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

Paris, 4-8 February 2013

A meeting of the OIE Scientific Commission for Animal Diseases (the Commission) was held at the OIE Headquarters in Paris, France from 4 to 8 February 2013.

### Opening

The Commission was welcomed by Dr Kazuaki Miyagishima, Deputy Director General and Head of the Scientific and Technical Department of the OIE, on behalf of Dr Bernard Vallat, Director General of the OIE.

Dr Miyagishima mentioned that a number of Member Countries had applied for the first time for official recognition of freedom from African horse sickness (AHS) after the revision of the relevant chapter in the *Terrestrial Animal Health Code (Terrestrial Code)*, to provide for the first equine disease to be officially recognised by the OIE for country or zonal freedom from disease. He further mentioned that following AHS, *peste des petits ruminants* (PPR) could also be considered as a candidate disease for official recognition of free status. Dr Miyagishima also indicated that the OIE was actively involved in the intended worldwide control of PPR under the umbrella of an OIE/FAO initiative for the “Global Framework for the progressive control of Transboundary Animal Diseases (GF-TADs)”. A working group had been tasked by the GF-TAD’s to work on a PPR Global Strategy, following the model of the Global Foot and Mouth Disease (FMD) Control Strategy.

In respect of FMD, it was mentioned that after the successful Global Conference on FMD Control held in Bangkok in June 2012, the partners involved in the Global Strategy had entered the implementation phase. Dr Miyagishima encouraged the Commission to continue to be involved actively in the Global FMD control programme. Another important development within the OIE was the establishment of an *ad hoc* group on the international movement of high -level competition horses with the collaboration and financial support of the Fédération Equestre Internationale (FEI). It was foreseen that the task of this *ad hoc* Group would include revision of the OIE *Terrestrial Manual* and *Terrestrial Code* chapters on horse diseases. The *ad hoc* Group would report to the two concerned Specialists Commissions (Biological Standards Commission and this Commission) while maintaining coordination with the Terrestrial Animal Health Standards Commission (Code Commission).

On administrative issues, Dr Miyagishima sought the opinion of the Commission on its willingness to work on electronic files of the working documents and discontinue use of hard copies, at least for those members who were ready to do so. He also requested the Commission to evaluate the need for and explore the possibility for extending its meeting beyond one week, in view of the Commission’s increasing work load. Another matter discussed was the desirability of including the draft revised chapters of the *Terrestrial Code* developed by *ad hoc* Groups as annexes to the *ad hoc* Groups’ reports. This would improve the traceability of documents and increase the transparency in the standard setting process to the benefit of Member Countries, without necessarily leading to confusion. Only the final report as approved by the Scientific Commission would be attached to the *ad hoc* Group’s report. The President of the Commission indicated that draft or amended chapters of the *Terrestrial Code* would not be

circulated with the reports of the Scientific Commission but only with the report of the Code Commission as decided by mutual agreement between the two Commissions. The main reason for this arrangement is to avoid confusion by Member Countries and to ensure that comments on draft or amended chapters from Member Countries are directed to the OIE in response to the report of the Code Commission. In view of the increased volume the Commission's report would acquire, Dr Miyagishima advised only the body of the report, containing the deliberation and decisions by the Commission would be printed for the General Session, but the complete version with the annexes would be distributed to OIE Delegates in a CD and through the OIE Delegates' website.

Finally, Dr Miyagishima announced his imminent departure from the OIE and thanked the Commission for its support to the staff of the Scientific and Technical Department. Dr Alessandro Ripani also announced his departure in coming months and thanked the Commission for the opportunity of having worked with them for several years.

In his response the President of the Commission regretted these departures and thanked the significant contribution of the departing staff to the work of the Commission.

#### Statement of the Director General

After joining the meeting at a later stage, Dr Vallat commented on important issues related to the working programme of the OIE. Firstly, the OIE had been requested to increase its involvement in implementing the global strategies to control diseases of importance, namely on FMD, PPR and rabies. For FMD, he reiterated that the Commission's work was essential in ensuring the OIE's involvement in the implementation of the recommendations of the Global Conference on FMD control (Bangkok, June 2012) by among others encouraging the further development of Veterinary Services and through the endorsement of the official control programmes for FMD. The OIE might consider increasing the number of experts involved in the evaluation of FMD dossiers, given the anticipated increase in the number of countries that would apply for endorsement of their control programme and eventually recognition of disease free status. The updated *Terrestrial Code* chapter on FMD was most welcome and would, after approval by the Scientific and Code Commissions, be ready for circulation for comments from Member Countries.

On PPR, there was an on-going project, supported by the Bill & Melinda Gates Foundation, to develop vaccination campaigns in Africa with some focus on backyard small ruminants. Dr Vallat also highlighted the importance of finalising the amended *Terrestrial Code* chapter on PPR that would support the political will of countries and donors to participate in the global control strategy which would include among others convincing animal owners on the need to vaccinate small ruminants for PPR.

On rabies, Dr Vallat urged that the inclusion in the *Terrestrial Code* of an article for the control of rabies in dogs would encourage and mobilise decision makers to invest in mitigating the public health risk by controlling rabies at its source as recommended at the Global Conference on Rabies Control held in Incheon-Seoul (September, 2011). Dr Vallat informed the Commission on the EU-funded rabies vaccine bank in Asia which had been deployed in Lao and Vietnam, and very soon in the Philippines, and that could provide up to 4 million vaccine doses. Other vaccine banks could be eventually created in Africa if the vaccine bank in Asia proved to be successful.

On official disease status recognition, Dr Vallat expressed his satisfaction on the number of country applications received and on the ongoing improvement in the evaluation system. Possible additions to the list of diseases with official status might include, apart from PPR, other diseases such as CSF and Glanders. The future validation of an improved diagnostic method would perhaps enable Glanders to be considered as a candidate disease for official disease status recognition. There were still Member Countries wishing to have CSF as a disease for official status recognition; however the wild and feral animal implication had so far complicated this possibility. Dr Vallat encouraged the Commission to increase the number of expert missions to visit countries not only in relation to FMD free status, but also for other diseases.

Dr Vallat supported the missions to southern African countries and other Member Countries planned for 2013. Finally, Dr Vallat expressed his opinion on how the Commission should deal with Bovine Spongiform Encephalitis (BSE), classical or atypical, stating that atypical BSE could be regarded as a rare disease. He indicated that the resource investment in risk status recognition as well as in standard setting for BSE should gradually be brought to a level proportionate to the real impact of the disease on the society, given the significant global decrease in the number of human and animal cases linked with BSE.

## 1. Adoption of the agenda

The meeting was chaired by Dr Gideon Brückner, President of the Scientific Commission, with the Scientific and Technical Department staff of the OIE, providing the preparation of the draft report.

The President expressed his appreciation for the work of the Scientific and Technical Department in the preparation of the working documents to be in time for the meeting and also commended the *ad hoc* Groups for the scientific quality of their reports.

The agenda, as adopted, and the list of participants, are attached as Annexes 1 and 2, respectively.

## 2. Issues from the last meeting of the Scientific Commission

The Commission reviewed salient points from the report of its previous meeting. The following issues emanating from and related to the previous meeting were discussed:

### 2.1. Principles on Disease Control (proposed new chapter for the *Terrestrial Code*): comments from Member Countries

The Commission had requested Member Countries to comment on the new proposed chapter on disease control for possible inclusion in the *Terrestrial Code*. Comments were received by the African countries and by Switzerland welcoming the chapter with minor suggestions. The Commission, on request of Switzerland, accepted to include “holders” in addition to “producers” in the disease control planning process. The inclusion of “institutional arrangements”, as suggested by Delegates from Africa as a factor to consider when planning a disease control programme, was accepted but as a socioeconomic consideration, rather than as a technical tool. Finally, a comment on communication was not accepted because the Commission considered it was sufficiently covered throughout the chapter.

The draft new chapter with the comments of Member Countries addressed was forwarded to the Code Commission for its further processing and possible final adoption by the World Assembly in May 2014.

### 2.2. Decision on the inclusion of the term “risk-based surveillance” in the Glossary

The term “risk based surveillance” had been drafted by the *ad hoc* Group on Epidemiology in 2011 for inclusion in the *Terrestrial Code* Glossary. Noting that the term was not used in the text of the *Terrestrial Code*, the Commission had postponed its decision for inclusion in the Glossary until the matter was discussed with the Code Commission.

The two Commissions agreed that they would discuss this matter at their next joint meeting.

### 2.3. Items consulted with experts to address Member Country comments or requests

#### a) Equine viral arteritis

The Code Commission had forwarded to the Scientific Commission some Member Country comments for discussion by the Scientific Commission at its meeting in August 2012. The Commission sought expert advice on a request by a Member Country on extending the period during which a colt is tested and vaccinated against Equine viral arteritis (EAV) from 9 months to 12 months. The expert advised that colts were considered pre-pubertal and required testing to ensure they had not been exposed, and vaccination following negative testing, to prevent the risk of being permanent carriers of the disease. After considering the expert opinion, the Commission dismissed the proposal, since the average age for puberty was considered to occur earlier and was dependent on breeds and also on seasonality<sup>1</sup>. Vaccinating colts at a later age than that recommended in the *Terrestrial Code* could pose a risk of developing persistent carrier status following EAV infection.<sup>2</sup>

The decision of the Commission was forwarded for information to the Code Commission.

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<sup>1</sup> Brown-Douglas, C.G., Firth, E.C., Parkinson, T.J., Fennessy, P.F., (2004), Onset of puberty in pasture-raised Thoroughbreds born in southern hemisphere spring and autumn. *Equine Vet. J.*, **36**, 499-504.

<sup>2</sup> Holyoak, G.R., Little, T.V., McCollam, W.H., Timoney, P.J., (1993), Relationship between onset of puberty and establishment of persistent infection with equine arteritis virus in the experimentally infected colt. *J. Comp. Pathol.*, **109**, 29-46.

## **b) Porcine Reproductive and Respiratory Syndrome (PRRS)**

The Commission had sought an expert opinion on the need to develop a *Terrestrial Code* chapter on PRRS following the requests of several Member Countries. The experts advised that a chapter should be drafted as the disease was widespread worldwide. There were also a number of countries that had achieved disease freedom through the implementation of control measures, and thus, international standards could help preventing the introduction of PRRS virus.

The Commission agreed with the expert opinion and recommended that the Director General convene an *ad hoc* Group to develop a *Terrestrial Code* chapter. The Code Commission was also informed of this proposal.

## **2.4. Guide on Terrestrial Animal Health Surveillance**

The Commission requested the Scientific and Technical Department to provide the Commission with a copy of the draft Guide for final endorsement by electronic correspondence with members of the Commission. The Commission reiterated its request from previous reports of the Commission that the proposed guide was an initiative of the Scientific Commission and thus the Commission maintains the right to finally endorse the proposed text. It was also regarded as essential, as had been previously requested, that a section in the Guide be dedicated to surveillance in respect of official disease status recognition as prescribed in the *Terrestrial Code*, to ensure that Member Countries fully realised the rationale for the specific surveillance strategies for diseases with an officially recognised status by the OIE.

The Commission was informed that, in the final draft, more cross-references to the *Terrestrial Code* Chapter 1.4 would be inserted.

## **3. Reports of *Ad hoc* Groups and Working Group on Wildlife Diseases**

### **■ Meeting reports for endorsement**

#### **3.1. *Ad hoc* Group on African Horse Sickness official disease status evaluations: 15-17 January 2013**

##### **a) Revision of Chapter 12.1. of the *Terrestrial Code***

The Commission reviewed the report of the *ad hoc* Group on African Horse Sickness (AHS), including the amendments suggested to the *Terrestrial Code* Chapter 12.1.

To harmonise Chapter 12.1 with other revised chapters in the *Terrestrial Code*, the case definition and the definition for infection were moved to the beginning of the General provisions in the chapter. The Commission recommended that this approach be followed for all disease specific chapters in the *Terrestrial Code*.

Similarly, in Article 12.1.5, the Commission added provisions for the occurrence of AHS virus (AHSV) within or outside the boundaries of the containment zone. Wording within this article was also harmonised with other chapters. The wording on the extension of the containment zone was removed from the same article because it was an unscientific statement/requirement subject to variable judgement and perceptions on what should be “large enough”.

The amended chapter with Member Country comments addressed was forwarded to the Code Commission for further processing together with the *ad hoc* Group’s report endorsed by the Commission.

The Commission took note of the *ad hoc* Group’s concern regarding a revision of the chapter on AHS in the *Terrestrial Manual* considering the different purposes for which the tests could be performed. The Commission requested that this issue be forwarded to the Biological Standards Commission for consideration.

**b) Evaluation of the requests from 59 Member Countries to be recognised as historically free from AHS**

The Commission assessed the recommendations of the *ad hoc* Group for country applications for historical AHS freedom. A simplified procedure had been offered to Member Countries applying for historical AHS freedom so that a baseline list of historically free Member Countries could be presented at the 81<sup>st</sup> General Session in May 2013. This shorter procedure would not be applicable once adopted at the 81<sup>st</sup> General Assembly. Member Countries complying with the requirements of the *Terrestrial Code* for historical freedom would still have the possibility to apply for it, but would have to provide evidence of compliance with the *Terrestrial Code*.

The Commission agreed that 57, out of the 59 Member Countries that had applied through this shorter procedure, fulfilled the conditions to be considered historical AHS free countries in accordance with Article 12.1.2. of the *Terrestrial Code*. The list of these Member Countries is in the report of the *ad hoc* Group.

The applications for historical freedom of the two remaining Member Countries were not approved and referred back to the applicant Member Countries with suggestions on actions to be taken to comply with the requirements of the *Terrestrial Code*.

**c) Evaluation of the requests from 2 Member Countries to be recognised as free from AHS**

Portugal and Spain applied for AHS country freedom through the ordinary procedure and the Commission determined that they fulfilled the conditions to be considered AHS free countries in accordance with Article 12.1.2. of the *Terrestrial Code*.

**d) Evaluation of the request from a Member Country for the establishment of a zone free from AHS**

The application of the Member Country was not approved by the Commission and the dossier was referred back to the applicant Member Country with the advice to the latter to fully consider the provisions in Article 12.1.2.

The Commission noted that, according to the *Terrestrial Code*, AHS-free countries adjacent to infected countries should have a 100–km surveillance zone, and that countries without an AHS-free status were considered as infected. The Commission did not find any scientific evidence to suggest that this distance be reduced except when geographical or ecological factors contribute to limit the risk of potential incursion. The Commission agreed that this provision should remain unchanged, given that a surveillance programme should be designed according to different factors and tools, including a risk assessment.

The Commission endorsed the report of the *ad hoc* Group on AHS, including the amendments suggested to the *Terrestrial Code* Chapter 12.1. and the procedure for annual reconfirmation form with minor changes. The report and Chapter 12.1 with proposed amendments were forwarded to the Code Commission for further processing. The endorsed report is attached as [Annex 3](#).

**3.2. *Ad hoc* Group on Antimicrobial Resistance: 8-10 January 2013**

The Commission endorsed the report of the *ad hoc* Group on Antimicrobial Resistance, which had addressed Member Country comments on *Terrestrial Code* Chapter 6.10. The *ad hoc* Group had updated the list of antimicrobial agents of veterinary importance. The Commission endorsed the list and proposed its adoption at the 81<sup>st</sup> General Session by Resolution. The endorsed report is attached as [Annex 4](#).

**3.3. *Ad hoc* Group on Bovine Spongiform Encephalopathy: 11-13 September 2012**

The Commission reviewed the report, including the proposed amendments to Article 11.5.22 in relation to the point targets for the different adult cattle population sizes in a country, zone or compartment, adjusted for countries with small cattle population. The proposal of the *ad hoc* Group for an amendment to the existing table in the *Terrestrial Code* was approved and forwarded to the Code Commission for further processing. The Commission commended the high quality of the *ad hoc* Group's report.

On atypical BSE, the Commission noted the main differences with classical BSE and considered the possibility of revising the existing *Terrestrial Code* to provide standards on atypical BSE.

