorded 391,000 movements for breeding, 1,016,586 for fattening and 1.6 million for slaughter carried out on 67,729 lorries per year. The average transport distance was 250 km.

The local veterinary units are mandated and accredited to certify movement of animals. Movement certification depends *inter alia* upon the correct vaccination status as recorded in the database.

The team found discrepancies in the recorded numbers of animals in some holdings which were explained as failure by the owners to report back when they purchase new animals. These failures of course compromise the identification and registration system, and they complicate the controls over the compulsory residence on a holding for export or regionalisation purposes, where it is necessary to separate various subpopulations.



**Figure 6: Bovine animal grazing along the border**

Work is currently under way to improve the database and in particular to network the various regional and local databases.

They maintain a number of strategically placed control posts on major roads and along the river. Most of the bovine animals go through the control post of Vista Alegre, Minas and Pozo Colorado in the Chaco area.

The mission team observed a check at control post Cruce Carolina Andrea carried out on a consignment of 18 cattle for slaughter. The control post was

equipped with a gantry to observe the animals from above and to verify correct branding on the

right hind leg site. About 130 consignments with up to 4500 animals pass the point per month. It was observed that the lorry stopped at the control post voluntarily without interference by the post itself.



**Figure 7: Border road in Paraguay**

They also have 6 BIPs on international borders to control all consignments of animal products, primarily meat from Argentina for export to Chile.

However, along the green border with Mato Grosso do Sul, the cattle population is not effectively separated from the cattle population in Brazil, and the officials reported that during the outbreak in 2005 in Brazil, on those farms situated directly next to the border the gates towards Brazil were officially chained and sealed to suspend movement of animals between the countries.

### 2.2.3. *Disease notification and control measures*

Since 1996, Paraguay reported one outbreak in October 2002 in the province of Canindeyú, east of the river Paraguay, and one outbreak in July 2003 in Boquerón, in the Chaco area. For neither of these outbreaks the origin of the virus was properly established.

### 2.2.4. *Vaccination*

About 70% of the required 22 million doses of vaccines are produced in Paraguay; the missing part is imported from Brazil. Until October 2004 vaccines were produced in Paraguay by Frenkel method; since 2005 on cell culture in rolling bottles. The last Frenkel vaccine was used in June 2005 throughout the country.

Vaccination is carried out in January/February and July/August. Pre-movement vaccination is required, except if the animals are destined for slaughter. It could not be clarified how many days before movement the animals are vaccinated or whether this vaccination is carried out during loading.

To carry out routine vaccination owners purchase the necessary quantities of vaccine based on the inventory of animals, vaccinate and report to the local veterinary unit, with details on cattle age and sex groups and other livestock on the farm.

Since 2003 the system was slightly modified. There are now 2494 accredited vaccinators and 885 supervisors. They agree with the farmers the dates of vaccination and select the holdings that are to be vaccinated. The vaccination is officially supervised and the cold chain is controlled by the official veterinarian. The vaccination report is issued in triplicate and signed by the owner, the supervisor of the vaccination and the responsible coordinator from the Commission and then the vaccination is recorded in the database. Vaccination on farms with more than 100 head of cattle is supervised, on farms with less than 100 head of cattle it is carried out by accredited vaccinators.

With the vaccination report the owner provides the invoice on the vaccines purchased for the campaign he is going to report and unused bottles of vaccines have to be returned.

However, the reports checked by the mission team indicated that the owners purchase vaccines exact by the number of doses they report as inoculated; i.e. no losses and no excess doses.

### 2.2.5. Surveillance

Surveillance is carried out on holdings in slaughterhouses and markets but also at control posts and this information is collected to give an overview of the situation. The services and the sector are constantly “sensitised” to ensure passive surveillance, and the GIA system conveys responsibility to the signing owner. However, active surveillance is complicated by lack of proper identification and insufficient traceability of animals due to insufficient networking of the various local databases.

In the framework of the national surveillance programme, about 18,000 samples per year are taken at slaughter houses and markets for surveillance and samples taken for other purposes are also used for FMD screening. The number of samples taken for surveillance generates inevitably suspicious cases that must be followed up by retesting and on-the-spot investigation. A manual of operating procedures for the surveillance has recently been introduced and is now being fully implemented by local units; there it is described what to do in case of suspicion. However, it would appear that their first suspicion is always vesicular stomatitis and not FMD.

In relation to outbreaks in MGS in Brazil, specific surveys were carried out in the border area in April 2006. About 7000 samples were taken for serology in accordance with an approved sampling plan. According to that plan they selected 150 herds in the area and within the herds they looked for young animals under 18 months of age and sampled animals were tagged.

Out of 7000 samples collected, around 6800 samples were actually tested by ELISA and EITB in the laboratory in Asuncion. Two ELISA positive animals were detected in one herd and as a matter of follow-up the whole herd was tested on the 15 May 2006 and probang samples were taken from the two animals and tested with negative results.

## 3. Conclusions and observations on Brazil and Paraguay

### 3.1. General structures of animal health controls

- In the case of Brazil, due to the size of the country, the veterinary administration has a complex structure that leaves room for more effective coordination to enhance confidence in the measures presented at international level by the central authorities.

### 3.2. Movement controls, traceability and separation of national herds

- At least along the dry border between the south of Brazil and Paraguay the national cattle populations cannot be considered as separated as there is uncontrolled cross border movement of animals and frequent exchange of labour (observed cattle in no-man’s-land, chaining of gates in Paraguay during the outbreak, shared properties, etc.)
- Databases used for movement permits are not networked and residency cannot be verified through the database due to lack of individual identification.
- While dispatch of animals is regulated, return information on arrival of animals on holdings is voluntary, and not required following delivery to a slaughterhouse
- Direct official veterinary supervision of dispatch of animals is not consistently enforced and thereby GIAs are issued on declaration by the owner

### 3.3. Disease control and outbreak investigation

- During the most recent outbreaks in Brazil measures were taken which contributed to limit the number of outbreaks to 34. During the outbreak in 2005 routine vaccination was suspended in Brazil, but emergency vaccination was carried out on a farm in Paraguay that belongs to a stamped out outbreak farm in Brazil with personnel working on both sides of the border. The failure to implement in Brazil a booster vaccination immediately after the outbreaks and before the May 2006 campaign left in particular the unprotected animals borne after the May 2005 campaign at great risk for an extended period of time.

- Outbreak investigation is not carried out systematically and post-outbreak surveys are not design to detect hidden pockets of infection. Lack of proper outbreak investigation led to a delayed declaration of at least one outbreak in the Japora municipality and potentially one undeclared outbreak.

### **3.4. Vaccination**

- Vaccination in politically distinct areas, that however represent a single ecological and epidemiological entity, is carried out at different times leaving constantly a certain proportion of animals incompletely protected.
- Vaccination is carried out predominantly by the owner and is declared rather than supervised, audited or even executed by the official services.
- The cold chain is controlled as long as the vaccines are under veterinary supervision, however no such control can be guaranteed when vaccination is carried out solely by the owner.
- No control is executed for residual quantities of vaccines and there appears to be no losses of vaccines during vaccination, and farmers buy always the exact number of doses of vaccines. It is also not excluded that the number of vaccinated animals is less than the real livestock figures, at least in MGS a state amnesty had to encourage owners to declare a proper inventory. In addition, unauthorised use of vaccine is considered as an explanation for the presence of antibodies against NSP.
- Emergency vaccination was not carried out in the outbreak affected municipalities of MGS in 2005, in order to avoid interference with surveillance. Impurities of vaccines with regard to NSP are frequently quoted as explanation for NSP-positive results thus preventing efforts to investigate outbreaks properly.
- Old methods have been used for the production of vaccines production until the end of 2004 and such vaccines have been used until mid 2005.

### **3.5. Surveillance**

- Systematic outbreak investigation for an early detection of remaining pockets of virus circulation and for the understanding of the epidemiology is in practice not carried out.
- Serological surveillance is predominantly aimed at documenting a status.
- Interpretation of test results is not always in compliance with OIE recommendations in order to improve specificity without incorporating changes in sensitivity into the surveillance scheme.

**CHAPTER 4**  
**Report Team C**  
**Visit to laboratories for diagnosis and for vaccine control**  
**in Argentina, Brazil and Paraguay**

**1. Mission objective**

The objective given to the Team C of the OIE delegation was complementary to the objectives of the Teams A & B. The Team C main objective was to assess the capacity of the National Laboratories for FMD Vaccine Control in Argentina, Brazil and Paraguay and consequently to give a report on Quality Control of the FMD vaccines used in these countries or exported in South America. The OIE team C consisting of Dr Rossana Allende in charge of vaccine control at PANAFTOSA and Dr. Michel Lombard, consultant in FMD vaccines presently retired from Animal Health Industry. The Team C visited three laboratories in order to:

- a) assess the application of the national regulation for FMD vaccine control and Quality of these Controls;
- b) assess the working capacity of the laboratories;
- c) assess the compliance with the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* of the OIE.

**2. Team C Itinerary**

Date	Subject
5.12.2006	Pre-mission briefing, Florianopolis, Santa Catarina
6.12.2006	<b>BRAZIL</b> , visit at LABORATORIO NACIONAL AGROPECUÁRIO – LANAGRO/RS in Porto Alegre (State of Rio Grande do Sul). Director Dr. Joao Mathias Becker
7.12.2006	<b>BRAZIL</b> , visit at LABORATORIO NACIONAL AGROPECUÁRIO – LANAGRO/RS in Porto Alegre (State of Rio Grande do Sul). Director Dr. Joao Mathias Becker
8.12.2006	<b>ARGENTINA</b> , visit at the LABORATORIO y control TECNICO of SENASA (National Service of Animal Health and Food Quality) in Buenos Aires. Director Mrs Dra. V. Torres Leedham
9.12.2006	<b>PARAGUAY</b> , visit at the General Direction of Laboratories DIGELAB of SENACSA (National Service of Quality & Animal Health) in Asuncion. Director Mrs Dra. N. Vergara.
10.12.2006	Return trip to Rio de Janeiro
11.12.2006	Meeting at PANAFTOSA
12.12.2006	Debriefing at PANAFTOSA
13.12.2006	Departure

**3. Main findings and observations**

**a) Pre-mission briefing in Florianopolis-BRAZIL.**

Dr. Rossana Maria Allende presented a comprehensive overview of the production of FMD vaccines by Animal Health Industry in South America (no production by government bodies) and the subsequent controls made on final products by the National Authorities.

From the presentation it can be deduced, that in the three countries visited, Argentina, Brazil and Paraguay, the vaccine production is satisfactory both in quality and quantity for the needs of these countries.

Cultures of viruses are carried out in inspected premises complying with national biosecurity requirements. The cultures are mainly performed using BHK 21 cell line, however, Argentina continues to accept two manufacturers using primary cell cultures of the tongue epithelium. It was explained that the latter method complies with GMP rules and allows the release of a consistent and save product.

All the inactivation processes turning virulent viruses into inactivated antigens are made using an inactivant of first order, Binary Ethylenimine (BEI) used twice and followed by a kinetic of inactivation. Consequently no virulent vaccine can be observed, which is exactly what we noticed during our visits. All the vaccines presented to National Controls are oil vaccines, an emulsion of water (with immunogens) in mineral oil.

The National Control Process is covered by a specific law in each country detailing all technical steps and methods, both for pre-registration control (Marketing Authorization) and for post-registration control (release of batches for sales). The current policy is the control of 100% of the batches before release for sales. The methods for control of Safety, Sterility and Stability are complying with the OIE *Terrestrial Manual* Chap. Foot and Mouth Disease.

The potency tests used in all South America are indirect tests based on the measure of antibodies by a Liquid Phase ELISA method. Some tests (Brazil & Paraguay) are derived from the initial study and publication by PANAFTOSA in Rio de Janeiro (revision in: Allende et al., 2003). This method is mentioned in the OIE *Terrestrial Manual* (web version May 2006) and should be referenced in the 2008 Edition of the OIE *Terrestrial Manual*. Countries like Brazil and Paraguay have simplified the potency test by PANAFTOSA bringing down the number of cattle in the test from 30 animals + 2 controls to 16 animals + 2 controls, but have kept the same correlation between antibody titres and protection. Argentina has developed its own method for Argentinean FMD strains (Periolo et al., 1993; Robiolo et al., 1995) and published a correlation based on antibody level tested at 60 days post vaccination instead of 30 days as prescribed in the PANAFTOSA method.

Vaccine strains are regularly matched against field virus isolates by PANAFTOSA experts in collaboration with country experts of South America and by Argentinean experts for Argentina.