The Commission agreed that the current procedure for official recognition of BSE risk status had been conceived with a focus on classical BSE. The Commission suggested that an *ad hoc* Group review the *Terrestrial Code* chapter on BSE to assess if a change to the current chapter on BSE was desirable (e.g. as was done for atypical scrapie).

In addition, the Commission noted that the notion of “compartment” was not applicable to BSE official risk status and agreed to recommend to the Code Commission that the word “compartment” be deleted throughout the Article 1.6.3.

The report of the *ad hoc* Group was endorsed by the Commission and is attached as [Annex 5](#).

The proposed change to Article 11.5.22 was forwarded to the Code Commission.

### **3.4. *Ad hoc* Group on Bovine Spongiform Encephalopathy risk status evaluations of Member Countries: 27-30 November 2012**

The Commission considered and endorsed the recommendations of the *ad hoc* Group on the applications from 9 Member Countries for the evaluation of their BSE risk status.

For the dossier related to the request of the United States of America to be considered as a negligible BSE-risk country, the Commission noted that the *Ad hoc* Group could not reach a consensus in making recommendation to the Commission. The Commission considered and discussed the analysis made and opinions expressed by the *ad hoc* Group. The Commission based its assessment on the provisions laid out in the *Terrestrial Code* and agreed that the release risk in the USA was negligible and that the BSE risk mitigating measures put in place by the country were commensurate with the assessed release risk. At the same time, the Commission decided to request the applicant Member Country to monitor annually - through the annual reconfirmation form - the continued implementation of the risk mitigation measures as described in the *Terrestrial Code*, especially those related to preventing the potential recycling and amplification of the BSE agent in the country at the rendering plants.

The Commission agreed to recommend the following Member Countries for adoption as having a negligible risk for BSE by the World Assembly of Delegates at the 81st General Session:

- Israel, Italy, Japan, the Netherlands, Slovenia and the USA

The Commission agreed to recommend the following Member Countries for adoption as having a controlled risk for BSE by OIE World Assembly of Delegates at the 81<sup>st</sup> General Session:

- Bulgaria and Costa Rica.

For the remaining Member Country, the application was not approved and referred back to the applicant Member Country with suggestions to the Member Country on actions to be taken to comply with the requirements of Chapter 11.5 of the *Terrestrial Code*.

The Commission adopted the report of the *ad hoc* Group. The report is attached as [Annex 6](#).

### **3.5. *Ad hoc* Group on Brucellosis: 9-11 January 2013**

The *ad hoc* Group on Brucellosis had restructured the *Terrestrial Code* draft chapter on Brucellosis in accordance to the comments received by Member Countries, the Scientific Commission and the Code Commission. The three pathogens, *Brucella abortus*, *B. melitensis* and *B. suis* were kept under the same multispecies chapter (8.x) but the provisions in the chapter were made species-specific. This way, the concept of disease free status at the country or zone level was considered for cattle, sheep and goats, camelids and cervids but not for pigs. Disease free status with vaccination was however currently possible only for cattle, sheep and goats, since there was not an appropriate vaccine for camelids or cervids. The *ad hoc* Group had also harmonised the language throughout the chapter.

The Commission recognised that the amendments proposed by the *ad hoc* Group to the draft *Terrestrial Code* chapter on Brucellosis would facilitate its use by Member Countries and endorsed the report.

The amended chapter was forwarded to the Code Commission for further processing.

The endorsed report is attached as [Annex 7](#).

### **3.6. *Ad hoc* Group on Contagious Bovine Pleuropneumonia (CBPP): 9-10 January 2013**

The *ad hoc* Group on CBPP had evaluated by electronic correspondence a single application for free status from a Member Country.

The Commission supported the findings of the *ad hoc* Group, and, after discussions with the Director General, decided, in accordance with the provisions of Resolution 25 of the 80<sup>th</sup> General Session, to request the Director General to mandate an expert mission to the country to enable the Commission to make an informed decision, taking into account the findings of the mission.

The Commission adopted the report of the *ad hoc* Group. The endorsed report is attached as [Annex 8](#).

### **3.7. *Ad hoc* Group on the inclusion of Classical Swine Fever in the list of diseases with official status: 16-18 October 2012**

The *ad hoc* Group had, at the request of the Scientific Commission and the Code Commission, revised the *Terrestrial Code* chapter on CSF and had included a new case definition for domestic and captive wild pigs, as well as reviewed the articles on surveillance for CSF together with the questionnaire that would allow the addition of CSF to the list of diseases for officially recognised status. The *ad hoc* Group had agreed that if a country found a wild boar positive for CSF it would have to be notified according to Chapter 1.1 but that its impact on its official disease status should be determined on a risk assessment, including surveillance and the evaluation of biosecurity measures to separate domestic and captive wild pigs from feral and wild pigs.

The Commission noted that the new case definition was in contradiction with Article 1.4.6 of the *Terrestrial Code* requiring that for official recognition of freedom there should be no evidence of infection in wildlife. In view of this, the Commission recommended that the Code Commission revise Article 1.4.6. to the effect that in points 1a) vi) and 1b) v) the sentence on wildlife be completed with “unless otherwise stated in the relevant *disease* chapter”.

The draft *Terrestrial Code* Chapter 15.2 and the accompanying questionnaire in relation to recognition of official disease status were endorsed by the Commission with some amendments. For example, vaccine strains were excluded from the definition of infection, and the Commission considered that it would be sufficient to detect infection by detection of viral RNA specific to a field strain of CSF virus, without necessarily linking the test result to an epidemiological investigation, since the use of real-time tests and in-tube reading could largely avoid the risk of false positive results. In addition, tests to detect RNA were generally validated and accredited to an appropriate quality standard, with adequate separation from areas where field virus are handled and with the use of positive controls. For these reasons, detection of RNA specific to a field strain of CSF virus was considered sufficient as a stand-alone test to define infection.

In relation to wild and feral pigs, the Commission expanded the requirement on separation of wild from domesticated pigs to include potential geographical barriers in addition to man-made ones. However, they considered that it would not be possible to establish containment zone if wild or feral pigs were infected. The Commission considered that the epidemiological situation within the containment zone should be sufficiently controlled to provide confidence to the capability of the country to control the disease and agreed to require that any new outbreak within or outside the containment zone result in the suspension of the status of the whole country or zone. The requirements on the annual reconfirmation of a CSF free status were also added. For the questionnaire, the *ad hoc* Group had suggested combining in a single questionnaire the requirements for a country/zone application. The Commission agreed to this suggestion and recommended that countries insert a heading in their application that would inform the Commission of the option chosen (country or zone).

Finally, the Commission was informed by the Scientific and Technical Department on the requirements for vaccines in the CSF chapter of the *Terrestrial Manual*, which had been reviewed by an *ad hoc* Group after the request from the Biological Standards Commission in September 2012. The *Terrestrial Manual* chapter had been recently finalised and was making reference to the availability of biotechnology derived marker vaccines and their corresponding tests that would allow for a DIVA strategy and a “vaccination to live” strategy.

The endorsed report, draft chapter and questionnaire were forwarded to the Code Commission for further processing. The endorsed report is attached as [Annex 9](#).

### **3.8. *Ad hoc* Group on Epidemiology: 2-4 October 2012**

The report of the October meeting of the *ad hoc* Group on Epidemiology contained the rationale for some of the changes proposed to the revised *Terrestrial Code* chapter on FMD. The revision of the FMD chapter had needed four *ad hoc* Group meetings; the *ad hoc* Group on Epidemiology also revisited the draft chapter with special emphasis on the articles on surveillance. However, the October meeting of the *ad hoc* Group on FMD proposed the final amendments to the Chapter.

The report was endorsed by the Commission and was forwarded to the Code Commission. The endorsed report is attached as [Annex 10](#).

### **3.9. *Ad hoc* Group on Epidemiology: 29 January 2013**

The report of the January meeting of the *ad hoc* Group on Epidemiology contained the rationale for the proposed amendments to the new surveillance articles for the *Terrestrial Code* chapter on PPR. It also carried a suggestion to the Commission to draft guidelines for the identification of factors that would guide risk based sampling as part of the horizontal chapters in the *Terrestrial Code*. The Commission endorsed the report and accepted the suggestions of the *ad hoc* Group, requesting the Director General to convene a meeting of the *ad hoc* Group on Epidemiology to address this matter. The report was forwarded to the Code Commission for information. The endorsed report is attached as [Annex 11](#).

### **3.10. *Ad hoc* Group on Foot and Mouth disease status evaluations of Member Countries: 9-11 October 2012**

#### **a) Revision of Chapter 8.5. of the *Terrestrial Code***

A merged version of the revised chapter after the work of four *ad hoc* Group meetings was presented to the Commission. The representative of the Commission at those meetings explained the rationale behind the proposed amendments to both the Scientific Commission and the Code Commission.

The main amendments were relative to the management of:

- Wildlife
- The process to be followed when a country/zone free with vaccination wishes to be recognised free without vaccination
- The compartment, which could be free with or without vaccination
- The containment zone: a new case, even within the containment zone, leads to withdrawal of the approval of the containment zone
- The recovery of free status for a zone/country (possibility for a country previously free without vaccination to recover free with vaccination).
- The border areas between a free country/zone/compartment and an infected area (truly infected or undefined)

The Commission also noted that the articles for country and zonal freedom with vaccination and country and zonal freedom without vaccination had been merged.

The Commission agreed to all amendments proposed by the *ad hoc* Group to the chapter on FMD, except for:

- Requiring additional warranties in the border areas between a free country/zone/compartiment and an infected area (truly infected or undefined status). The Commission considered this an unnecessary burden, since the maintenance of a free status already require strict preventive measures.
- Differentiating serotypes of FMD virus when importing from vaccinated countries. The Commission did not accept this as it could implicate trade barriers

In addition, the Commission also discussed the duration of the period during which a status of a country or zone could remain suspended and the period for which a containment zone could be implemented. The Commission decided not to indicate a prescriptive duration but amended the corresponding text in the Chapter to indicate that the duration of these periods should be limited in time.

The Commission also suggested that the questionnaire for a country free without vaccination be merged with the questionnaire for a zone free without vaccination, and that the questionnaire for a country free with vaccination be merged with the questionnaire for a zone free with vaccination. The report of the *ad hoc* Group and the revised draft *Terrestrial Code* Chapter 8.5 were endorsed and forwarded to the Code Commission with the explicit request that the draft amended chapter be circulated for Member Country comments. The Commission requested that the OIE Secretariat of the *ad hoc* Group on FMD attend the Code Commission meeting when FMD would be discussed. The endorsed report is attached as [Annex 12](#).

**b) Evaluation of the request from three Member Countries for the endorsement of their official control programme for FMD**

The Commission reviewed and endorsed the recommendations of the *ad hoc* Group on the application of three Member Countries for the endorsement of their official control programmes. These three applications were not approved by the Commission and the dossiers were referred back to the applicant Member Countries inviting them to fully observe the provisions in Article 8.5.48.

The Commission emphasised the need to develop and implement a quality filter to avoid that Member Countries apply for the endorsement of their official FMD control programmes without meeting the requirements of the relevant chapter of the *Terrestrial Code*. In discussions with the Director General, the Commission was informed that the OIE had initiated regional activities to assist in providing a filtering mechanism for applications such as for example the proposed OIE Animal Health Centre dedicated to FMD in Kazakhstan to help the Member Countries of the sub-region.

**3.11. *Ad hoc* Group on Foot and Mouth disease status evaluations of Member Countries: 10-14 December 2012**

The Commission representative on the *ad hoc* Group provided a summary of the *ad hoc* Group meeting outcomes to the Commission.

The Commission acknowledged that the increased number of Spanish-speaking experts in the *ad hoc* Group would facilitate the evaluation of dossiers submitted in Spanish. The Commission also noted that the expert of the *ad hoc* Group from Africa would be replaced by another expert from the same country (Botswana).

The Commission noted that the *ad hoc* Group had received and evaluated five dossiers for disease status recognition from four Member Countries (one country applied for two zones) and two dossiers to be evaluated for the endorsement of official control programmes for FMD. The *ad hoc* Group had evaluated all the dossiers in detail and requested additional information from some of the applicant Member Countries. The *ad hoc* Group also evaluated the additional information provided by a Member Country that had applied in 2011 and whose evaluation had been suspended awaiting this complement of information.

**a) Evaluation of the request from three Member Countries for the establishment of a zone free from FMD where vaccination is not practised**

The Commission reviewed and endorsed the recommendations of the *ad hoc* Group on the application of three Member Countries for the establishment of an FMD free zone where vaccination is not practised. The Commission determined that the following zones fulfilled the conditions to be considered as FMD free zone without vaccination in accordance with Article 8.5.4. of the *Terrestrial Code*:

- The summer pasture zone in the province of San Juan in Argentina;
- The regions of Lima, Lambayeque, La Libertad, Ancash and parts of Piura and Cajamarca in Peru, with the understanding that this new zone would be merged to the existing zone as recognised in Resolution No. 14 adopted at the 80th General Session, to constitute a single free zone where vaccination is not practised.

The application of the third Member Country was not approved by the Commission and the dossier was referred back to the applicant Member Country, inviting the country to fully observe the provisions in Article 8.5.4.

Two members of the Commission excused themselves from the meeting during the discussions on the applications for FMD disease status of their respective home countries.

**b) Evaluation of the request from three Member Countries for the establishment of a zone free from FMD where vaccination is practised**

The Commission reviewed and endorsed the recommendations of the *ad hoc* Group on the application of three Member Countries for the establishment of a FMD free zone where vaccination is practised. The Commission determined that the following zones fulfilled the conditions to be considered FMD free zone with vaccination in accordance with Article 8.5.5. of the *Terrestrial Code*:

- The regions of Chaco and part of Valles in Bolivia;
- The regions of Tumbes and parts of Piura and Cajamarca in Peru.

In the case of the third application, the Commission, after a meeting with a Delegation from the applicant Member Country, decided, in line with Resolution 25 of the 80<sup>th</sup> General Session, to request the Director General to mandate an expert mission to the country to enable the Commission to make an informed decision, taking into account the findings of the mission.

**c) Evaluation of the request from two Member Countries for the endorsement of their official control programme for FMD**

The Commission reviewed and endorsed the recommendations of the *ad hoc* Group on the application of two Member Countries for the endorsement of their official control programme for FMD. The Commission determined that the official control programme of Bolivia fulfilled the conditions to be endorsed by the OIE in accordance with Article 8.5.48. of the *Terrestrial Code*. The application of the other Member Country was not approved by the Commission and the dossier was referred back to the applicant Member Country, inviting the country to fully observe the provisions in Article 8.5.48.

The endorsed report is attached as Annex 13.

### 3.12. *Ad hoc* Group on Peste des petits ruminants (PPR): 27-29 November 2012

The Commission noted the need of Member Countries in having the *Terrestrial Code* chapter on PPR revised to provide for official disease status recognition as well as for a Global Control Strategy for PPR. The development of the Global Control Strategy would be coordinated by the Working Group set up under GF-TADs<sup>3</sup> for FMD. In addition, the Commission was informed of the Bill & Melinda Gates' Foundation project to establish a pilot protocol for different vaccination strategies, establishing a PPR vaccine bank and strengthening the vaccine quality control system in West Africa.

The main issues discussed in amending the *Terrestrial Code* chapter included the questionnaire for official disease status recognition and the relevance of free status recognition with the involvement of wildlife for PPR. The Commission noted that there was published scientific evidence that suggested that wildlife did not play a significant role in maintaining PPR infection. However, the *ad hoc* Group had indicated that sampling animals other than the target population (domestic and captive wild sheep and goats) could be useful for sentinel surveillance purposes. The Commission requested the *ad hoc* Group by electronic consultation to clarify what actions should be taken when positives were found in wildlife in a free country or zone.

The Commission harmonised the amended chapter with other disease specific chapters in the *Terrestrial Code* and proposed several amendments. The main additions were in relation to Article 14.8.3 (PPR free country or zone), where the Commission included a provision for applicant countries to submit evidence of the system that would prevent the entry of the virus into the proposed free country or zone; and the specification that a containment zone does not follow the recovery pathway, since once the outbreaks had been resolved the restrictions on the containment zone would be lifted.

Two members of the *ad hoc* Group had also been responsible for the revision of the *Terrestrial Manual* chapter on PPR. The *ad hoc* Group provided comments on the revision of the requirements for vaccines and vaccination. The Commission recommended that this information was shared with the Biological Standards Commission.

The Scientific Commission endorsed the report of the *ad hoc* Group and discussed the revised version of Chapter 14.8 on PPR and accompanying questionnaires for official disease status. These documents were forwarded to the Code Commission for further processing of the draft revised chapters.

The endorsed report is attached as [Annex 14](#).

### 3.13. Working Group on Wildlife Diseases: 12-15 November 2012

The Chairperson of the Working Group on Wildlife Diseases (hereafter the Working Group), provided an overview to the Commission on the recent activities of the Working Group as reflected in the report of the meeting held in November 2012 and to discuss future work of the Working Group. The Working Group recognised and appreciated the value of having a member of the Commission in the Working Group and pointed out the importance of maintaining this presence in future meetings. The Commission was also informed of the actions planned by some members of the Working Group for World Rabies Day 2013, in view of the implications of rabies on wildlife.

The Commission discussed the report of the Working Group and noted with appreciation the excellent work it had done in support of the objectives of the Commission and the OIE. The Commission supported the involvement of members of the Working Group in the establishment of an OFFLU group focused on influenzas in wildlife. The Commission also supported the proposal to dedicate a day, at the next meetings of the Working Group, to a brainstorming session with representatives from a range of relevant international organisations engaged in wildlife, biodiversity management and health. The

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<sup>3</sup> OIE/FAO Global Framework for the progressive control of Transboundary Animal Diseases

Commission noted the reference to and importance of Appendix III of the report of meeting of the *ad hoc* Group on Wildlife Disease Notification from July 2008 providing the basis for the current version of the list of pathogens in wildlife for voluntary reporting. The Commission suggested that the OIE provide easy access to this Appendix III and the current list on the OIE website. The Commission requested the Working Group to address, at its next meeting in November 2013, Member Country comments on relevant articles of draft disease-specific chapters in relation to the implication of wildlife and surveillance (e.g. Article 1.4.6., update of Chapter 14.8. on PPR, revision of Chapter 15.2. on CSF of the *Terrestrial Code*). The Commission further requested the Working Group to explore possible ways for the OIE to address the challenges of the management of Trans-Frontier Conservation Areas related to disease status and animal movements, and to provide its view to the Commission.

The Commission was informed by the Scientific and Technical Department on the training of National Focal Points for Wildlife. It was indicated that the third cycle of this training would start in November 2013 and that the focus could be on risk assessment, *WAHIS-Wild* and validation of diagnostic tests. This could provide an opportunity to Member Countries to develop more specific priority-setting approaches based on needs and concerns in order to provide a better focus in their surveillance activities.

The report of the Working Group was adopted (81 SG/13 GT)

#### ■ Programme and priorities

The following *ad hoc* Groups were identified as pending work from the Commission and as potential new work:

#### 3.14. *Ad hoc* Group on Glanders

The Commission recommended that an *ad hoc* Group be convened during the second half of 2013, if there was sufficient justification and rationale for including Glanders in the list of diseases for official status recognition. In this new work, both experts on Glanders diagnostics and control as well as those from the *ad hoc* Group on the temporary movements of high health, high performance horses would be consulted by the OIE. The Commission emphasised the importance of timely communication and consultation between several *ad hoc* Groups and Specialist Commissions on this cross-over subject.

#### 3.15. *Ad hoc* Group on Rift Valley Fever (RVF): tentative date 4-6 June 2013

The Commission was informed about the consultation process with experts on the justification for an update of the RVF *Terrestrial Code* chapter. Four experts had provided a consolidated report with their arguments, highlighting the reasons why an update to the *Terrestrial Code* chapter was recommended. The experts also pointed out the inconsistency amongst *Terrestrial Code* chapters of several vector-borne diseases and suggested that when making a revision, achieving harmonisation between these chapters also be considered.

The Commission took note of the proceedings from the RVF inter-regional conference for East Africa and Middle East, held in November 2012 in Mombasa, which had just been finalised and which contained important information, also worth considering by an *ad hoc* Group to be set up for RVF.

#### 3.16. *Ad hoc* Group on International Horse Movements: 24-26 April 2013

The Commission was informed on the development of work in relation to equine diseases relevant to the temporary movement of “high performance, high health” horse subpopulations. The events/activities that had taken place since the first joint OIE/FEI conference in Guadalajara in 2011 were summarised. These activities now culminated into a 3-year Collaboration Agreement between OIE and FEI under which funds would be available to carry out a 3-year work programme.

While the work was to be guided by an *ad hoc* Group to meet for the first time on 24 – 26 April this *ad hoc* Group should report to this Commission as well as to the Code and Biological Standards Commissions.

Furthermore, the Commission was informed that the requested baseline document on “Biosecurity Guidelines” and a “Definition” for these particular “high health, high performance” horses had been produced in close collaboration with a consultant and this would form the basis of work for the first meeting of the *ad hoc* Group. It was also noted that the 3-year agreement had some funding for selection, research and development on diagnostic tests and vaccines for equine diseases.

The draft Terms of Reference and provisional agenda for the *ad hoc* Group meeting were endorsed by the Commission.

**3.17. *Ad hoc* Group on Harmonisation of the *Terrestrial Code* Chapters on Infection with Bluetongue Virus, Infection with African Horse Sickness Virus and Infection with Epizootic Haemorrhagic Disease Virus: tentative dates 20-22 August 2013**

The Commission reiterated its previous decision on the need to convene an *ad hoc* Group to harmonise all three chapters on vector borne diseases caused by Orbivirus and transmitted by Culicoides, taking into consideration Member Country comments, the latest revised chapters endorsed by the Commission for ‘case’ and ‘infection’ definitions and also the *Terrestrial Code* chapter on vector surveillance.

The draft Terms of Reference and provisional agenda for the *ad hoc* Group meeting were endorsed by the Commission.

**3.18. *Ad hoc* Group on Tuberculosis: tentative dates 9-11 April 2013**

The Commission noted the need to combine the *Terrestrial Code* chapters on Tuberculosis into a single chapter in view of the pathogen-oriented approach followed in the *Terrestrial Code*. The Commission discussed this matter with the Code Commission and agreed that they would wait Member Country comments on the revised chapter on Brucellosis before starting to harmonise the approaches. Nevertheless, the Commission recommended that an *ad hoc* Group be convened to discuss some requests by the Biological Standards Commission and by the Code Commission on the latest scientific information in relation to gamma interferon tests as well as on the development of DIVA tests given that vaccination for tuberculosis was currently not an option considered.

The Code Commission and the Scientific Commission agreed that representatives from both Commissions should be present at this *ad hoc* Group meeting.

The draft Terms of Reference and provisional agenda for the *ad hoc* Group meeting were endorsed by the Commission.

**3.19. *Ad hoc* Group on PRRS: tentative dates 9-11 July 2013**

The Commission had requested an expert opinion at its last meeting to take a scientifically sound decision to recommend the development of a *Terrestrial Code* chapter on PRRS as had been requested by Member Countries. Following the opinion of experts that there was now sufficient scientific knowledge to allow the drafting of a *Terrestrial Code* chapter on PRRS, the Commission recommended that an *ad hoc* Group be convened.

The draft Terms of Reference and provisional agenda for the *ad hoc* Group meeting were endorsed by the Commission.

**4. Official disease status**

**4.1. Brazil’s BSE Risk Status**

The Commission was advised that Brazil, which had been granted a negligible BSE risk status in May 2012, had detected the first case of BSE in its territory and submitted the immediate notification to the OIE in December 2012. It was also noted that the OIE had requested Brazil to provide all relevant information to the Commission at the current meeting.

The Commission was informed by a Delegation from Brazil on the sequence of events leading to the delay in the notification to the OIE of the first case of BSE in their country. The Commission decided, in accordance with the standards of the OIE *Terrestrial Code*, not to withdraw the "negligible risk" status of Brazil.

The Commission also affirmed that the identification of this single case of BSE was not putting the country's or its trading partners' animal and public health at risk, notably because the animal was destroyed and no parts of it had entered the food or feed chain.

The Commission, however, noted with concern that there had been a considerable delay before Brazil sent the clinical samples for a confirmatory diagnosis to an OIE Reference Laboratory. The Commission therefore agreed that it needed more detailed information on the procedures in place for processing samples and the improvement of the surveillance system in the country so as to further monitor the continuous compliance by Brazil with the relevant provisions of the *Terrestrial Code* to be respected for the sustainable maintenance of its official status for BSE.

At its next meeting in September 2013 the Commission should again assess the additional information to be provided by Brazil.

#### **4.2. Evaluation of the request from a Member Country for the establishment of a zone free from FMD where vaccination is not practised**

The Commission evaluated an application from a Member Country that was received after the meeting of the *ad hoc* Group on evaluation of FMD official disease status had taken place. After discussions with the Director General, the Commission decided to apply the provisions of Resolution No. 25 adopted at the 80<sup>th</sup> General Session - as part of the evaluation of the Member Country dossier - and requested the Director General to mandate an expert mission to the country to enable the Commission to make an informed decision, taking into account the findings of the mission.

#### **4.3. Revision of the questionnaires (harmonisation between country and zone) for the annual reconfirmation of disease status**

The Commission endorsed the revision of the forms for the annual reconfirmation for FMD and CBPP free status as proposed by the Scientific and Technical Department. The wording was harmonised between the diseases, and between the forms for free zones and free countries.

#### **4.4. Guidance on preliminary evaluations made by the secretariat and the experts evaluating Member Country applications**

The Commission agreed that the Scientific and Technical Department should document the good practices already implemented by some *ad hoc* Groups for the evaluation of Member Countries disease status into a standard generic procedure so that such practices be systematically followed. Such procedure would support the experts from *ad hoc* Groups in their task, and improve the transparency and objectivity in the work of the OIE in this area.

### **5. Matters of interest for consideration**

#### **5.1. Rinderpest**

The Commission was provided with the latest information on the rinderpest post-eradication activities. The second meeting of the Joint OIE/FAO Advisory Committee on Rinderpest had taken place in October 2012 and a further meeting was scheduled for February 2013. The Committee was working to develop guidelines to ensure safe destruction of rinderpest virus (RPV) containing material and criteria to evaluate research proposals that involve the manipulation of RPV containing material. For the evaluation to take place, laboratories and other institutions should submit a completed application form to the Committee. On the advice of this evaluation, FAO and OIE would have to reach a decision on whether to authorise the research. Once the research application criteria had been in place, the moratorium of RPV research would be lifted and the Committee would evaluate each application based on the criteria.

Furthermore, the Committee was also developing criteria to evaluate applications from laboratories and other institutions wishing to host an approved facility in which RPV containing material would be stored. The application forms for different categories of containment facilities were under development.

The Committee would also provide its view on an international contingency plan as the tool through which the different players interact; such a plan should be consistent with the provisions of the *Terrestrial Code*. The Commission wished to be kept informed of the progress being made by the Committee.

Finally the Commission was informed about advocacy activities and funding related to rinderpest.

#### **5.2. Opinion on the *ad hoc* Group on Notification of Animal Diseases and Pathogenic Agents: feedback from experts on *Leptospira* serovars candidates for listing and on the comments received by a Member Country**

The Commission decided to refrain from providing an opinion on which diseases should remain listed since it was clear from the extensive comments (some of them conflicting) from Member Countries that this issue needed to be discussed thoroughly before identifying a way forward.

#### **5.3. Emerging diseases**

Some of the recent examples of emerging diseases had identified the need to revise the definition of “emerging diseases” as it appeared in the Glossary of the *Terrestrial Code* especially in relation to the duration of time under which a disease would remain classified as “emergent” and to the notification obligations of Member Countries. An internal technical group constituted at the OIE Headquarters had preliminary discussions on this issue. Its preliminary findings and proposals, while still under debate, were presented to the Commission.

The Commission was of the opinion that a listed disease should be also considered as emerging when it appeared in a new geographical area— for example, the occurrence of BTV8 in Europe. At the same time, the Commission took note of the fact that unjustified barriers to trade could sometimes be enforced, as result of notification to the OIE. In view of this, the Commission proposed that instead of stating that the definition of emerging diseases would exclude listed diseases, some wording is added to the definition to indicate that either the definition excluded listed diseases for notification purposes, or that listed diseases were covered elsewhere.

The Head of the OIE Animal Health Information Department joined the Commission meeting. He delivered a presentation to indicate that, for the majority of OIE listed diseases, a case definition had not been defined in the *Terrestrial Code*. He suggested that all disease specific chapters in the *Terrestrial Code* be harmonised to include, in the first article, the name of the pathogenic agent, the diagnostic procedure which determine a case on the basis of the *Terrestrial Manual*, and the conditions for notification (differentiating between the species that would have an impact on trade for that particular disease from the species that would not).

The Commission supported the proposal for a change in the first article of the disease chapters in the *Terrestrial Code* and also indicated that the chapters revised during the current meeting by the Commission had been amended accordingly in relation to case and infection definitions.

#### **5.4. Decision on the publication of a paper on the background information related to bee diseases**

The Code Commission requested the Scientific Commission to consider the publication of the paper ‘Background to the *Terrestrial Code* chapters on bee diseases’ that had been presented to the Code Commission as an annex to the report of the meeting of the *ad hoc* Group on Diseases of Honey Bees endorsed by the Scientific Commission at its last meeting. The paper contained very useful background information but its format and nature was not appropriate for inclusion in the *Terrestrial Code*. The Scientific Commission recommended that the paper be published in the OIE website, as a stand-alone document, under “Our scientific expertise” once the chapters on bee diseases had been adopted by the World Assembly of Delegates.

## 5.5. Schmallenberg virus in semen

At the recent findings on the infectious Schmallenberg virus and its genome detection in cattle semen in experimental studies, the OIE had contacted the experts of the *ad hoc* Group on Schmallenberg virus and requested that the OIE Technical Factsheet be updated. There was some debate on the need to keep the appendix of the technical factsheet, considering that on-going studies seemed to demonstrate a low impact of the disease and that the endemicity of the situation had led to the discontinuation of notification to the OIE by countries that previously detected the infection. The Commission considered that the information in the appendix was still needed, especially given new research findings that could update the information about Schmallenberg virus. The Commission agreed on the revised technical factsheet.

## 6. OIE Collaborating Centres

### 6.1. Collaborating Centre in Cuba

At its previous meeting, the Commission had requested the applicant country to provide a summary of proposed activities and services with clear objectives and had suggested a suitable title to the proposed Collaborating Centre that would better reflect the expertise described in the dossier.

The Commission examined the re-submitted dossier and decided that, for harmonisation across all three OIE official languages, the most appropriate title should be “Collaborating Centre for the Reduction of the Risk of Disasters in Animal Health”.

The Commission agreed to confirm the designation of the Collaborating Centre, which had been approved on a temporary basis, with the recommendation that the Centre also manage other disasters that would have an impact on the health and welfare of animals and not only those caused by pathogenic agents.

### 6.2. Collaborating Centre in New Zealand

The Commission evaluated a new application for a Collaborating Centre for Veterinary Epidemiology and Public Health in the Asia-Pacific region. The Commission recommended that the New Zealand centre be recognised as “Collaborating Centre for Veterinary Epidemiology and Public Health”, noting that the mandate of a Collaborating Centre was global and not limited to a specific region.

## 7. Liaison with other Commissions

### 7.1. Issues with the Terrestrial Animal Health Commission

A joint meeting between the President and a Vice-President of the Code Commission with the Scientific Commission took place on Friday 8 February 2013. The minutes of the joint meeting will be published in the Code Commission report. Below is a summary of the main points discussed:

#### a) Rabies: new *Terrestrial Code* article proposed by the Code Commission

Consistent with the OIE, WHO and FAO’s efforts to work on a global strategy for rabies control in collaboration with other key partners, the Code Commission had revisited the *Terrestrial Code* chapter on Rabies and had proposed the re-insertion of an article that would allow countries to self-declare freedom in dog populations.