**b) BRAZIL National Control Laboratory for FMD vaccines.**

The laboratory situated 20 km from Porto Alegre city accommodates several small units for the control of various vaccines used in Brazil, among them the FMD vaccine control laboratory. This is a tiny unit in charge of the tests of sterility, stability and potency for FMD vaccine for domestic use and for export.

The tests for Innocuity (research for virulent virus in the aqueous phase of the vaccine emulsions) are carried out in another unit (Standard Protection Level 2) situated in an OIE declared endemic FMD area of Brazil, in the city of Recife (State of Pernambuco), 3700 km further in the North East of the country.

For the same security reasons, vaccine/field strains matching tests are performed in a P2 unit located in Belem, State of Pará (declared FMD endemic to the OIE). These vaccine matching tests are made in collaboration between PANAFTOSA and national experts.

Situated 350 km north-west of the Porto Alegre Control laboratory, there is a farm which accommodates the cattle necessary to the potency tests and where the OIE mission did not go. With a yearly maximum capacity of controlling 240 vaccine batches a year, the capacity of the farm exceeds largely the laboratory capacity for serological tests.

The laboratory work complies with the Brazilian law referenced *Portaria N°713 dated 1 Nov. 1995*, amended by the *Technical Note DDA N°23/2002* the title of which is in English Standards for Production, Control and Use of vaccines against FMD. This law explains the requirements for registration of FMD vaccines in Brazil as well as their control after registration and before release on the market. The vaccine samples are taken randomly by Public Officers of the Ministry of Agriculture at the Quarantine of a Central Store belonging to the Animal Health Industry and called "*Central de Selagem*" situated in the vicinity of the city of Campinas (State of Sao Paulo), then the vaccine samples are sent by air under very strict conditions to the National laboratory in Porto Alegre.

The potency test used is a serological method (LP ELISA) published by the Pan American Centre for FMD in Rio de Janeiro (revision in: Allende et al, 2003) and called EPP (Expected Percentage of Protection). The method is mentioned as an alternative method for FMD Vaccine Potency Control in the current web version May 2006 of the OIE *Terrestrial Manual* Chap 2.1.1 FMD.

The original method was simplified by the Brazilian Authorities and consists in the vaccination in a blind way with a full cattle commercial dose (5ml oil vaccine) of 18 double tagged cattle of 18 - 24 months of age, preliminary recognized free from FMD and NSP antibodies. These animals are bred in several controlled farms located in the state of Rio Grande do Sul and after selection are accommodated in the farm of the Control Laboratory where the vaccination is carried out. The costs of the animals is supported by the Animal Health Industry.

The bleeding session for antibody test is performed at 28 - 30 days post vaccination and the Liquid Phase ELISA technique described in the law is carried out on the sera entirely by hand (no robot). For the calculation of the EPP, special software is used and the cattle serum of the highest and the cattle serum of the lowest titres are not taken in account. Two negative control cattle are used in each run of vaccine batch control (a run corresponds approximately 10 commercial batches).

All the tests used, except the NSP test, comply with the recommendations of the OIE *Terrestrial Manual* (web edition 2006). Test requirements for NSPs are going to be included in the new version of the law that is currently under review.

A particularity of the Brazilian control is a completely randomized process and in the use of a vaccine as reference for each batch control run. The reference vaccine is a commercial vaccine used in each run and during its all shelf life (2 years) and the repeatability of the results statistically monitored. Another findings specific to the Brazilian control remains the obligation by each manufacturer to receive the sera collected after vaccination with its own production and to titrate them according to the LP ELISA technique used by the National Control Laboratory. The results of this titration are sent back to the National Laboratory for evaluation of the internal Quality Controls of each manufacturer. Manufacturer representatives have also the possibility to be present during some phases of the tests including their own vaccine batches.

The pass-mark for the three valences (O1 Campos, A24 Cruzeiro and C3 Indaial) necessary to release FMD vaccines on Brazilian market is 80% of Expected Protection (EPP).

The OIE mission visited the laboratory which has the required equipments but is under-staffed with regard to the quantity of batches controlled (229 batches controlled in cattle in 2006 corresponding to 512 million trivalent doses). The personnel in the laboratory at Porto Alegre could be classified into 3 permanent persons (2 veterinarians and 1 technician) and 3 technicians under short-term contract.

#### c) ARGENTINA National Control Laboratory for FMD vaccines.

The laboratory situated in the suburb of Buenos Aires city is a part of the unit "*Coordinacion General de Laboratorio Animal*" which is with the "*Coordinacion General de Laboratorio Vegetal*", the core of the activities of the Direction of the Laboratory and Technical Controls of SENASA.

The FMD Coordination Unit is an entity distinct from the Unit devoted to Control of the Viral diseases & Exotic Diseases. Under the direction of Dr E. Maradei the FMD coordination unit is responsible of the Biosecurity and Quality Assurance of the following laboratories: Virus diagnosis laboratory (including field strains/vaccine matching activities), Serological diagnosis laboratory, sero-epidemiological control laboratory and a vaccine control laboratory including a farm. The farm is located 1100 km South to Buenos Aires where the OIE mission did not go.

The laboratory for Vaccine Control is under the responsibility of Dr. R. D'Aloia and performs the tests described in the law referenced "*Resolucion 351/2006*" which actualizes the registration and the control of FMD vaccine batches before release on the market.

The main requirements for post-registration control are: the presentation of a full batch dossier about antigen-vaccine Production and Quality Control Protocols by the manufacturer, and successful evaluation by the National Laboratory for final products (Innocuity, Safety, Sterility, Viscosity measure, Stability, Potency, and finally for evidence of purification of antigens from the Viral Non Structural Proteins – NSPs)

All the tests are performed in the same building of SENASA, which includes a small laboratory complying with the Biosecurity level 3 for Agriculture and which is used for the vaccine matching and Innocuity tests.

All the tests used comply with the OIE *Terrestrial Manual* (web edition May 2006).

The potency test is performed using cattle selected in Patagonia a region of Argentina recognized free of FMD without vaccination by the OIE. The cattle are tested for freedom of antibodies against the FMD viruses and NSPs and are gathered and sent to the SENASA farm, by several merchants under contract with SENASA, which supports the costs of all the controls. In the farm, animals are vaccinated and kept during the control period. For purpose of licensing a new product the PGP test is required, and then vaccinated animals are sent to Buenos Aires by trucks and accommodated into the official bio-containment facilities where the PGP test is performed. For batch to batch control the LP-ELISA is used.

The vaccine samples to be tested are taken randomly by SENASA Officers at the Quarantine store of each of the three Argentinean vaccine manufacturers all situated in the area of Buenos Aires City. Then the vaccine samples are brought under very strict conditions to the National laboratory.

The potency test used in Argentina is an Argentinean serological method (LP ELISA) published jointly by CEVAN (Argentinean Center for Animal Virology) and SENASA in 1993 (Periolo & al.) and in 1995 (Robiolo & al). This EPP method (Expected Percentage of Protection) is considered as an alternative method for FMD Vaccine Potency Control in the future 2008 Edition of the OIE *Terrestrial Manual of Standards for Diagnostic Tests and Vaccines* Chap 2.1.1 FMD. (Method not referenced in the current 2004 Edition and in the 2006 Edition in press). The Argentinean method differs slightly from the method used in Brazil and Paraguay and consists in the vaccination in a blind way with a full cattle commercial dose (2ml oil vaccine, only) of 17 double tagged cattle of 24 months of age, These animals are accommodated in the farm of the laboratory at 1100km from Buenos Aires. The bleeding sessions for antibody tests are performed at 0, 30, 60 and 90 days post vaccination. The Liquid Phase ELISA technique described in the law is carried out entirely by hand (no robot) on the sera taken at day 60 (30 days later than in Brazilian and Paraguayan Controls for EPP). For the calculation of the EPP, the cattle serum of the lowest titre is not taken in account. Two negative control cattle are used in each run of vaccine batch control (a run corresponds approximately to 5 batches control)

Each manufacturer receives the sera collected after vaccination with its own production for titration which allows comparison with the results obtained officially by SENASA

The pass-mark for the four valences (O1 Campos, A24 Cruzeiro, A Argentina 2001 & C3 Indaial) necessary to release FMD vaccines on Argentinean market is 75% of Expected Protection (EPP) i.e. 12 protected among 16 vaccinated animals. We were informed that a test using monoclonal antibodies (CEVAN) could be used in the future to check the identity of the four strains used in the vaccine.

With regard to purification of the vaccines from non-structural proteins, Argentinean law requires the use of sera from 16 bovines at 60 dpv. If none of the vaccinated animals sero-converted for NSP, the vaccine is approved, if there are more than two reactors the vaccines is discarded. In the case of one or two reactors the vaccine is re-tested on a new group of 16 bovines and if ion this new group there are one or two reactors, the animals are revaccinated and tested for antibody to NSP at 30 days post revaccination; and only if there is no further sero-conversion the vaccine is approved. (ref: Res. 351/06).

The OIE mission visited the laboratory (the P3 part excluded) which is sufficiently equipped and staffed for the quantity of batches controlled (57 batches controlled in 2006 corresponding to 127.7 million tetravalent doses). The personnel in the laboratory at Buenos Aires are working on a permanent basis (7 persons) and have time for training sessions, conferences etc.. An important point to demonstrate the quality of the laboratory work shall be stressed, the award of the standard ISO 17025 expected for February 2007 (already obtained for the laboratory "*Coordinación General de Laboratorio Vegetal*").

**d) PARAGUAY: National Control Laboratory for FMD vaccines.**

The laboratory situated at 18km from the city of Asuncion is a part of the unit “DIGELAB Dirección General de Laboratorios” which is one of the five technical units of SENACSA the National Service for Quality and Animal Health of Paraguay. The Vesicular Diseases Coordination Unit is an entity, which hosts the FMD department for diagnosis, sero-surveillance and control of FMD vaccine batches before release in Paraguay. Under the direction of Mrs Dr N. Vergara the Coordination Unit is responsible of the Biosecurity and Quality Assurance of the following laboratories: Virus diagnosis laboratory, Serological diagnosis laboratory, sero-epidemiological control laboratory and a vaccine control laboratory including a farm, not visited by the OIE mission and described hereunder.

The laboratory for Vaccine Control is under the responsibility of Mrs Dr. N. Ortiz Rodriguez and performs the tests described in the laws referenced “Ley 1267/67; 675/77; 808/96 & 2044/02” which actualize the specifications for vaccines manufacturing and control for the National Control Programme for the Control of FMD in Paraguay (pre-registration and post-registration requirements). The post-registration requirements consist in the presentation of a full batch dossier about antigen Production and Quality Control Protocols by the manufacturer, and successful evaluation by the National Laboratory for final products (Innocuity, Safety, Sterility, Stability, and Potency).

Evidence of purification of antigens by research of antibodies against Viral Non Structural Proteins – NSPs is still not an official requirement even if these tests are time to time unofficially performed on vaccines and the manufacturers informed of the results (inconstant positive results after one inoculation according to batches)

All the tests are carried out in the same building with two accesses, male and female change for clothes and possibility of showers because the small room for the Innocuity tests (research for virulent virus in the aqueous phase of the vaccine emulsions) does not comply with the Biosecurity level 3 for Agriculture.

The process for FMD field virus identification is carried out in another place as explained later. All the tests used are complying with the future edition 2006 of the OIE *Terrestrial Manual*. The potency test used in Paraguay is similar to the one carried out in Brazil, because their both origins are the work published by the Panaftosa on Expected Percentage of Protection by ELISA serology in cattle (Allende et al., 2003) as explained previously. The method complies with the OIE *Terrestrial Manual* (web edition 2006).

Nevertheless the original method was differently simplified by the Paraguayan Authorities and consists in the vaccination in a blind way with a full cattle commercial dose (5ml oil vaccine) of 16 double tagged cattle of 15 to 24 months of age, preliminary recognized free from FMDV and NSPs antibodies.

These animals are bred in a farm belonging to SENACSA and located at Quyquyho 120km south-east of Asuncion. In the farm the compulsory vaccination campaigns are not enforced, nevertheless around **5% of the animals not vaccinated are rejected for the Potency Test due to the presence of NSPs antibodies.** Vaccination for Potency test is also carried out at this place. The cost of the animals is supported by the Government. The bleeding session for antibody test is performed at the 30<sup>th</sup> day post vaccination and the Liquid Phase ELISA technique described in the law is carried out on the sera entirely by hand (no robot). Two negative control cattle are used for each run of control batches. Manufacturers do not receive the sera collected after vaccination with their own productions.

The pass-mark for the two valences (O1 Campos, A24 Cruzeiro) necessary to release FMD vaccines on Paraguayan market is 75% of Expected Protection (EPP) but is 79% EPP for C type. To be noticed, the imported FMD vaccines even if still fully tested by the Government Control Laboratory of the country of origin, are again fully tested by the Authorities of Paraguay before release.