The Commission noted that the *ad hoc* Group on Rabies that developed the amended chapter on rabies for the *Terrestrial Code* in 2011 had proposed a similar article and suggested to the Code Commission that the wording proposed by the *ad hoc* Group be used for this article. The Code Commission agreed to this proposal after a joint discussion on the matter, with the condition that the wording should clearly indicate that the provision was for public health purposes and not for trade purposes.

The Director General of the OIE suggested that the agreed article between the two Commissions be proposed for adoption at the forthcoming General Session in May 2013.

## b) *Terrestrial Code* chapters with Member Country comments

The Commission received from the Code Commission the Member Country comments on *Terrestrial Code* Chapters 6.9 (responsible and prudent use of antimicrobial agents), 8.3 (Bluetongue), 8.12 (Rinderpest), 9.1-9.6 (Bee diseases), and the draft chapter on Epizootic Haemorrhagic Disease. The Commission provided its opinion to the Member Country comments and forwarded the revised chapters back to the Code Commission, noting that some of the comments on Bluetongue and Epizootic Haemorrhagic Diseases would be dealt with at a later stage by the *ad hoc* Group on Harmonisation of African Horse Sickness, Bluetongue and Epizootic Haemorrhagic Diseases and would thus be revisited by the Commission at its next meeting in September 2013.

Regarding the comments on the chapters on bee diseases, views of the relevant *ad hoc* Group had been sought by correspondence. The main changes/replies to the comments were (1) to remove eggs from the safe commodities for American and European Foulbrood (chapters 9.2. and 9.3.) although it was highlighted that for American Foulbrood a risk analysis had been conducted by New Zealand concluding that eggs were safe (<http://www.biosecurity.govt.nz/files/regs/imports/risk/honey-bee-genetic-material-ra.pdf>) and that this position had also been supported by other Member Countries, (2) to propose a higher level of irradiation in the articles 7, 8 and 9 of the chapter on European Foulbrood (Chapter 9.3.) based on a scientific publication (Hornitzky MAZ [1994]). Commercial use of gamma radiation in the beekeeping industry. Bee World 75, 135-142), (3) to highlight that the different levels of irradiation for mites and beetles (chapters 9.4. to 9.6.) were based on the recommendations developed by the International Plant Protection Convention (IPPC): IPPC (2003) Guidelines for the use of irradiation as a phytosanitary measure, FAO, Rome, Publication No. 18. April 2003, and (4) to change the definition of varroosis (Chapter 9.6.) stating that varroosis is a disease caused by varroa mites and highlighting however the importance of viruses in the disease. The Commission endorsed the *ad hoc* Group changes to the chapter and forwarded it to the Code Commission.

The Commission did not have enough time to address the Member Country comments on antimicrobial agents and suggested that, in view of the importance of the issue for public health as well as of the forthcoming OIE Global Conference on Antimicrobial Resistance in March 2013, these comments be given the highest priority to be reviewed by the Code Commission and if an expert review was required to address any of them, the comments be forwarded to the President of the Scientific Commission for further circulation among relevant experts. Two clarifications on Chapter 6.9 of the *Terrestrial Code* required input from the experts. The proposals from the experts, endorsed by the President of the Scientific Commission, related to: a) the merging of sub-articles 1 (Marketing authorisation), 2 (Submission of data for the granting of the marketing authorisation) and 3 (Marketing authorisation approval) into a single sub-article called "Marketing authorisation" in Article 6.9.3 (Responsibilities of the Competent Authority); and b) changes to sub-article 1 of Article 6.9.8 (Responsibilities of animal feed manufacturers) based on Member Country comments.

## c) Sharing of documents between Commissions

The Code Commission requested that the *ad hoc* Group meeting reports were shared between the Scientific and Technical Department and the International Trade Department of the OIE as soon as they were finalised and approved. The Scientific Commission requested that all of the Member Country comments of a scientific nature be shared between the International Trade Department and the Scientific and Technical Department as soon as they were received. The two Commissions agreed that, for traceability purposes, the Scientific Commission would provide the Code Commission with the revised chapters with the changes indicated in relation to the last version considered by the Code Commission (published in the Code Commission report with Code Commission changes included) in which the version (Scientific Commission meeting of month/year) would be specified.

To facilitate communication between the two Commissions on the work in progress, a summary table of the Commission decisions/actions relative to *Terrestrial Code* chapters was included in the Commission's report as Annex 15.

## **7.2. Issues with the Biological Standards Commission**

The reports of the *ad hoc* Group meetings on PPR and AHS would be shared with the Biological Standards Commission as they contained information relevant to the work of that Commission. In addition, the Scientific Commission requested the Biological Standards Commission to kindly provide the latest scientific updates within its mandate on tuberculosis, Rift Valley Fever and glanders in view of the potential *ad hoc* Group meetings that would be convened in the near future.

## **8. Country missions of the Commission**

The country visits of the Commission projected for the near future were prioritised. The mission on FMD control in the southern African region had been postponed several times and should thus be scheduled as a priority followed by missions related to pending country applications for official disease status.

## **9. Any other business**

### **9.1. FAO intervention on Post Vaccination Monitoring (PVM) for FMD**

Dr Samia Metwally, Animal Health Officer, FAO, was invited to this meeting to provide detailed information on the working group she had been leading on FMD Post Vaccination Monitoring (PVM), in which a number of virologists, diagnosticians, epidemiologists, statisticians and field veterinarians were being involved. Dr Metwally had been tasked to develop this work by the OIE/FAO FMD Reference Laboratory Network, in liaison with the OIE and to develop guidelines for PVM. At the last meeting of the Commission, it was recommended that an OIE *ad hoc* Group with nominees from both FAO and OIE be convened to assist in the production of the guidelines for PVM. However, since the last meeting of the Commission, the working group led by Dr Metwally had made a significant progress in the development of the guidelines, which were presented at the OIE/FAO FMD Reference Laboratories network meeting in Jerez, Spain, in October 2012. In this context, the Commission was requested to express an opinion on establishing an expert panel under the auspices of GF-TADs, instead of convening an OIE *ad hoc* Group.

Dr Metwally gave a presentation to the Commission in which she summarised the objectives of this initiative, its link to the Global FMD Control Strategy and explained the different parts of the outline of the Guidelines. She stated that a number of country contributions had already been received (e.g. China, India), others were expected (Kenya, SADC, Brazil) shortly and that the draft document was to be reviewed by an expert panel (i.e. GF-TADs expert group). This expert panel would be coordinated jointly by FAO and OIE, and would meet in April/May 2013. Ideally, the goal of reviewing the document should be attained with one single meeting. The Guidelines would then be validated through pilot implementation in countries and the document would be revised as necessary.

The Commission took note that the Belgium Institute was involved in the DISCONVAC project and that one of the project outputs was also a PVM guide that would be shared with the OIE and FAO. A synergy between the two initiatives was proposed.

The Commission requested to have an opinion on the list of experts that would participate in this initiative. Dr de Clercq would represent the Commission at the expert panel (i.e. GF-TADs meetings) on FMD-PVM.

### **9.2. Information on the global FMD situation by the OIE/FAO World Reference Laboratory for FMD**

The Head of the Pirbright Institute's World Reference Laboratory (WRL) for FMD was invited to the meeting of the Commission to provide details on the latest advances in FMD control and to make a presentation on the FMD serotypes' worldwide distribution and trends. The need for different control strategies adapted to the regional needs and using tailored vaccines was highlighted. There had been increased activity of serotypes Asia 1 in the Middle East and SAT-2 in North Africa during the year 2012. A high quality of vaccines used against FMD was of paramount importance to achieve effective control.

A summary of the outcomes of the meeting of the FMD Reference Laboratory Network that had taken place back to back with the EU FMD meeting in October 2012 in Jerez, Spain was also provided. The Commission was informed that the Pirbright Institute had been designated as the global coordinating laboratory for the OIE/FAO Global Control Strategy for FMD as well as for laboratory testing training.

The Commission informed the representative of Pirbright on the FMD PVM work that would be carried out under GF-TADs and on the development of an OIE World Assembly Resolution on global data sharing for FMD, which would be presented at the 81<sup>st</sup> General Session as a follow up of the Global Conference on FMD Control held in Bangkok in 2012.

#### **10. Adoption of the report**

The Commission briefly reviewed the main decisions taken during the week to make sure that they were appropriately recorded in the report. The Commission agreed to circulate the draft report electronically for comments before adoption.

The next meeting of the Commission will be from 2 to 6 of September 2013.

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.../Appendices



## MEETING OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 4 – 8 February 2013

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### Agenda

#### Opening

#### 1. Adoption of the draft agenda

#### 2. Issues from the last meeting of the Scientific Commission

- 2.1. Principles on Disease Control (proposed new chapter for the *Terrestrial Code*): comments from Member Countries
- 2.2. Decision on the inclusion of the term “risk-based surveillance” in the Glossary
- 2.3. Items consulted with experts to address Member Country comments or requests: Equine viral arteritis, porcine reproductive and respiratory syndrome (PRRS)
- 2.4. Guide on Terrestrial Animal Health Surveillance

#### 3. *Ad hoc* and Working Groups:

##### Meeting reports for endorsement

- 3.1. *Ad hoc* Group on African Horse Sickness official disease status evaluations: 15-17 January 2013
- 3.2. *Ad hoc* Group on Antimicrobial Resistance: 8-10 January 2013
- 3.3. *Ad hoc* Group on Bovine Spongiform Encephalopathy: 11-13 September 2012
- 3.4. *Ad hoc* Group on Bovine Spongiform Encephalopathy risk status evaluations of Member Countries: 27-30 November 2012
- 3.5. *Ad hoc* Group on Brucellosis: 9-11 January 2013
- 3.6. *Ad hoc* Group on Contagious Bovine Pleuropneumoniae (CBPP): 9-10 January 2013
- 3.7. *Ad hoc* Group on the inclusion of Classical Swine Fever in the list of diseases with official status: 16-18 October 2012
- 3.8. *Ad hoc* Group on Epidemiology: 2-4 October 2012
- 3.9. *Ad hoc* Group on Epidemiology: 29 January 2013
- 3.10. *Ad hoc* Group on Foot and Mouth disease status evaluations of Member Countries: 9-11 Oct 2012
- 3.11. *Ad hoc* Group on Foot and Mouth disease status evaluations of Member Countries: 10-14 Dec 2012
- 3.12. *Ad hoc* Group on *Peste des petits ruminants*: 27-29 November 2012
- 3.13. Working Group on Wildlife Diseases: 12-15 November 2012

##### Programme and priorities

- 3.14. *Ad hoc* Group on Glanders
- 3.15. *Ad hoc* Group on Rift Valley Fever (RVF): tentative date 4-6 June 2013
- 3.16. *Ad hoc* Group on International Horse Movements: 24-26 April 2013
- 3.17. *Ad hoc* Group on Harmonisation of BT, AHS, EHD Code Chapters: tentative date 20-22 August 2013
- 3.18. *Ad hoc* Group on Tuberculosis: tentative date 9-11 April 2013
- 3.19. *Ad hoc* Group on PRRS: tentative date 9-11 July 2013

#### 4. Official disease status

**5. Matters of interest for Consideration**

- 5.1. Rinderpest
- 5.2. Opinion on the *ad hoc* Group on Notification of Animal Diseases and Pathogenic Agents: feedback from experts on *Leptospira* serovars candidates for listing and on the comments received by a Member Country
- 5.3. Emerging diseases
- 5.4. Decision on the publication of a paper on the background information related to bee diseases
- 5.5. Schmallenberg virus in semen

**6. OIE Collaboration Centres**

- 6.1. Collaborating Centre in Cuba
- 6.2. Collaborating Centre in New Zealand

**7. Liaison with other Commissions**

- 7.1. Issues with the Terrestrial Animal Health Standards Commission
- 7.2. Issues with the Biological Standards Commission

**8. Country missions of the Commission**

**9. Any Other Business**

**10. Adoption of the report**

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## MEETING OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 4 – 8 February 2013

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**MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION  
OF AFRICAN HORSE SICKNESS STATUS OF MEMBER COUNTRIES**

**Paris, 15 – 17 January 2013**

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A meeting of the OIE *ad hoc* Group on the Evaluation of the African Horse Sickness (AHS) Status of Member Countries (hereafter the Group) was held at the OIE Headquarters from 15 to 17 January 2013.

**1. Opening**

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Kazuaki Miyagishima, Deputy Director General, welcomed the Group. He emphasized that this was an epoch-making meeting in that applications of Member Countries for official recognition of AHS free status would be evaluated for the first time.

Dr Miyagishima informed the Group that the OIE process for granting official recognition of disease status was under close scrutiny by the applicant Member Countries and other OIE partners. He emphasised the importance of the work carried out by the *ad hoc* Groups in charge of evaluating dossier for official recognition of disease status. In accordance with the OIE Standard Operating Procedures (SOPs) governing official recognition of disease status, he recommended the Group to produce a detailed report in order to give clear understanding to the Scientific Commission and to the applicant Member Countries on possible information gaps and/or specific areas that should be addressed in the future.

Dr Miyagishima advised the Group to actively communicate with the applicant Member Countries during the meeting and to send them a request for clarification as soon as information gaps were identified between the requirements of the *Terrestrial Animal Health Code (Terrestrial Code)* and the dossier. He also stated that such questions could be formulated when the experts analysed the dossiers prior to the meeting so as to be send in advance to the applicant Member countries through the OIE secretariat.

Finally, Dr Miyagishima explained the standing OIE policy concerning declaration of interest and confidentiality of information. He invited experts who were in the situation of a potential conflict of interest to voluntarily withdraw from the discussion on specific dossiers in question.

**2. Adoption of the agenda and appointment of chairperson and rapporteur**

The Group was chaired by Dr Stéphan Zientara and Dr Alf-Eckbert Füssel acted as rapporteur. The Group adopted the proposed agenda as agenda for the meeting.

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

**3. Chapter 12.1. – consideration of Member Countries' comments raised during the 80th General Session**

The Group was asked to review the comments made by Member Countries on the Chapter on African horse sickness of the *Terrestrial Code* during the 80th General Session in relation to the following points:

General comment: The Group agreed that there was no reason to differentiate in the *Terrestrial Code* permanent from temporary movements of equidae between countries or zones by not requiring the same risk mitigation measures for their introduction. However, the requirement relating to the 40 days residence in an AHSV free country or zone as stated in Article 12.1.7. could be amended so that 40 days residence in more than one country or zone free of AHS would be considered as equivalent. Such amendment would have a significant benefit for the movement of horses.

Article 12.1.1.: Some Member Countries had requested the OIE to review the duration of the infective period in the Chapter - currently set at 40 days - for equidae because the viraemia in horses was considered to last no more than 21 days. The Group discussed this request and agreed that the infective period was more than the viraemic phase of an infection. The Group was of the opinion that the infective period, defined as the longest period during which an affected animal could be a source of infection, included the incubation period, the viraemic phase and a safety margin. The request to shorten the infectious period below 40 days was not considered as being supported by scientific evidence. The Group agreed, in the absence of scientific evidence, not to amend the Chapter as regards the period of 40 days mentioned in several articles in the Chapter.