The OIE mission visited the laboratory after a change of clothes. The premises are sufficiently equipped and staffed for the quantity of batches controlled (21 batches controlled in 2006 corresponding to 25 million trivalent doses). The personnel in the laboratory at Asuncion are mainly working on a permanent basis (8 persons plus 3 under contract) and have time for training sessions, conferences and technical trainings abroad (formerly in Winnipeg-Canada and Valdeolmos-Spain for Biosecurity, and Tokyo for PCR).

The FMD field virus identification is performed exclusively by SENACSA experts on the epithelium received in ad hoc containers from all the country, not at the National Laboratory but in the Quality Control area (Biosecurity level P3) belonging to a Private vaccine manufacturer (Lauda). The OIE mission did not visit this P3 unit but was told that this Quality Control Department of the vaccine factory is only since 2004 separated from the production unit.

Regarding the field virus/vaccine strain matching test, it is entrusted to Panaftosa experts, who in absence of P3 premises in Rio de Janeiro, carry out the test in Belem, State of Pará, Brazil, in a P2 unit situated in an FMDV endemic area of Brazil as stated before.

#### **4. Conclusions and observations**

During these 4 full days of visit, collect of information and exchanges with the staff involved in the Laboratory work in the three countries visited, the members of the Team C of the OIE mission have kept the conviction that:

- (1) The Control Laboratory in Argentina complies with the Chapter I.1.2. Quality Management in Veterinary Testing Laboratories of the OIE *Terrestrial Manual* while the laboratories in Brazil and Paraguay do not.
- (2) The national regulations and laws are scrupulously applied in the three countries visited.

In these three countries, 100% of the FMD vaccine batches released for use in the National Programmes for FMD Control have complied with the totality of the requirements (and in all the valences for potency test at a level well above the legal pass-marks). Few of the presented batches failed (between 2 and 3%) and their destruction is always well documented.

- (3) The duration of laboratory control work (average of 60 days for Brazil and Paraguay and 80 days for Argentina) is not a source of short supply for FMD vaccines in the fields thanks to the implementation of calendars for vaccine batch controls. Controlled vaccines are available on time and in excess for each vaccination campaign in the three countries.

In Brazil the structure of the control laboratory in Porto Alegre is too fragile and moreover heavily overloaded. Unlike in Argentina, Brazil and Paraguay have not their own official Biosecurity P3 level laboratory for handling FMDV field strains and for allowing vaccine strain matching and Innocuity tests. We were told that in the near future, Brazil will start such activities in a P3 BS Laboratory at Pedro Leopoldo (State of Minas Gerais).

- (4) All the tests used for controlling the Final Product (FMD vaccine batches to be released on the market) are complying with Chapter 2.1.1.C. of the OIE *Terrestrial Manual* (Edit.2004) for Safety, Sterility and Stability in the all three countries.

For Expected Percentage of Potency, all the tests used in South America are mentioned in the OIE *Terrestrial Manual* (web edition 2006) and should be described in the future 2008 Edition, in preparation.

- (5) Only Argentina has defined in its legislation on compulsory control for vaccine batch release, a test measuring the purification of antigens from viral NSP, including a pass-mark. Brazil and Paraguay have not adopted such test, but new Regulations are at present in discussion for including it, based on recommendation of PANAFTOSA. Such a test is referenced in the 2006 Edition in press of the OIE *Terrestrial Manual*. It is important to incorporate standards for admission and random batch controls that would reflect realistic vaccination/revaccination scenarios.
- (6) Currently tests for matching Vaccine strains against field virus isolates are performed by Argentina for Argentinean strains and by PANAFTOSA for Brazil and Paraguay. It shall be stressed that Argentina has the use of a Biosecurity P3 level laboratory in Buenos Aires, whereas PANAFTOSA shall use a P2 level laboratory of the Brazilian Veterinary Services situated in Belem, State of Pará, an endemic FMD area declared to the OIE.

- (7) Obviously the laboratory in Porto Alegre Brazil in its present status represents the “Achilles heel” of the flow chart of the release for the fully controlled vaccine doses necessary for the Brazilian Eradication Programme. At least the laboratory should be managed with permanent staff where the positions are occupied by technicians under short-term contracts. The Brazilian Authorities should also consider seriously to invest for laboratory robots and to appoint more permanent experts to cope with the huge workload and the subsequent problems arising from the quantity of batches controlled or re-controlled.

TABLE 1: Official FMD vaccine batch controls

Country	Vaccine Strains	Culture	Inactivant/ Emulsion (Cattle Dose)	EPP Pass- mark	2006 observed EPP for O type	<u>3ABC</u> <b>2006</b>	<u>SEROLOGY</u> Pass-mark
<b>Argentina</b>	O1 Campos A Arg.2001 A24 Cruzeiro C3 Indaial	BHK cells + Frenkel	BEI SOE  (2 ml)	75%	Average  95.0%	<b>YES</b>	< 2 / 16
<b>Brazil</b>	O1Campos A24Cruzeiro C3Indaial	BHK cells	BEI SOE (5 ml)	80%	Average  95.6%	<b>NO</b>	In preparation
<b>Paraguay</b>	O1Campos A24Cruzeiro C3Indaial	BHK cells	BEI SOE (5 ml)	75% (79%C3)	Average  97.7%	<b>NO</b>	In preparation

BHK cells: Baby Hamster Kidney cells.

Frenkel: Cattle tongue epithelia.

BEI: Binary Ethylene Imine inactivant.

SOE: Single Oil Emulsion, water in oil type.

3 ABC Serology: ELISA method for the detection of antibodies against the FMD virus non-structural proteins

TABLE 2: Statistics and work load in vaccine control laboratories

Country	Size of Laboratory Premises	<u>Personnel</u> <b>Permanent</b> + Contract	Number of batches controlled in 2006	Cattle doses controlled in 2006*	Vaccine needs in 2006*	Number of vaccinated cattle in 2006**
<b>Argentina</b>	Large (P3 lab)	<b>8</b> + 1	57 4 valences	127.7	120	58.6
<b>Brazil</b>	Tiny (no P3 lab)	<b>5</b> + 5	229 3 valences	512.0	378	201.7
<b>Paraguay</b>	Sufficient (no P3 lab)	<b>8</b> + 3	21 3 valences	25.0	19	9.5

\* figures in million cattle doses,

\*\* in million heads

## CHAPTER 5

### Conclusions and Recommendations

1. The Mission acknowledges the fact that the long term solution for the recurrent outbreaks of foot and mouth disease in the frontier areas of ARGENTINA, BOLIVIA, BRAZIL and PARAGUAY necessitates a regional approach with the support of all the countries concerned and recognises the major efforts made so far. However, it recommends that the improvement of such a regional approach should be urgently discussed between the Delegates of all the concerned countries to achieve a more harmonised vaccination, control and surveillance system on both sides of the border.
2. The opportunities given to the Mission to have complete access to all records and to verify the implementation of the vaccination, movement and other risk mitigation policies, by means of on-site visits to farms and control points, rendered sufficient assurances that Argentina is already successfully applying more stringent and updated control measures to minimise the risk for the introduction of FMDV into the territory and to assist early detection and rapid response to an incursion of the disease.
3. Argentina, Bolivia, Brazil and Paraguay should continue to improve and strengthen the working relations along their borders, including
  - a. the definition of common protocol for outbreak management in the border area;
  - b. harmonisation of the procedures for vaccination including vaccination of all susceptible animals where this is not already done, better co-ordination of times of vaccination at adjoining holdings and harmonised vaccination cycles, and
  - c. establishment of joint surveillance and international transit controls of animals and products.
4. Given the obligations under the *Terrestrial Animal Health Code* to either reconfirm annually to the OIE the status “free of FMD with vaccination” on the basis of evidence and documentation of active surveillance aiming to detect possible virus circulation in the country, or to apply for the reinstatement of that status on a similar basis; and taking into account evidence of an endemic situation in the border areas between Argentina, Bolivia, Brazil and Paraguay affecting a shared ecosystem and a common population of susceptible animals, the Mission recommend the following:
  - (1) to agree and harmonise within the CVP of Mercosur a transboundary FMD control and eradication programme including at least the following elements:
    - (a) the establishment along the borders of the mentioned countries, a trans-boundary area of control of livestock, intensive vaccination and sero-epidemiological surveillance program during sufficient period of time;
    - (b) the establishment around the buffer zone of a *surveillance zone* of sufficient size in which an intensified surveillance programme is implemented over a sufficient period of time to detect and identify remaining pockets of virus infection and circulation;
    - (c) the implementation of a program for the registration of holdings keeping animals of susceptible species as well as an individual animal identification and registration system for cattle, sheep and goats as well as batch identification for pigs to allow effective control of movements as well as vaccination and surveillance;
  - (2) to institute precise and auditable benchmarks for each phase and the final outcome of the programme;
  - (3) to carry out the action under the responsibility of the participating countries and with the technical cooperation and supervision of the regional FMD OIE reference laboratory;
  - (4) to develop and implement harmonised standard operating procedure for outbreak investigations, emergency measures, vaccination and surveillance with the assistance of the regional FMD OIE reference laboratory;

The authority and responsibility of the national veterinary service should be well identified and both correspond to the relevant OIE standards and permit effective control of all factors influencing the efficacy of the program. Vaccination procedures should be carried out under the direct control of the official veterinary service;

- (5) to agree on a periodic evaluation of the success of the programme and to introduce modifications to it where necessary or appropriate;
  - (6) to assess and discuss the results of the programme at regular joint meetings of the participating countries and the international organisations, organised by and within the participating countries.
5. In view to improve the epidemiological situation against FMD in the three countries visited by the use of vaccination, the team recommends that:
- (1) the present policy of controlling 100% of the vaccine batches before release for sale shall be continued as well as the policy of due destruction of the failing batches;
  - (2) the present policy of checking the vaccine strains protection against new virus isolates shall be continued;
  - (3) funding the National Control Laboratory of Brazil shall be an urgent necessity regarding the huge workload, the low number of staff and the small size of the premises;
  - (4) the potency control tests for FMD vaccines used in South America already mentioned in the 2006 web-edition of the *Manual* should be revised and included in the 2008 edition of the OIE *Terrestrial Manual*;
  - (5) the control of NSP antibodies at the end of the potency test should be adopted by law in Brazil and Paraguay;
  - (6) the pass-mark adopted in Argentina of 2 cattle positive out of 16 (i.e. 12,5%) for NSP antibody presence 60 days after a single injection of one commercial dose of vaccine but without further sero-conversion following re-vaccination, shall be seen as a transitory measure, to allow Private Animal Health Industry to adapt to the new situation for purified vaccines;
  - (7) Vaccines should only be released if they fully comply with the national legislation, such as in Argentina, and/or with the recommendations of PANAFTOSA on their potential to induce NSP antibodies. The scenarios on which vaccines are tested for absence of NSP must be reviewed regularly in the light of the vaccination practices and epidemiological findings in the field;
- The competent authority must be able to carry out surveys for the detection of virus circulation or outbreak investigations in full faith that any detected NSP-related sero-conversion is of epidemiological importance and not induced by a single or repeated administration of poorly purified vaccines..
6. Outbreaks as defined by OIE must be notified according to the OIE and efficiently investigated to better understand the epidemiology of the disease in the region.

## CHAPTER 6

### Recommendations to the OIE

1. The OIE should recommend to Argentina, Bolivia, Brazil and Paraguay to implement the recommendations made by the OIE Mission as outlined in Chapter 5 to ensure a more harmonised approach is taken by all the countries concerned.
2. The Mission is satisfied that measures required in Article 2.2.10.7 of the *Terrestrial Animal Health Code* have been effectively applied in the zone of Argentina previously recognised as free from FMD with vaccination. However, the regional situation as mentioned above ought to be taken into account, in particular the facts that animal movement in the frontier area cannot be fully controlled and that FMD is endemic in the frontier area.
3. In view of the overall mission findings, the OIE should, if possible under its procedures and rules and as sensible precaution, not re-instate the status of any of the countries in the region affected by this situation and consider the possibility of suspending the status of those countries/zones currently listed free from FMD with vaccination, until a regional solution has been found with coordinated approach together with all the countries of the region, and which presents a joint zoning perspective, different from the previously adopted.
4. The OIE should review the process to be followed in assessing an application where an area is established free without vaccination in a section of the existing zone that was previously declared free with vaccination, as the current *Terrestrial Animal Health Code* does not provide for a transition from free with vaccination to free without vaccination.
5. As the OIE *Terrestrial Animal Health Code* stipulates that a criterion for regaining FMD free status following an outbreak, if vaccine is used, is to carry out surveillance for virus circulation by use of tests for the detection of antibody to NSP, the Mission recommends that where an application of a member country is examined this being made conditioned to the following:
  - a. the control of NSP antibodies at the end of the potency test should be adopted by law;
  - b. realistic test protocols and sampling schemes to be developed for surveillance using NSP-tests in vaccinated animals, with more realistic standards reflecting the vaccination programmes in the fields, i.e. several vaccinations without induction of NSP antibodies to allow conclusive epidemiological surveys for tracing possible virus circulation; and
  - c. the submission to the OIE must not only describe the principles but also the real state of implementation of legislated vaccination protocols.
6. As the status of “free with vaccination” is granted subject to compliance with certain requirements for the use of vaccines, it is recommended to obtain a scientific opinion on:
  - a. standards regarding the induction of NSP's antibodies by FMD vaccines after a number of injections with a specified payload;
  - b. whether the administration of half a cattle dose of vaccine to young bovine animals with possible maternal immunity is appropriate, or whether such practice impairs a protective immune response.