#### **4. Clarification on seasonal freedom and self-declaration**

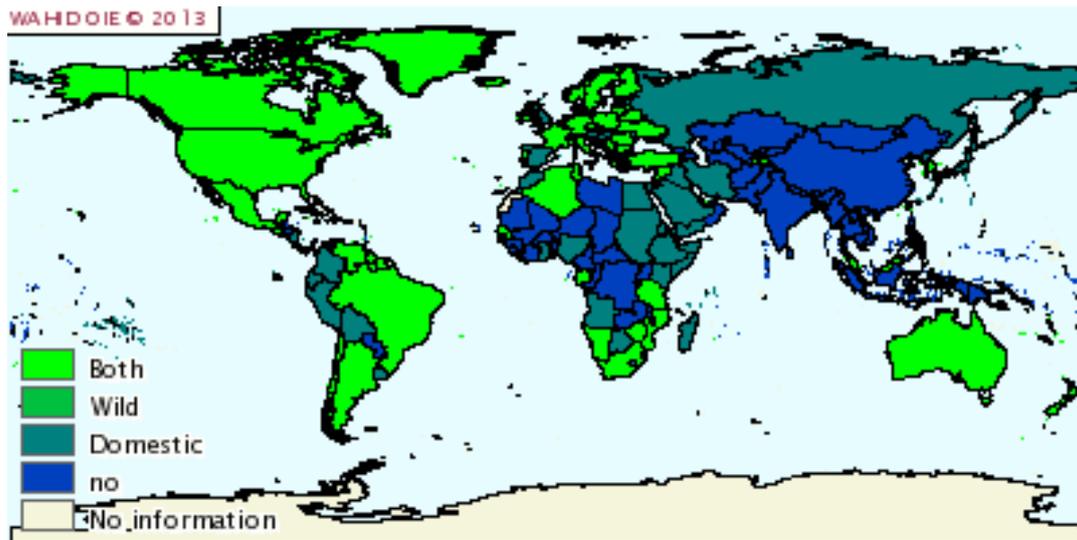
The Group recalled that in accordance with Article 1.6.1 of the *Terrestrial Code*, OIE Member Countries had the possibility to self-declare their country or a zone within their territory free from any OIE-listed disease other than those diseases for which the OIE had established a specific procedure for official recognition of disease status such as AHS, contagious bovine pleuropneumonia (CBPP), foot and mouth disease (FMD) and bovine spongiform encephalopathy (BSE).

In light of this, the Group considered that Article 12.1.3. in the Chapter on AHS (relating to the possibility for a Member Country to self-declare itself as seasonally free from AHS) was not in compliance with the principle set out in Article 1.6.1 dealing with the procedures for self declaration and for official recognition by the OIE.

The Group therefore agreed to propose the removal of Articles 12.1.3 and 12.1.8 and all the references relating to seasonally free country or zone throughout the Chapter.

#### **5. Evaluation of requests from Member Countries for recognition of historical freedom and establishment of a base list of historically free Member Countries for AHS**

The Group noted a list of applicant Member Countries, provided by the OIE secretariat, grouped by OIE region. The Group considered the requirement of disease reporting according to the *Terrestrial Code* and verified the statements made by the applicants in their dossiers against the information previously reported to the OIE through the World Animal Health Information System (WAHIS-WAHID) (Figure 1), especially relating to the history of disease reporting and the legal notifiability of AHS in the country. Based on the outcome of this verification, the Group agreed to request clarification from Member Countries where the information contained in their dossiers was inconsistent with the data submitted through WAHIS-WAHID. The following Members Countries were requested to provide clarification: Azerbaijan, Oman, Paraguay and Qatar.

**Figure 1: Map displaying AHS notifiability as reported by Member Countries through WAHIS/WAHID**

The Group then proceeded with evaluation of individual country applications, in the light of the additional information where it was supplied during the meeting, as follows:

### 5.1. The Americas

A total of ten Member Country applications for recognition of historical freedom had been received by the OIE from the Americas region covering the whole continent with the exception of some Andean countries, Central America and the Caribbean islands.

The Group noted that these applicant countries had no history of AHS outbreaks.

The Group received from Paraguay confirmation that AHS had been notifiable in the country for the past ten years.

The Group agreed to recommend that Argentina, Bolivia, Brazil, Canada, Chile, Mexico, Paraguay, Peru, the United States of America and Uruguay be included in the list of Member Countries officially recognised free of AHS by the OIE.

### 5.2. Asia and Pacific

A total of six Member Country applications for recognition of historical freedom had been received by the OIE from the Asia and the Pacific region.

The Group noted that these applicant countries had no history of AHS outbreaks.

The Group agreed to recommend that Australia, Chinese Taipei, Malaysia New Caledonia, New Zealand and Singapore be included in the list of Member Countries officially recognised free of AHS by OIE.

### 5.3. Europe

A total of 32 Member Country applications for recognition of historical freedom had been received by the OIE from the region of Europe.

The Group noted that these applicant countries had no history of AHS outbreaks.

The Group received from Azerbaijan confirmation that AHS had been notifiable in the country for the past ten years.

The Group agreed to recommend that Austria, Azerbaijan, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malta, Norway, Poland, Romania, Slovak Republic, Slovenia, Sweden, Switzerland, The Netherlands and the United Kingdom be included in the list of Member Countries officially recognised free of AHS by the OIE.

At the same time, the Group noted the below:

- Greenland and Faroe Islands were not included in the scope of the application for AHS freedom submitted by Denmark
- Dutch Caribbean Islands were not included in the Netherlands' application.
- Gibraltar was not included in the UK application.
- San Marino and Andorra (both OIE Member Countries) had not submitted an application while the Holy See and Monaco (both non OIE Member Countries) were not yet in a position to apply for a status officially recognised by the OIE.

#### 5.4. Africa

A total of two Member Country applications for recognition of historical freedom had been received by the OIE from the region of Africa.

The Group noted that these applicant countries had a record of AHS outbreaks during the last 50 years and were situated in a region considered at risk for AHS.

The Group agreed to recommend that Algeria and Tunisia be included in the list of Member Countries officially recognised free of AHS by the OIE.

In doing so, the Group agreed that Algeria and Tunisia should be made aware of their obligation to carry out surveillance for annual reconfirmation as required by the *Terrestrial Code* because they had common borders with countries where AHSV was detected or suspected recently. Once the free status granted by the World Assembly to them, Algeria and Tunisia would be requested to provide detailed surveillance information when reconfirming annually its AHS free status.

#### 5.5. Middle East

A total of nine Member Country applications for recognition of historical freedom had been received by the OIE from the region of Middle East.

The Group received from Oman confirmation that AHS had been notifiable in the country for the past ten years and from Qatar insurance that AHS had never been reported in the country.

The Group noted that Kuwait, Oman and Qatar had no record of AHS outbreaks. Cyprus, Jordan, Lebanon and Turkey were affected by the 1960s AHS pandemic. These countries met the requirements for granting the AHS free status based on requirements laid out in the *Terrestrial Code* for historically freedom.

The Group recommended that Cyprus, Jordan, Kuwait, Lebanon, Oman, Qatar and Turkey be included into the list of Member Countries officially recognised free of AHS by the OIE.

The Group agreed not to accept applications from the two other countries because they did not meet the requirements for granting the AHS free status.

## 5.6. General recommendations

The Group reiterated that surveillance for AHS must be enhanced in those countries of the Middle East and North Africa which would be recognised by the OIE as free from AHS. On-going surveillance should be conducted according to the Articles 12.1.13. to 12.1.15. of the *Terrestrial Code*. Countries with a large African donkey population which would be not in direct contact with unvaccinated horses could not rely solely on clinical surveillance. In addition it was of paramount importance that all equidae be imported strictly in accordance with the relevant Articles of the *Terrestrial Code*.

In accordance with the surveillance requirements contained in the Chapter on AHS of the *Terrestrial Code*, the absence of AHS free status of certain countries and territories might have consequences for the surveillance activities required in adjacent countries.

## 6. Evaluation of requests from Member Countries for recognition of free status (other than historical freedom)

### 6.1. Portugal

The Group evaluated the dossier submitted by Portugal and concluded that the dossier met the requirements for an application for freedom as laid out in Article 12.1.2. of the *Terrestrial Code* Chapter on AHS and recommended that Portugal be included in the list of AHS free countries.

### 6.2. Spain

During the evaluation of the present the expert from Spain left the meeting in accordance with the OIE policy on the management of potential conflict of interest.

The Group evaluated the dossier submitted by Spain for the recognition of its AHS free status in accordance with Article 12.1.2. of the *Terrestrial Code*.

The Group received from Spain confirmation that, in contrast to the title of the application, the dossier referred to the whole Spanish territory, including islands and Ceuta and Melilla.

Spain provided additional data on the surveillance implemented in Andalusia, Doñana National Park, on semi-feral horses. These semi-feral horses were the object of passive surveillance as they were regularly inspected by National Park guards.

At the Group's request, Spain also provided detailed information on the specific conditions for the movement of equidae from the islands and from Ceuta and Melilla to the Spanish mainland.

The Group was satisfied with the additional information and recommended that Spain be included in the list of AHS free countries.

### 6.3. Evaluation of the request from a Member Country for the establishment of a zone free from AHS

The Group assessed the request of a Member Country for the recognition of a zone free from AHS which did not meet the requirements of the *Terrestrial Code*; the dossier was referred back to the corresponding Member Country.

All the Member Countries to which the Group recommended to grant an AHS free status are summarised in [Appendix III](#).

## 7. Other matters

- The Group agreed that the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* was in need of an internationally agreed and validated PCR test because the agent identification could not be done by virus isolation in less than 21 days (see Article 12.1.9 (3)(c)) of the *Terrestrial Code*. Movement of equidae could not be expedited using the currently prescribed agent identification test. At the same time, the Group reaffirmed that any prescribed agent identification test must be absolutely reliable because any false negative result would have catastrophic consequences.

In this context, the Group consulted with the Scientific and Technical Department on plans to review the Chapter 2.05.01 of the *Terrestrial Manual*. The Group specifically referred to the need to ensure that only validated tests become prescribed tests. The Group discussed the usefulness to consider the different purposes for which the tests could be performed: e.g. for the certification that individual animals were not infected, for the detection of the virus in a population, and the confirmation of the diagnosis of AHS. It was recommended that validation data for OIE prescribed tests be made available for Member Countries that would request to consult these data. Precise indications of test parameters would be necessary for scientifically justified surveillance strategies.

François Diaz from the Scientific and Technical Department explained the procedures for adopting new tests by the Biological Standard Commission and Sara Linnane also from the Scientific and Technical Department clarified that the Chapter had recently been updated.

- Draft declaration form for annual reconfirmation.

The Group prepared a draft form for annual reconfirmation of AHS free status ([Appendix IV](#)). Some flexibility was built into the form to consider that existing national import regulations may be stricter than the *Terrestrial Code* and being amended to be fully compliant with the *Terrestrial Code*.

## 8. Adoption of the report

The Group reviewed and amended the draft report provided by the rapporteur. The Group agreed that the report captured the discussions.

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.../appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON EVALUATION  
OF AFRICAN HORSE SICKNESS (AHS) DISEASE STATUS OF MEMBER COUNTRIES  
Paris, 15 – 17 January 2013**

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**Agenda**

1. Opening
  2. Adoption of the agenda and appointment of chairperson and rapporteur
  3. Chapter 12.1. – consideration of Member Countries' comments raised during the 80<sup>th</sup> General Session
  4. Clarification on seasonal freedom and self-declaration
  5. Evaluation of requests from Member Countries for recognition of historical freedom and establishment of a base list of historically free Member Countries for AHS
  6. Evaluation of requests from Member Countries for recognition of free status (other than historical freedom)
  7. Other matters
  8. Adoption of report
-

Appendix II

**MEETING OF THE OIE AD HOC GROUP ON EVALUATION  
OF AFRICAN HORSE SICKNESS (AHS) DISEASE STATUS OF MEMBER COUNTRIES**

**Paris, 15 – 17 January 2013**

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**List of participants**

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## Appendix III

## List of Member Countries for which the Group recommended to grant an AHS free status

Region	Country
<b>Africa</b>	Algeria
	Tunisia
<b>Americas</b>	Argentina
	Bolivia
	Brazil
	Chile
	Mexico
	Paraguay
	Peru
	Uruguay
	USA
	Canada
	<b>Asia Pacific</b>
Chinese Taipei	
Malaysia	
New Caledonia	
New Zealand	
Singapore	
<b>Middle-East</b>	Cyprus
	Jordan
	Kuwait
	Lebanon
	Oman
	Qatar
	Turkey

Region	Country
<b>Europe</b>	Austria
	Azerbaijan
	Belgium
	Bosnia and Herzegovina
	Bulgaria
	Croatia
	Czech Republic
	Denmark
	Estonia
	Finland
	Former Rep. Yug. of Macedonia
	France
	Germany
	Greece
	Hungary
	Iceland
	Ireland
	Italy
	Latvia
	Liechtenstein
	Lithuania
	Luxembourg
	Malta
	Norway
	Poland
	Portugal
	Romania
	Slovak Republic
	Slovenia
	Sweden
	Spain
	Switzerland
	The Netherlands
United Kingdom	

## Appendix IV

**Form for the annual reconfirmation of the African Horse Sickness(AHS)  
free status of OIE Member Countries  
(to be submitted during the month of November each year)**

**AHS free country**

QUESTION	YES	NO
1. Is your country on the list of OIE Member Countries-officially recognised as free from AHS by the OIE?		
2. Is the official AHS free status of the country suspended?		
3. Has routine vaccination against AHS been carried out during the past 12 months in the country?		
4. If imported (including for temporary residence, return and transit), are equids imported in accordance with requirements at least as strict as those in Articles 12.1.7. and 12.1.9?		
5. If imported, are equine semen, embryos and oocytes imported in accordance with requirements at least as strict as those in Articles 12.1.10 and 12.1.11?		
6. Have there been any changes to the regulatory measures for the early detection, prevention and control of AHS during the past 12 months? If yes, please attach a brief report.		
7. Have any changes occurred in the epidemiological situation or other significant events regarding AHS during the past 12 months? If yes, please attach a brief report.		
8. Is your country adjacent to any country or zone considered as infected with AHS according to Article 12.1.4?		
9. Is the official AHS free status of any adjacent country or zone suspended?		
<b>If you answered yes to at least one of Questions 8 or 9, please submit documented evidence that surveillance is implemented in your country in accordance with Articles 12.1.13. to 12.1.15.</b>		
<p><b>Furthermore, I certify that:</b></p> <ul style="list-style-type: none"> <li>- there has been no outbreak of AHS during the past 12 months,</li> <li>- there has been no evidence of AHS virus infection during the past 12 months.</li> </ul>		
Date:	Signature of Delegate :	

**[Reference to the relevant article in the AHS chapter of the *Terrestrial Animal Health Code* (2012)]**

## Article 12.1.2.

**AHSV free country or zone**

1. A country or zone may be considered free from AHSV when African horse sickness (AHS) is notifiable in the whole country, systematic vaccination is prohibited, importation of equids and their semen, oocytes or embryos are carried out in accordance with this chapter, and either:
  - a. historical freedom as described in Chapter 1.4. has demonstrated no evidence of AHSV in the country or zone; or
  - b. the country or zone has not reported any case of AHS for at least two years and is not adjacent to an infected country or zone; or
  - c. a surveillance programme has demonstrated no evidence of AHSV in the country or zone for at least 24 months; or
  - d. the country or zone has not reported any case of AHS for at least 40 days and a surveillance programme has demonstrated no evidence of *Culicoides* for at least two years in the country or zone.
2. An AHS free country or zone adjacent to an infected country or infected zone should include a zone in which surveillance is conducted in accordance with Articles 12.1.13. and 12.1.15. Animals within this zone should be subjected to continuing surveillance. The boundaries of this zone should be clearly defined, and should take account of geographical and epidemiological factors that are relevant to AHS transmission.
3. An AHSV free country or zone will not lose its free status through the importation of vaccinated or seropositive equids and their semen, oocytes or embryos from infected countries or infected zones, provided these imports are carried out in accordance with this chapter.
4. To qualify for inclusion in the list of AHSV free countries or zones, a Member should:
  - a. have a record of regular and prompt animal disease reporting;
  - b. send a declaration to the OIE stating:
    - i. the section under point 1 on which the application is based;
    - ii. no routine vaccination against AHS has been carried out during the past 12 months in the country or zone;
    - iii. equids are imported in accordance with this chapter;
  - c. supply documented evidence that:
    - i. surveillance in accordance with Articles 12.1.13. and 12.1.15. is applied;
    - ii. regulatory measures for the early detection, prevention and control of AHS have been implemented.
5. The Member will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 4b) ii) and iii) and 4c) ii) above be re-submitted annually and changes in the epidemiological situation or other significant events be reported to the OIE according to the requirements in Chapter 1.1., and in particular, formally state that:
  - a. there has been no outbreak of AHS during the past 12 months in the country or zone;
  - b. no evidence of AHSV infection has been found during the past 12 months in the country or zone.