The role of sheep in the epidemiology of FMD in the area may need better understanding, because sheep are not always subject to the same movement controls as bovines and surveillance in sheep is, despite their non-vaccination status, carried out with tests of lesser sensitivity than those used for the detection of antibodies to structural proteins in accordance with the *Manual*.

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Comité Veterinario Permanente del Cono Sur *“para una sanidad regional de excelencia”*

**COMITÉ VETERINARIO PERMANENTE DEL CONO SUR (CVP)**

SECRETARÍA TÉCNICA CON SEDE EN EL IICA URUGUAY

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## **Specific Foot and Mouth Disease Control and Surveillance Actions in the Border Regions**

### **Argentina/Bolivia/Brazil/Paraguay**

#### **1. Introduction**

Following the recommendations of the OIE Mission that visited the region on December 6<sup>th</sup> to 13<sup>th</sup>, 2006, the heads of the Veterinary Services of the South Cone Permanent Veterinary Committee (CVP), with the Panamerican Foot and Mouth Disease Center's (PANAFTOSA) support, defined the zoning to be implemented in the **border** region and described the common actions to be adopted in this regard.

#### **2. Objectives**

- Reduce the **risk of the** Foot and Mouth Disease virus introduction and dissemination to other areas, implementing **harmonized** sanitary actions in the border regions of Argentina, Bolivia, Brazil and Paraguay.
- **Reinforce** the continuity of the Foot and Mouth Disease eradication national programs and other actions and regional strategies to identify the primary sources of infection.

#### **3. Implementation and Execution**

The program will have **initial** duration of 2 years, and will be subject to periodic reviews and evaluations, at least once (~~every~~) a year, by means of joint technical meetings of **the CVP's** Veterinary Services, with participation of the private sector, OIE's Reference Laboratories, and other relevant participants in order to detect the **needs of** up-dating and modifications of the program (~~my need~~), including its duration. The execution of these actions will be **the** responsibility of the National Veterinary Services.

Part of the actions to be described, are already under execution.

This program will be incorporated to the countries' legal frameworks.

#### **4. Coordination**

The program's activities will be coordinated by **the** CPV.

#### **5. Financing**

The program activities will be financed with funds contributed by individual countries and additional funds that may be obtained from the World Bank and the Interamerican Development Bank, among others.

## 6. Auditing

**The** CVP, assisted by PANAFTOSA and the participation of experts nominated by **the OIE** will carry out at least one audit per annum.

## 7. Zonification

A High Level Surveillance zone is established, comprising a strip with a width of approximately 15 km, to each side of the countries' borders. The width may vary according to geographical conditions.

### 7.1. Brazil/Paraguay border:

#### Brazil

- **Infected zone:** Comprises three municipalities with Foot and Mouth Disease occurrence since 2005 (El Dorado, Japorã and Mundo Novo)
- **High Level Surveillance Zone:** Comprises the municipalities in the immediate border with Paraguay and with the infected zone (Antônio João, Aral Moreira, Bela Vista, Caracol, Coronel Sapucaia, Iguatemi, Itaquiraí, Paranhos, Ponta Porã, Porto Murtinho, Sete Quedas and Tacuru); and Lago Itaipu

#### Paraguay

- **High Level Surveillance Zone:**
- **First Stage:** Comprises Canindeyú Dept.: Districts of Ypejhu, Corpus Christi, Salto del Guairá and Nueva Esperanza. Amambay Dept.: districts of Bella Vista, Pedro Juan Caballero and Capt. Bado,
- **Second Stage:** Departments of Concepción, Alto Paraguay and Alto Parana.

### 7.2. Bolivia/Brazil border:

#### Brazil

- **High Level Surveillance Zone:** Comprises part of the Corumbá Municipality, on the Rio **Paraguay** right bank.

#### Bolivia

- **High Level Surveillance Zone:** Department of Santa Cruz, in the Puerto Quijarro and Puerto Suarez Municipalities.

### 7.3. Argentina/Bolivia border:

#### Argentina

- **High Level Surveillance Zone:** Consists of a 15 km wide **strip**, starting from the international border limits in the Salta Province (Santa Victoria, Orán, Iruya, General José de San Martín and Rivadavia Departments).

#### Bolivia

- **High Level Surveillance Zone:** Comprises a strip of approximately 15 km in width, involving the Tarija Department in the Villa Montes, Yacuiba, Carapari, Bermejo and Padcaya Municipalities.

### 7.4. Argentina/Paraguay border:

#### Argentina

- **High Level Surveillance Zone:** Comprises a 15 km wide strip starting from the international border in the Formosa Province (Departments of Ramón Lista, Bermejo, Pilagás, Pilcomayo, Formosa and Lahisi); Chaco Province (Bermejo Department); Corrientes Province (Departments of Capital, San Cosme, Iratí, Berón de Astrada, San Miguel and Ituzaingó) and Misiones Province (Departments of Capital, Candelaria, San Ignacio, General San Martín and Montecarlo).

**Paraguay**

- **High Level Surveillance Zone:**
- **First Stage:** Comprised by an approximately 15 km wide strip that includes Pedro P. Peña Municipality in the Boquerón Department (15 km of border line).
- **Second Stage:** Comprised by Presidente Hayes, Ñeembucu, Itapúa y Misiones Departments.

**7.5. Paraguay/Bolivia border****Paraguay**

- **High Level Surveillance Zone**, includes the Boquerón Department with the Pedro P Peña and Infante Rivarola districts; a zone exist in the northern part, which includes Boquerón and Alto Paraguay Departments, where the High Level Surveillance cordon will **not** be implemented due to the desert-type characteristics and its very low livestock activity and other susceptible species density.

**Bolivia**

- **High Level Surveillance Zone**, includes the Tarija and Chusquisaca Departments, in the Macharety and Villa Montes Municipalities.

A zone exist in the north, that includes the Boyuibe and Charagua Municipalities, where the High Level Surveillance **strip** is not going to be implemented due to the desert-type characteristics and very low livestock activity and other susceptible species **density**.

Annexes 1 to 3 show the maps and a description of zones, for each border region.

**8. Actions to be implemented****8.1. General actions:**

- Strengthening and maintenance of the veterinary attention structure in the zones, with the implementation of local offices, human resources, communications and **diffusion**, among others.
- **Utilization** of a standardized and unique procedure for the attention of outbreaks and suspects, as described in the “**Manual de Procedimientos para la Atención de Ocurrencias de Fiebre Aftosa y Otras Enfermedades Vesiculares**”, (Manual of Procedures for the Attention of Foot and Mouth Disease and other Vesicular Diseases Occurences) prepared by Panaftosa.
- **Harmonization of the Holdings register records, using the geo-referencing system.**
- Harmonization, shared availability and accessibility to the information systems in **relation** to: record of notifications and suspects of vesicular disease, cadastre, animal movement, identification of susceptible animals, vaccination and sero-surveillance.
- Periodic contacts and bilateral actions between the veterinary services staff of the border areas (meetings, inspection visits to local offices and **holdings** and information exchange).
- The vaccine-manufacturing countries of the region, **will** incorporate to their legal framework, the non-structural protein control, according to results of the research (~~to be~~) carried out in the region and to the OIE standards.
- Harmonization of periods, duration and vaccination procedures in the areas of geographical contiguity
- **Vaccinations will be carried out under the Veterinary Services supervision and responsibility.**
- Strengthening of the laboratories’ network for vaccine control, to cover the countries’ demand, supported by PANAFTOSA.

- Implementation of a **joint harmonized** design of sero-epidemiologic monitoring, scientifically validated, with the support of PANAFTOSA.
- Permanent training of the sanitary agents involved in the prevention and early detection of FMD **outbreaks**, among other aspects.

## 8.2. Specific actions:

### Infected Zone in Brazil:

- **Maintenance of the interdiction zone until the absence of viral circulation is verified.**
- **Cadastre up-dating of all Holdings.**
- Implementation of individual identification of the susceptible domestic species (bovine, bubaline, swine, caprine and ovine).
- Sanitary slaughter of all susceptible domestic animals located in ranches with reactivity to the diagnosis system for NSP.
- **Maintenance of the fixed and mobile control posts.**
- Strengthening of the control and surveillance system.
- Vaccination carried out by official veterinarians, of all bovine animals, every 6 months and an additional dose for bovines of less than 12 months of age.
- **Transit restriction of susceptible animals and their products and sub-products of risk, excepting the outgoing of:**

Bovines for immediate slaughter in the High Level Surveillance area, following bio-security procedures, and treatment of products and by-products, according to OIE recommendations.

Products and sub-products subjected to Foot and Mouth Disease virus inactivation treatments, according to OIE recommendations.

### High Level Surveillance Zone:

- **Cadastre up-dating of all the Holdings that hold susceptible animals.**
- Implementation of an individual identification system of all susceptible domestic species.
- **The records of Holding, animal identification and movement, will be kept in the local Veterinary Service offices.**
- **Harmonization of periods, duration and vaccination procedures in the contiguous geographical zones.**
- Systematic vaccination of all bovines, twice a year.
- Vaccination of other susceptible species (swine, ovine and caprine) will be carried out momentarily only in Argentina, the other countries will send a technical report to the Scientific Commission, justifying the non-vaccination.
- **Animal movement authorization for bovines, granted only for animals with at least two vaccinations against FMD within the previous year. An additional dose will be applied to bovines of less than 12 months of age that is intended for mobilization.**
- Vaccine applications will be carried out under supervision and responsibility of the Official Veterinary Services.

- **Movement** of susceptible animals with destination to other zones will be authorized after fulfilling the following procedures:

**Official dispatch issued with a previous authorization and inspection, sealing of transport vehicles, out-going authorization issued by destination, arrival confirmation and surveillance at the holding of destination. The entry of susceptible animals to these zones should comply with the same requirements as those for out-going animals.**

- Animal movement control, by means of fixed and mobile control posts.
- Harmonization and shared availability of the information systems in regard to: Notification records and vesicular disease suspects, cadastre, animal movement, susceptible animal identification, vaccination and sero-surveillance.
- Harmonization of scientifically validated sero-epidemiological monitoring methodology, with the support of PANAFTOSA.
- Epidemiological surveillance sampling will be carried out according to harmonized procedures, using statistical designs with an adequate level of confidence in order to detect viral circulation.

Field sampling activities will be implemented with the joint participation of the official staff of the each countries and the samples will be forwarded to the OIE Reference Laboratory in Brazil – PANAFTOSA, who will report about results to the countries and to CVP.

- The sero-epidemiological surveillance will be supplemented with clinical and documentary inspections during the vaccination activities, animal concentrations and during the animal entries or out-goings.
- **For every outbreak, all necessary studies will be carried out to establish the origin of the infection.**
- **In all suspects and findings of positive sero-conversion, the necessary studies will be carried out to determine if the case is due to viral circulation and to reach a conclusive diagnosis.**

## 9. Role of the PANAFTOSA-OPS/OMS Foot and Mouth Disease Reference Laboratory

PANAFTOSA will keep on providing technical cooperation in the following areas:

- **Sero-surveillance sampling design**
- **Implementation of the diagnosis procedure for samples received from the countries, in regard to the joint surveillance samplings.**
- Definitive diagnosis in emergency cases
- Vaccine quality control
- Analysis and interpretation, jointly with the CVP of the results of the serological samplings.

Annex 1

**Specific Actions for Foot and Mouth Disease Control and Surveillance  
in the border regions**



Annex 2

Region Directly Involved in the Joint  
Actions of the Border Area

Schematic Representation of the Zone



-  Border Zone considered for the implementation of actions
-  Border with natural barriers

Annex 3

Region Directly Involved in the Joint  
Actions of the Border Area

Schematic Representation of the Zone



-  Immediate implementation
-  Border Zone considered for the implementation of actions
-  Border with natural barriers

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