**Form for the annual reconfirmation of the African Horse Sickness (AHS) free status of  
OIE Member Countries  
(to be submitted during the month of November each year)**

**AHS free zone**

QUESTION	YES	NO
1. Is your zone on the list of zones officially recognised as free from AHS by the OIE?		
2. Is the official AHS free status of your zone suspended?		
3. Has routine vaccination against AHS been carried out during the past 12 months in the zone?		
4. If equids are imported into the zone (including for temporary residence, return and transit), are they imported in accordance with requirements at least as strict as those in Articles 12.1.7. and 12.1.9 of the <i>Terrestrial Animal Health Code</i> ?		
5. If equids are introduced into the zone from the infected zone, are they introduced in accordance with requirements at least as strict as those in Articles 12.1.7. and 12.1.9?		
6. If imported into the zone, are equine semen, embryos and oocytes imported in accordance with requirements at least as strict as those in Articles 12.1.10 and 12.1.11?		
7. If introduced into the zone from the infected zone, are equine semen, embryos and oocytes introduced in accordance with requirements at least as strict as those in Articles 12.1.10 and 12.1.11?		
8. Have there been any changes to the regulatory measures for the early detection, prevention and control of AHS within your country and the zone during the past 12 months? If yes, please attach a brief report.		
9. Have any changes occurred in the epidemiological situation or other significant events regarding AHS during the past 12 months? If yes, please attach a brief report.		
10. Is the official AHS free status of any adjacent zone or country suspended?		
<b>If you answered yes to Question 10, please submit documented evidence that surveillance is implemented in your zone in accordance with Articles 12.1.13. to 12.1.15.</b>		
<p><b>Furthermore, I certify that:</b></p> <ul style="list-style-type: none"> <li>- there has been no outbreak of AHS in the zone during the past 12 months,</li> <li>- there has been no evidence of AHS virus infection in the zone during the past 12 months.</li> </ul>		
Date:	Signature of Delegate :	

**[Reference to the relevant article in the AHS chapter of the *Terrestrial Animal Health Code* (2012)]**

## Article 12.1.2.

**AHSV free country or zone**

1. A country or zone may be considered free from AHSV when African horse sickness (AHS) is notifiable in the whole country, systematic vaccination is prohibited, importation of equids and their semen, oocytes or embryos are carried out in accordance with this chapter, and either:
  - a. historical freedom as described in Chapter 1.4. has demonstrated no evidence of AHSV in the country or zone; or
  - b. the country or zone has not reported any case of AHS for at least two years and is not adjacent to an infected country or zone; or
  - c. a surveillance programme has demonstrated no evidence of AHSV in the country or zone for at least 24 months; or
  - d. the country or zone has not reported any case of AHS for at least 40 days and a surveillance programme has demonstrated no evidence of *Culicoides* for at least two years in the country or zone.
2. An AHS free country or zone adjacent to an infected country or infected zone should include a zone in which surveillance is conducted in accordance with Articles 12.1.13. and 12.1.15. Animals within this zone should be subjected to continuing surveillance. The boundaries of this zone should be clearly defined, and should take account of geographical and epidemiological factors that are relevant to AHS transmission.
3. An AHSV free country or zone will not lose its free status through the importation of vaccinated or seropositive equids and their semen, oocytes or embryos from infected countries or infected zones, provided these imports are carried out in accordance with this chapter.
4. To qualify for inclusion in the list of AHSV free countries or zones, a Member should:
  - a. have a record of regular and prompt animal disease reporting;
  - b. send a declaration to the OIE stating:
    - i. the section under point 1 on which the application is based;
    - ii. no routine vaccination against AHS has been carried out during the past 12 months in the country or zone;
    - iii. equids are imported in accordance with this chapter;
  - c. supply documented evidence that:
    - i. surveillance in accordance with Articles 12.1.13. and 12.1.15. is applied;
    - ii. regulatory measures for the early detection, prevention and control of AHS have been implemented.
5. The Member will be included in the list only after the submitted evidence has been accepted by the OIE. Retention on the list requires that the information in points 4b) ii) and iii) and 4c) ii) above be re-submitted annually and changes in the epidemiological situation or other significant events be reported to the OIE according to the requirements in Chapter 1.1., and in particular, formally state that:
  - a. there has been no outbreak of AHS during the past 12 months in the country or zone;
  - b. no evidence of AHSV infection has been found during the past 12 months in the country or zone.



**REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON ANTIMICROBIAL RESISTANCE**  
**Paris, 8 – 10 January 2013**

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**1. Opening**

The OIE *ad hoc* Group on Antimicrobial Resistance met for the fifth time from 8 to 10 January 2013 at the OIE Headquarters in Paris, France. Dr Elisabeth Erlacher-Vindel, Deputy Head of the Scientific and Technical Department, provided the Group with information on relevant OIE activities including the OIE Global Conference on the Responsible and Prudent Use of Antimicrobial Agents for Animals, to be held in Paris (France), from 13 to 15 March 2013.

Dr Bernard Vallat, OIE Director General, joined the meeting on Thursday 10 January. He thanked the Group for its support to OIE's activities in the area of antimicrobial resistance, and expressed high expectations for the Group to actively contribute to standard setting of the OIE. He hoped that the OIE's global conference would make policy makers aware of OIE's initiatives taking place in the veterinary sphere. He informed the Group that he would deliver two key messages to the Conference: (i) Although Member Countries differed in the degree to which they had addressed the issue of antimicrobial resistance all the Member Countries should give due attention to this issue and allocate appropriate resources including to developing countries to address this global problem; and (ii) the veterinarians should play an important role in ensuring in the field responsible and prudent use of antimicrobial agents, by minimising unregulated *ad hoc* use in Member Countries with no regulations.

The Group noted that the main objective of its meeting was to finalise the review of the technical comments received from OIE Member Countries on the proposed updated version of Chapter 6.10. (Risk analysis for antimicrobial resistance arising from the use of antimicrobial agents in animals) of the OIE *Terrestrial Animal Health Code (Terrestrial Code)* and to review and update the OIE list of antimicrobial agents of veterinary importance.

**2. Appointment of chairperson and rapporteur**

The meeting was chaired by Dr Herbert Schneider and Mr Christopher Teale acted as rapporteur.

**3. Adoption of the agenda**

The adopted Agenda and List of Participants are presented in Appendices I and II of this report, respectively.

**4. Review of the technical comments received from OIE Member Countries on the proposed updated version of Chapter 6.10.: "Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals" of the *Terrestrial Animal Health Code***

The Group reviewed the technical comments received from OIE Member Countries relating to Chapter 6.10. of the *Terrestrial Code* on risk analysis for antimicrobial resistance arising from the use of antimicrobial agents in animals. The Chapter was revised accordingly.

Many Member Countries had sent comments proposing addition or deletion of text. The Group noted that there were considerable differences between Member Countries in the degree of advancement of the regulatory measures they had adopted relating to the use of antimicrobial agents and to mitigate the development of antimicrobial resistance. In addition, it was noted that Member Countries were applying, to different degrees, the standards set out in the chapters of the *Terrestrial Code* relating to control of antimicrobial resistance. The Group recalled that the *Terrestrial Code* standards were intended for use by all Member Countries and aimed at meeting the needs of Member Countries with varying capacities to implement regulatory measures. The Group agreed that the current structure of individual chapters covering specific subjects and having a separate focus was appropriate because it assisted Member Countries in their implementation of the provisions in different chapters according to their needs and priorities.

The Group discussed in detail all the comments and accepted, where appropriate, amendments proposed by Member Countries.

The Group took note of the differences in the risk analysis frameworks used by Codex Alimentarius and by the OIE in relation to antimicrobial resistance. The Group reiterated its previous recommendation from the meeting of December 2011 that Appendix C of the paper by Vose *et al.* published in the OIE Scientific and Technical Review (20 (3), 811-827 (2001), entitled “Antimicrobial Resistance: risk analysis methodology for the potential impact on public health of antimicrobial resistant bacteria of animal origin”, which compared the OIE and Codex Alimentarius risk analysis systems, should be updated in view of the recently adopted Codex Alimentarius “Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance” [CAC/GL77-2011].

In revising Chapter 6.10. the Group also took into consideration the Codex Alimentarius Guidelines CAC/GL77-2011.

The Group did not include a reference to the WHO<sup>1</sup> List of Critically Important Antimicrobials in this chapter as the most relevant information would be reflected in the updated OIE list.

A summary of the Group’s review of Chapter 6.10. is given below (A number of changes were made for clarification without altering the sense of the existing text. These changes are not listed individually):

In reply to a comment requesting retention of the original title, the Group agreed to retain the previously revised chapter title, particularly because hazard identification was a component of the OIE risk analysis framework but not of risk assessment. This is described in detail in Chapter 2.1. of the *Terrestrial Code*.

The Group also specified that Chapter 6.10. followed the OIE risk analysis framework and was sub-divided into sections covering analysis of risks to human health and analysis of risks to animal health. The Group did not accept a comment requesting to limit the risks to human health at “food safety which impact human health” and preferred to address “human health” in general.

Regarding a comment from a Member Country on the need to cross-reference Codex texts in the Chapter 6.10., the Group noted that a general reference to Codex texts was already included in the General Introduction to Chapters (Chapter 6.6.). The Group was also informed that, at its November 2012 meeting, the OIE Animal Production Food Safety Working Group had recommended that the *ad hoc* Group take into account if possible the ‘Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance’ (CAC/GL 77-2011), and include a specific reference to this text in the updated version of Chapter 6.10.. In view of these, the Group added a sentence in the point 2 Objectives of the article 6.10.1. to refer to CAC/GL 77-2011.

In reply to comments from Member Countries requesting the addition of risk analysis factors to take into consideration to the lists of bullet points in several articles within the chapter, the Group noted that, in some cases, the proposed factors were already addressed in other bullet points. In a general way, the Group considered that the lists of factors were not intended to be exhaustive but to provide illustrations. A general statement was added to the introduction of the chapter to clarify this issue.

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1 WHO: World Health Organization

The Group took note of comments that micro-organisms displaying resistance to antimicrobial agents which are not used in animals may however occur and that resistant pathogens could be transmitted to animals from other sources. However, this was considered outside the current scope of the chapter which was focusing on antimicrobial resistance arising from the use of antimicrobial agents in animals.

The Group agreed to a comment requesting to delete a part of the last sentence in the second paragraph of the point 1 of the article 6.10.1. , as this part of the sentence was related to the hazard and not to the risk.

In point 4 “Exposure assessment” of the article 6.10.2., the Group did not agree to the comments requesting to re-arrange the order of the bullet point following a feed, animals, food and human approach, as there was no intended order of priority for the factors presented.

In the same part of the article, the Group agreed that knowledge of the prevalence of commensal bacteria which were able to transfer resistance to human pathogens was often limited. The Group considered that the prevalence of resistant micro-organisms at the point of consumption or exposure should be included, in order to account for human exposure at sites other than the final point of consumption. Exposure was considered to include all relevant routes of transmission and sources of resistant micro-organisms. The Group preferred the term “establishment” to “colonisation” because the latter was considered to have a restrictive connotation.

In point 5 “Consequence assessment” of the article 6.10.2., the Group, in a reply to a comment, observed that a secondary risk could be defined as “a risk created by the response to another risk” or as “a risk being a consequence of dealing with the original risk” (definition coming from Project Management Knowledge website: <http://project-management-knowledge.com/definitions/s/secondary-risk/>, accessed on 10 January 2013).

The Group took into consideration a comment and harmonised the part on the “release assessment” of the articles 6.10.2. and 6.10.3. as the same factors were relevant for the release assessment in human health and animal health.

The Group discussed the use of the terms “prevalence” and “occurrence” in Chapter 6.10. The Group noted that a precise definition of “prevalence” was included in the *Terrestrial Code*, whereas “occurrence” was understood generally in a more general meaning and was not defined in the *Terrestrial Code*. Where reference was made to animal feed, the Group preferred to use the term “occurrence” instead of “prevalence”, otherwise the term “prevalence” was favoured.

In response to a comment, the Group noted that “off-label use” and “extra-label use” may have specific and different meanings when used in some Member Countries, though they were used synonymously in Chapter 6.10. The Group agreed to leave these words as were.

## 5. Finalisation of the OIE List of antimicrobial agents of veterinary importance

The Group re-visited the OIE List of antimicrobial agents of veterinary importance, highlighted antimicrobial agents used only in animals in bold and agreed that the updated preamble to the list and the current format were suitable for submission to the OIE Scientific Commission for Animal Diseases and the Aquatic Animal Health Standards Commission for review, and to Member Countries for comment.

The major changes considered in relation to the list were:

- Text was added to the recommendations section of the list covering responsible and prudent use, stating that any use should be in accordance with the provisions of the *Terrestrial Code* as set out in article 6.9.6.
- The recommendations were altered for clarity relating to fluoroquinolones and the third and fourth generation cephalosporins, to state that these two classes should be used according to the following recommendations:
  - o Not to be used as preventive treatment applied by feed or water in the absence of clinical signs in the animal(s) to be treated.

- Not to be used as a first line treatment unless justified; when used as a second line treatment it should ideally be based on the results of bacteriological tests.
  - Extra-label/off-label use should be limited and reserved for instances where no alternatives are available. Such use should be in agreement with the national legislation in force.
- The Group decided not to include antimicrobial classes / sub classes used only in human medicine in this OIE List. Recognising the need to preserve the effectiveness of the antimicrobial agents in human medicine, careful consideration should be given regarding their potential use (including extra-label/off-label use) / authorisation in animals.

The Group discussed the relevance of the list in addressing public and animal health issues relating to particular antimicrobial agents. The Group recommended that there was a requirement for periodic joint review of the WHO and OIE lists by WHO and the OIE to address issues relating to particular antimicrobial agents.

The OIE List of antimicrobial agents of veterinary importance, as updated by the Group, is presented in Appendix III of this report.

## **6. Discussion the OIE Global Conference on Responsible and Prudent Use of Antimicrobial Agents for Animals, Paris (France), 13-15 March 2013**

The Group discussed the draft programme for the OIE Global Conference on the Responsible and Prudent Use of Antimicrobial Agents for Animals, Paris, France, from 13 to 15 March 2013. The programme might be subject to minor revision but had been broadly finalised. Abstracts were awaited for the oral presentations. A brief paper (approximately 3 pages in length) would be requested from each speaker for publication shortly after the Conference by the OIE. The format selected for publication would enable inclusion of appropriate diagrams or graphs.

The objectives of the Conference were further discussed, including the desirability of achieving international solidarity on the global issue of responsible and prudent use of antimicrobial agents. The need was identified to cater to the needs of all Member Countries with various degrees of programmes and experience in this area.

## **7. Other business**

The Group reiterated the definite need to strengthen co-ordination between the terrestrial and aquatic sectors, including co-ordination between the relevant *ad hoc* Groups on specific issues and between the different bodies of the OIE (Specialist Commissions, Working Groups and *ad hoc* Groups).

## **8. Adoption of the report**

The Group adopted the report prepared by the rapporteur assisted by the OIE secretariat.

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.../Appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON ANTIMICROBIAL RESISTANCE**  
**Paris, 8 – 10 January 2013**

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**Agenda**

1. Opening
  2. Appointment of chairperson and rapporteur
  3. Adoption of agenda
  4. Review of the technical comments received from OIE Member Countries on the proposed updated version of Chapter 6.10.: “Risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals” of the *Terrestrial Animal Health Code*
  5. Finalisation of the OIE list of antimicrobial agents of veterinary importance
  6. Discussion on the OIE Global Conference on the Prudent Use of Antimicrobial Agents for Animals, Paris (France), 13-15 March 2013
  7. Other business
  8. Adoption of report
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Appendix II**MEETING OF THE OIE AD HOC GROUP ON ANTIMICROBIAL RESISTANCE****Paris, 8 – 10 January 2013****List of Participants****MEMBERS****Dr Tetsuo Asai**

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Appendix III**OIE LIST OF ANTIMICROBIAL AGENTS OF VETERINARY IMPORTANCE**

The OIE International Committee unanimously adopted the List of Antimicrobial Agents of Veterinary Importance at its 75<sup>th</sup> General Session in May 2007 (Resolution No. XXVIII).

**Background**

Antimicrobial agents are essential drugs for human and animal health and welfare. Antimicrobial resistance is a global public and animal health concern that is influenced by both human and non-human antimicrobial usage. The human, animal and plant sectors have a shared responsibility to prevent or minimise antimicrobial resistance selection pressures on both human and non-human pathogens.

The FAO/OIE/WHO Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance held in Geneva, Switzerland, in December 2003 (Scientific Assessment) and in Oslo, Norway, in March 2004 (Management Options) recommended that the OIE should develop a list of critically important antimicrobial agents in veterinary medicine and that WHO should also develop such a list of critically important antimicrobial agents in human medicine.

Conclusion No. 5 of the Oslo Workshop is as follows:

5. The concept of “critically important” classes of antimicrobials for humans should be pursued by WHO. The Workshop concluded that antimicrobials that are critically important in veterinary medicine should be identified, to complement the identification of such antimicrobial agents used in human medicine. Criteria for identification of these antimicrobial agents of critical importance in animals should be established and listed by OIE. The overlap of critical lists for human and veterinary medicine can provide further information, allowing an appropriate balance to be struck between animal health needs and public health considerations.

Responding to this recommendation, the OIE decided to address this task through its existing ad hoc Group on antimicrobial resistance. The terms of reference, aim of the list and methodology were discussed by the ad hoc Group since November 2004 which was subsequently endorsed by the Biological Standards Commission in its January 2005 meeting and adopted by the International Committee in May 2005. Thus, the work was officially undertaken by the OIE.

**Preparation of the draft list**

The Director General of the OIE sent a questionnaire prepared by the ad hoc Group accompanied by his letter explaining the importance of the task to OIE Delegates of all Member Countries and international organisations having signed a Co-operation Agreement with the OIE in August 2005.

Sixty-six replies were received. This response rate highlights the importance given by OIE Member Countries from all regions to this issue. These replies were analyzed first by the OIE Collaborating Centre for Veterinary Drugs, then discussed by the ad hoc Group at its meeting in February 2006. A list of proposed VCIA was compiled together with an executive summary. This list was endorsed by the Biological Standards Commission and circulated among Member Countries aiming for adoption by the OIE International Committee during the General Session in May 2006.

**Discussion at the 74<sup>th</sup> International Committee in May 2006**

The list was submitted to the 74<sup>th</sup> International Committee where active discussion was made among Member Countries. Concerns raised by Member Countries include: 1) the list includes substances that are banned in some countries; 2) some of the substances on the list are not considered “critical”; 3) nature of the list – is this mandatory for Member Countries?; and 4) the use of antimicrobial agents as growth promotor is included. While many Member Countries appreciated the work, it was considered appropriate to continue refinement of the list. The list was adopted as a preliminary list by Resolution No. XXXIII.

## Refinement of the list

The *ad hoc* Group was convened in September 2006 to review the comments made at the 74<sup>th</sup> General Session of the OIE International Committee, and Resolution No. XXXIII adopted at the 74<sup>th</sup> General Session. Based on the further analysis provided by the OIE Collaborating Centre for Veterinary Medicinal Products, the *ad hoc* Group prepared its final recommendations of the list of antimicrobial agents of veterinary importance together with an executive summary. Once again, this was examined and endorsed by the Biological Standards Commission in its January 2007 meeting and circulated among Member Countries.

## Adoption of List of antimicrobial agents of Veterinary Importance

The refined list was submitted to the 75<sup>th</sup> International Committee during the General Session in May 2007 and adopted unanimously by Resolution No. XXVIII.

### CRITERIA USED FOR CATEGORISATION OF VETERINARY IMPORTANT ANTIMICROBIALS

In developing the list, the *ad hoc* Group agreed that any antimicrobial agent authorised for use in veterinary medicine according to the criteria of quality, safety and efficacy as defined in the *Terrestrial Animal Health Code* (Appendix 3.9.3. Guidelines for the responsible and prudent use of antimicrobial agents in Veterinary Medicine) is important. Therefore, the Group decided to address all antimicrobial agents used in food-producing animals to provide a comprehensive list, divided into critically important, highly important and important antimicrobial agents.

In selecting the criteria to define veterinary important antimicrobial agents, one significant difference between the use of antimicrobial agents in humans and animals has to be accounted for: the many different species that have to be treated in veterinary medicine.

The following criteria were selected to determine the degree of importance for classes of veterinary antimicrobial agents.

#### **Criterion 1. Response rate to the questionnaire regarding Veterinary Critically Important Antimicrobial Agents**

This criterion was met when a majority of the respondents (more than 50%) identified the importance of the antimicrobial class in their response to the questionnaire.

#### **Criterion 2. Treatment of serious animal disease and availability of alternative antimicrobial agents**

This criterion was met when compounds within the class were identified as essential against specific infections and there was a lack of sufficient therapeutic alternatives.

On the basis of these criteria, the following categories were established:

- Veterinary **Critically Important Antimicrobial Agents (VCIA)**: are those that meet **BOTH** criteria 1 **AND** 2
- Veterinary **Highly Important Antimicrobial Agents (VHIA)**: are those that meet criteria 1 **OR** 2
- Veterinary **Important Antimicrobial Agents (VIA)**: are those that meet **NEITHER** criteria 1 **OR** 2

#### **Revision of the list of antimicrobial agents of Veterinary Importance (July 2012)**

The FAO/WHO/OIE Expert Workshop on Critically Important Antimicrobials held in Rome, Italy, in November 2007, recommended that the list of critically important antimicrobials should be revised on a regular basis and that the OIE further refine the categorisation of critically important antimicrobials with respect to their importance in the treatment of specific animal diseases.

The OIE *ad hoc* Group on Antimicrobial Resistance met in July 2012 to review and update the OIE List of antimicrobial agents of veterinary importance (OIE List) taking into account the top three critically important antimicrobials of the WHO list of the critically important antimicrobials for human medicine.

The Group made recommendations for the use of the updated OIE List.

### **Recommendations**

Any use of antimicrobial agents in animals should be in accordance with the OIE Standard on the responsible and prudent use laid down in the Chapter 6.9. of the *Terrestrial Code*.

According to the criteria detailed above, antimicrobial agents in the OIE List are classified according to three categories, Veterinary Critically Important Antimicrobial Agents (VCIA), Veterinary Highly Important Antimicrobial Agents (VHIA) and Veterinary Important Antimicrobial Agents (VIA).

However, a specific antimicrobial/class or subclass may be considered as critically important for the treatment of a specific disease in a specific species (See specific comments in the following table of categorisation of veterinary important antimicrobial agents for food-producing animals).

For a number of antimicrobial agents, there are no or few alternatives for the treatment of some specified disease in identified target species as it is indicated in the specific comments in the OIE List. In this context, particular attention should be paid to the use of VCIA and of specific VHIA.

Among the VCIA in the OIE List, some are considered to be critically important both for human and animal health; this is currently the case for Fluoroquinolones and for the third and fourth generation of Cephalosporins. Therefore these two classes should be used according to the following recommendations:

- Not to be used as preventive treatment applied by feed or water in the absence of clinical signs in the animal(s) to be treated.
- Not to be used as a first line treatment unless justified, when used as a second line treatment, it should ideally be based on the results of bacteriological tests.
- Extra-label/off label use should be limited and reserved for instances where no alternatives are available. Such use should be in agreement with the national legislation in force.

The OIE List of antimicrobial agents of veterinary importance is based on expert scientific opinion and will be regularly updated when new information becomes available.

Antimicrobial classes / sub classes used only in human medicine are not included in this OIE List. Recognising the need to preserve the effectiveness of the antimicrobial agents in human medicine, careful consideration should be given regarding their potential use (including extra-label/off-label use) / authorisation in animals.

### **Abbreviations:**

Animal species in which these antimicrobials are used are abbreviated as follows:

AVI:	avian	EQU:	Equine
API:	bee	LEP:	Rabbit
BOV:	bovine	OVI:	Ovine
CAP:	caprine	PIS:	Fish
CAM:	camel	SUI:	Swine

VCIA: Veterinary Critically Important Antimicrobials

VHIA: Veterinary Highly Important Antimicrobials

VIA: Veterinary Important Antimicrobials

**CATEGORISATION OF VETERINARY IMPORTANT ANTIMICROBIAL AGENTS  
FOR FOOD-PRODUCING ANIMALS**

ANTIMICROBIAL AGENTS (CLASS, SUB-CLASS, SUBSTANCE)	SPECIES	Specific comments	VCIA	VHIA	VIA
<b>AMINOGLYCOSIDES</b>					
<b>AMINOCYCLITOL</b>					
Spectinomycin	AVI, BOV, CAP, EQU, LEP, OVI, PIS, SUI	The wide range of applications and the nature of the diseases treated make aminoglycosides extremely important for veterinary medicine.	Y		
Streptomycin	API, AVI, BOV, CAP, EQU, LEP, OVI, PIS, SUI				
Dihydrostreptomycin	AVI, BOV, CAP, EQU, LEP, OVI, SUI				
<b>AMINOGLYCOSIDES +2 DEOXYSTREPTAMINE</b>		Aminoglycosides are of importance in septicaemias; digestive, respiratory and urinary diseases.			
Kanamycin	AVI, BOV, EQU, PIS, SUI	<b>Gentamicin is indicated for <i>Pseudomonas aeruginosa</i> infections with few alternatives. Spectinomycin, Apramycin and Fortimycin are currently only used in animals.</b> Few economic alternatives are available.			
Neomycin	API, AVI, BOV, CAP, EQU, LEP, OVI, SUI				
Framycetin	BOV, CAP, OVI				
Paromomycin	<u>AVI, BOV</u> , CAP, OVI, LEP, <u>SUI</u>				
Apramycin	AVI, BOV, LEP, OVI, SUI				
<u>Fortimycin</u>	<u>AVI, BOV, LEP, OVI, SUI</u>				
Gentamicin	AVI, BOV, CAM, CAP, EQU, LEP, OVI, SUI				
Tobramycin	EQU				
Amikacin	EQU				
<b>ANSAMYCIN – RIFAMYCINS</b>		This antimicrobial class is authorised only in a few countries and with a very limited number of indications (mastitis) and few alternatives.			
Rifampicin	EQU	<b>Rifampicin is essential in the treatment of <i>Rhodococcus equi</i> infections in foals. However it is only available in a few countries, resulting in an overall classification of VHIA.</b>		Y	
Rifaximin	BOV, CAP, EQU, LEP, OVI, SUI				
<b>ARSENICAL</b>		<u>Arsenicals are used to control intestinal parasitic coccidiosis. (<i>Eimeria</i> spp.).</u>			<u>Y</u>
<u>Roxarsone</u>	<u>AVI, SUI</u>				
<u>Nitarsonsone</u>	<u>AVI, SUI</u>				
<b>BICYCLOMYCIN</b>		Bicyclomycin is listed for digestive and respiratory diseases in cattle and septicaemias in fish.			Y
Bicozamycin	<u>AVI</u> , BOV, PIS, <u>SUI</u>				
<b>CEPHALOSPORINS</b>					
<b>CEPHALOSPORIN 1G FIRST GENERATION</b>					
Cefacetrile	BOV	Cephalosporins are used in the treatment of septicemias, respiratory infections, and mastitis. <del>Alternatives are limited in efficacy through either inadequate spectrum or presence of antimicrobial resistance.</del>	Y	<u>Y</u>	
Cefalexin	BOV, CAP, EQU, OVI, SUI				
Cefalotin	EQU				
Cefapryrin	BOV				
Cefazolin	BOV, CAP, OVI				
Cefalonium	BOV, CAP, OVI				
<b>CEPHALOSPORIN 2G SECOND GENERATION</b>					
Cefuroxime	BOV				

ANTIMICROBIAL AGENTS (CLASS, SUB-CLASS, SUBSTANCE)	SPECIES	Specific comments	VCIA	VHIA	VIA
<b>CEPHALOSPORIN 3G-THIRD GENERATION</b> Cefoperazone Ceftiofur Ceftriaxone	BOV, CAP, OVI AVI, BOV, CAP, EQU, LEP, OVI, SUI AVI, BOV, OVI, SUI	<u>The wide range of applications and the nature of the diseases treated make cephalosporin third and fourth generation extremely important for veterinary medicine.</u>  Cephalosporins are used in the <u>treatment of septicemias, respiratory infections, and mastitis.</u> <u>Alternatives are limited in efficacy through either inadequate spectrum or presence of antimicrobial resistance.</u>	Y		
<b>CEPHALOSPORIN 4G-FOURTH GENERATION</b> Cefquinome	BOV, CAP, EQU, LEP, OVI, SUI				
<b>FOSFOMYCIN</b> Fosfomycin	AVI, BOV, PIS, SUI	This antimicrobial is authorised only in a few countries. Fosfomycin has a limited number of alternatives in some fish infections. <b>Critically important for fish.</b>		Y	
<b>FUSIDIC ACID</b> Fusidic acid	BOV, EQU	Fusidic acid is used in the treatment of ophthalmic diseases in cattle and horses.			Y
<b>IONOPHORES</b> Lasalocid Maduramycin Monensin Narasin Salinomycin Semduramicin	AVI, BOV, LEP, OVI AVI API, AVI, BOV, CAP AVI, <u>BOV</u> AVI, LEP, <u>BOV, SUI</u> AVI	Ionophores are essential for animal health because they are used to control intestinal parasitic coccidiosis. ( <i>Eimeria</i> spp.) where there are few or no alternatives available. <b>Ionophores are critically important in poultry.</b> <b>This class is currently <u>only used in animals</u></b>		Y	
<b>LINCOSAMIDES</b> Pirlimycin Lincomycin	BOV, SUI, AVI API, AVI, BOV, CAP, OVI, PIS, SUI	Lincosamides are essential in the treatment of Mycoplasma pneumonia, infectious arthritis and hemorrhagic enteritis of pigs.		Y	
<b>MACROLIDES (C refers to the chemical structure)</b>					
<b>MACROLIDES C14</b> Erythromycin Oleandomycin	API, AVI, BOV, CAP, EQU, LEP, OVI, PIS, SUI BOV				
<b>MACROLIDES C15</b> Gamithromycin Tulathromycin	BOV BOV, CAP, LEP, OVI, SUI	The wide range of applications and the nature of the diseases treated make macrolides extremely important for veterinary medicine.			
<b>MACROLIDES C16</b> Carbomycin Josamycin Kitasamycin Spiramycin Tilmicosin Tylosin Mirosamycin Terdecamycin Tildipirosin Tyvalosin	AVI AVI, PIS, SUI AVI, SUI, PIS AVI, BOV, CAP, EQU, LEP, OVI, PIS, SUI AVI, BOV, CAP, LEP, OVI, SUI API, AVI, BOV, CAP, LEP, OVI, SUI API, AVI, SUI, PIS AVI, SUI BOV AVI, SUI	<b>Macrolides are used to treat Mycoplasma infections in pigs and poultry, haemorrhagic digestive disease in pigs (<i>Lawsonia intracellularis</i>) and liver abscesses (<i>Fusobacterium necrophorum</i>) in cattle, where they have very few alternatives.</b>  This class is also used for respiratory infections in cattle	Y		
<b>MACROLIDES C17</b> Sedecamycin	SUI				

ANTIMICROBIAL AGENTS (CLASS, SUB-CLASS, SUBSTANCE)	SPECIES	Specific comments	VCIA	VHIA	VIA
<b>AMINOCOUMARIN</b> Novobiocin	BOV, CAP, OVI, PIS	Novobiocin is used in the local treatment of mastitis and in septicaemias in fish.			Y
<b>ORTHOSOMYCINS</b> Avilamycin	AVI, LEP	Avilamycin is used for enteric diseases of poultry and rabbit. <b>This class is currently <u>only used in animals</u>.</b>			Y
<b>PENICILLINS</b>					
<b>NATURAL PENICILLINS (including esters and salts)</b>					
Benzylpenicillin	AVI, BOV, CAM, CAP, EQU, LEP, OVI, SUI				
Penethamate (hydriodide – BAN)	BOV, SUI, AVI, OVI				
Benzylpenicillin procaine / Benzathine penicillin	BOV, CAM, CAP, EQU, OVI, SUI				
<b>AMIDINOPENICILLINS</b> Mecillinam	BOV, SUI				
<b>AMINOPENICILLINS</b>					
Amoxicillin	AVI, BOV, CAP, EQU, OVI, PIS, SUI	The wide range of applications and the nature of the diseases treated make penicillins extremely important for veterinary medicine.			
Ampicillin	AVI, BOV, CAP, EQU, OVI, PIS, SUI				
Hetacillin	BOV				
<b>AMINOPENICILLIN PLUS BETALACTAMASE INHIBITOR</b>					
Amoxicillin + Clavulanic Acid	AVI, BOV, CAP, EQU, OVI, SUI	This class is used in the treatment of septicaemias, respiratory and urinary tract infections.	Y		
Ampicillin + Sulbactam	AVI, BOV, SUI	This class is very important in the treatment of many diseases in a broad range of animal species.			
<b>CARBOXYPENICILLINS</b>					
Ticarcillin	EQU				
Tobicillin	PIS	Few economical alternatives are available.			
<b>UREIDO PENICILLIN</b> Aspoxicillin	BOV, SUI				
<b>PHENOXYPENICILLINS</b>					
Phenoxymethylpenicillin	AVI, SUI				
Phenethicillin	EQU				
<b>ANTISTAPHYLOCOCCAL PENICILLINS</b>					
Cloxacillin	BOV, CAP, EQU, OVI, SUI				
Dicloxacillin	BOV, CAP, OVI, AVI, SUI				
Nafcillin	BOV, CAP, OVI				
Oxacillin	BOV, CAP, EQU, OVI, AVI, SUI				
<b>PHENICOLS</b>					
Florphenicol	AVI, BOV, CAP, EQU, LEP, OVI, PIS, SUI	The wide range of applications and the nature of the diseases treated make phenicols extremely important for veterinary medicine.			
Thiamphenicol	AVI, BOV, CAP, OVI, PIS, SUI	<b>This class is of particular importance in treating some fish diseases, in which there are currently no or very few treatment alternatives.</b>	Y		
		This class also represents a useful alternative in respiratory infections of cattle, swine and poultry.			
		This class, in particular florfenicol, is used to treat pasteurellosis in cattle and pigs.			

ANTIMICROBIAL AGENTS (CLASS, SUB-CLASS, SUBSTANCE)	SPECIES	Specific comments	VCIA	VHIA	VIA
<b>PHOSPHONIC ACID</b> Fosfomycin	AVI, BOV, PIS, SUI	<b>Fosfomycin is essential for the treatment of some fish infections with few alternatives however it is only available in a few countries, resulting in an overall classification of VHIA.</b>		<u>Y</u>	
<b>PLEUROMUTILINS</b> Tiamulin Valnemulin	AVI, CAP, LEP, OVI, SUI AVI, SUI	<b>The class of pleuromutilins is essential against respiratory infections in pigs and poultry.</b>  <b>This class is also essential against swine dysentery (<i>Brachyspira hyodysenteriae</i>) however it is only available in a few countries, resulting in an overall classification of VHIA.</b>		Y	
<b>POLYPEPTIDES</b>					
Enramycin Gramicidin Bacitracin	AVI, SUI EQU AVI, BOV, LEP, SUI, OVI	Bacitracin is used in the treatment of necrotic enteritis in poultry.  This class is used in the treatment of septicaemias, colibacillosis, salmonellosis, and urinary infections.		Y	
<b>POLYPEPTIDES CYCLIC</b>					
Colistin Polymixin	AVI, BOV, CAP, EQU, LEP, OVI, SUI BOV, CAP, EQU, LEP, OVI, AVI	Cyclic polypeptides are widely used against Gram negative enteric infections.			
<b>QUINOLONES</b>					
<b>QUINOLONES FIRST GENERATION</b>					
Flumequin Miloxacin Nalidixic acid Oxolinic acid	AVI, BOV, CAP, EQU, LEP, OVI, PIS, SUI PIS BOV AVI, BOV, LEP, PIS, SUI, OVI	Quinolones of the 1st generations are used in the treatment of septicaemias and infections such as colibacillosis.		Y	
<b>QUINOLONES SECOND GENERATION (FLUOROQUINOLONES)</b>					
Ciprofloxacin Danofloxacin Difloxacin Enrofloxacin Marbofloxacin Norfloxacin Ofloxacin Orbifloxacin Sarafloxacin	AVI, BOV, SUI AVI, BOV, CAP, LEP, OVI, SUI AVI, BOV, LEP, SUI AVI, BOV, CAP, EQU, LEP, OVI, PIS, SUI AVI, BOV, EQU, LEP, SUI AVI, BOV, CAP, LEP, OVI, SUI AVI, SUI BOV, SUI PIS	The wide range of applications and the nature of the diseases treated make fluoroquinolones extremely important for veterinary medicine.  Fluoroquinolones are critically important in the treatment of septicaemias, respiratory and enteric diseases.	Y		
<b>QUINOXALINES</b>					
Carbadox Olaquinox	SUI SUI	Quinoxalines (carbadox) is used for digestive disease of pigs (e.g. swine dysentery). <b>This class is currently <u>only used in animals.</u></b>			Y

ANTIMICROBIAL AGENTS (CLASS, SUB-CLASS, SUBSTANCE)	SPECIES	Specific comments	VCIA	VHIA	VIA
<b>SULFONAMIDES</b> Sulfacetamide Sulfachlorpyridazine Sulfadiazine  Sulfadimethoxine  Sulfadimidine (Sulfamethazine, Sulfadimerazin) Sulfadoxine Sulfafurazole Sulfaguanidine Sulfamerazine Sulfadimethoxazole Sulfamethoxine Sulfamonomethoxine Sulfanilamide Sulfapyridine Phthalylsulfathiazole Sulfaquinoxaline	AVI, SUI, BOV BOV, CAP, OVI, SUI, AVI  AVI, BOV, CAP, EQU, LEP, OVI, PIS, SUI AVI, BOV, CAP, EQU, LEP, OVI, SUI EQU, SUI, BOV, OVI PIS, BOV CAP, OVI, AVI  AVI, BOV, SUI AVI, PIS, SUI AVI, PIS, SUI AVI, BOV, CAP, OVI BOV, SUI SUI AVI, BOV, CAP, LEP, OVI	The wide range of applications and the nature of the diseases treated make sulfonamides extremely important for veterinary medicine.  <b>These classes alone or in combination are critically important in the treatment of a wide range of diseases (bacterial, coccidial and protozoal infections) in a wide range of animal species.</b>	Y		
<b>SULFONAMIDES+ DIAMINOPYRIMIDINES</b> Sulfamethoxypyridazine Ormetoprim+ Sulfadimethoxine Trimethoprim+ Sulfonamide	AVI, BOV, EQU, SUI PIS AVI, BOV, CAP, EQU, LEP, OVI, PIS, SUI				
<b>DIAMINOPYRIMIDINES</b> Baquiloprim Trimethoprim Ormetoprim	SUI, BOV AVI, BOV, CAP, EQU, LEP, OVI, SUI AVI				
<b>STREPTOGRAMINS</b> Virginiamycin	AVI, BOV, OVI, SUI	Virginiamycin is an important antimicrobial in the prevention of necrotic enteritis ( <i>Clostridium perfringens</i> )			Y
<b>TETRACYCLINES</b> Chlortetracycline Doxycycline Oxytetracycline Tetracycline	AVI, BOV, CAP, EQU, LEP, OVI, SUI AVI, BOV, CAM, CAP, EQU, LEP, OVI, PIS, SUI API, AVI, BOV, CAM, CAP, EQU, LEP, OVI, PIS, SUI API, AVI, BOV, CAM, CAP, EQU, LEP, OVI, PIS, SUI	The wide range of applications and the nature of the diseases treated make tetracyclines extremely important for veterinary medicine  This class is critically important in the treatment of many bacterial and chlamydial diseases in a wide range of animal species.  <b>This class is also critically important in the treatment of animals against heartwater (<i>Ehrlichia ruminantium</i>) and anaplasmosis (<i>Anaplasma marginale</i>) due to the lack of antimicrobial alternatives.</b>	Y		
<b>THIOSTREPTON</b> Nosiheptide	AVI, SUI	This class is currently used in the treatment of some dermatological conditions.			Y

**MEETING OF THE OIE AD HOC GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)  
RISK STATUS EVALUATION OF MEMBER COUNTRIES**

**Paris, 11 – 13 September 2012**

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A meeting of the *ad hoc* Group on bovine spongiform encephalopathy (BSE) risk status evaluation of Member Countries (hereafter the Group) was held at the OIE Headquarters from 11-13 September 2012.

**1. Opening**

On behalf of the Director General of the OIE, Dr Kazuaki Miyagishima, Deputy Director General and Head of the Scientific and Technical Department, welcomed the Group and provided a contextual background to the three major tasks assigned to the Group. Dr Miyagishima reiterated the need to address the challenges that the current surveillance requirements in the *Terrestrial Animal Health Code (Terrestrial Code)* provisions were posing for Member Countries with small cattle populations despite the options proposed by the Group to date. He trusted that a recent dialogue with the BSurvE authors might support greater latitude in addressing these challenges. Dr Miyagishima reminded the Group that five years had passed since the OIE last examined the impact of atypical BSE cases and noted that the increased public attention given to atypical BSE cases could be a result of the successful mitigation efforts which decimated the incidence of classical BSE. In respect of dossier reviews, the Group was requested to conduct preliminary reading of dossiers to be assessed in November 2012. In order to better address the demand of Member Countries to obtain detailed information on the outcome of dossier evaluations, the Group was requested to make its future reports more informative and communicative, with a broader target audience in mind.

Dr Dagmar Heim could not attend the meeting but participated in parts of discussion via teleconference on 12 September 2012.

**2. Adoption of the agenda and appointment of chairperson and rapporteur**

The Group adopted its agenda of the meeting. Dr John Kellar was appointed Chair of the meeting and Dr Koen Van Dyck acted as rapporteur.

The agenda and list of participants are provided as [Appendices I](#) and [II](#), respectively.

**3. BSE surveillance: Options to adjust Member Countries with a small cattle population**

The Group recalled the background of the issue as follows:

- From the inception of the BSE surveillance provisions in the *Terrestrial Code*, the OIE had employed current science in the goal to establish practicable standards applicable throughout the diversity of bovine husbandry and population sizes resident among its Member Countries. To that end, in 2004 the Group had been tasked to review the BSE chapter of the *Terrestrial Code* and had endorsed the findings of a project conducted by the European Union Transmissible Spongiform Encephalopathies (TSE) Community Reference Laboratory, Veterinary Laboratories Agency in Weybridge, United Kingdom. Currently commonly referred to as the BSurvE study, the applied research had formed the foundation of Tables 1 and 2 for achieving the surveillance targets points and credits in the current BSE Chapter 11.5.

- As predecessor to Table 1 of the current Chapter, the BSurvE authors in 2004 had generated a ‘points target’ to be reached in a revised surveillance strategy. The points target increased linearly with the adult cattle population size, before levelling off at an upper limit for national herds comprising one million head or more. With the services of an OIE Collaborating Centre, the OIE had adopted the BSurvE authors’ surveillance strategy. In the process, the OIE had retained the pre-existing 95% confidence level of Table 1 of Appendix 3.8.4 of the 2003 *Terrestrial Code*. At the same time, the OIE had increased the design prevalence from its original of 1 in 1,000,000 (2004) to 1 in 100,000 (Surveillance A) and 1 in 50,000 (Surveillance B) of the current Table 1. For simplification of interpretation of points targets, the OIE had compressed into the discrete population categories of Table 1 the continuous distribution of populations generated by the BSurvE authors. The simplicity of Table 1 is appealing. However, categorisation is not without challenges. In Table 1, a country at the lower bound of a category should collect as many surveillance points as one at the upper bound. The problem magnifies as the cattle population decreases.
- As predecessor to Table 2 of the current Chapter, the BSurvE authors in 2004 had determined how many samples would have to be collected randomly throughout the general population to provide the same likelihood of detecting infected cattle as one specimen harvested from an animal of a given age in each of the four respective subpopulations from which samples were to be collected in a revised surveillance strategy. With the services of an OIE Collaborating Centre, the OIE had adopted the BSurvE authors’ surveillance strategy. In the process, for simplification of interpretation, the OIE had compressed into the age categories of Table 2 the continuous age distribution range that had been generated by the BSurvE authors. In so doing, the OIE had assigned points to each age category in each surveillance stream. The number of points assigned equalled the number of random samples which would have to be collected in the general population to generate the same probability of detecting BSE as each sample from each respective age category in each respective surveillance stream. The OIE’s allotment of points by age category in Table 2 is conservative when compared to the points allotted in 2004 in the BSurvE authors’ original continuous distribution.
- The BSurvE authors considered that a country could assess its BSE risk status through the aggregation of samples over an interval (< 15 years) equivalent to the rate of turnover of the cattle population. In adopting the BSurvE findings, the OIE instead retained the truncated interval it had established years before upon the introduction of clinical surveillance. The retained interval was based on the upper 95% bound of the distribution of age (7 years) at clinical appearance and was approximately half of the interval considered by the BSurvE authors.
- Notwithstanding the OIE’s continuing efforts to achieve an “optimal equilibrium” between science and practicability in the interests of all Member Countries in setting the surveillance targets of the current Table 1, inherent limitations persisted. An innate, statistical advantage benefited countries with adult cattle populations equal to or greater than one million head. The categorisation process inadvertently benefited countries with cattle populations at the upper bound of each population size category. Notwithstanding a less demanding design prevalence and categorisation, practical experience gained in the assessment of 55 original dossiers highlighted the particular challenge faced by countries with smaller adult cattle populations (< 100,000).
- In its desire to support all Member Countries’ efforts to gain an official BSE risk status, the OIE contacted the BSurvE authors and requested them to study a set of options developed by the Group.

The Group, at the present meeting, considered the feedback from the BSurvE authors and discussed a number of alternatives potentially applicable to countries with small adult cattle populations, as follows:

- The time period over which surveillance points were accumulated could be extended toward the upper bound cited by the BSurvE authors.
  - In earlier meetings, the Group had discussed prolongation as well as truncation of the existing time period of 7 years in the Chapter on BSE. Both were deemed epidemiologically defensible as long as Member Countries sampled a birth cohort spectrum equivalent to that of the existing protocol and provided a supportive risk assessment. The Group determined that the supportive risk assessment could not comprise an epidemiological interval shorter than the one driven by the underlying pathogenesis of BSE and embodied within the current *Terrestrial Code* Chapter. Truncation of the surveillance interval would not permit truncation of the risk assessment.

- The extension of the time period would also affect the demands placed upon the supportive risk assessment. The Chapter's scientific basis would be defended only if all surveillance points derived from an interval of assessed risk. Were the current time period extended for small adult cattle populations, their risk assessment interval would have to be prolonged in parallel. The Group sought avoidance of the confusion which would accompany such variability among countries - not only in terms of surveillance but also risk assessment interval. The Group supported retention of the existing, uniform time period for all Member Countries.
- The confidence level associated with Table 1 could be altered for small adult cattle populations when supported by appropriately robust risk assessments.
  - The BSurVE authors stated that the existing 95% confidence level could be reduced to 90% for smaller adult cattle populations when accompanied by a robust risk assessment. The associated points targets in Table 1 would decrease by 30%. The Group agreed that this option was defensible in theory. The Group noted that a robust risk assessment was desirable in all dossiers. The Group found, however, from experience in reviewing the risk assessments of 55 original dossiers, that adoption of this option would create difficulties in objectively determining and defending the risk assessment-enabled confidence interval applicable to each dossier. From the viewpoint of practicability, the Group sought an option less potentially divisive and more objectively applicable to all Member Countries.
- The *Terrestrial Code's* compartmentalisation concept could be invoked to focus uniquely on the sub-population at higher risk of BSE exposure.
  - Compartmentalisation had been applied successfully at the herd level, for example in bovine brucellosis control, for more than half a century. The OIE had been developing the concept for application at the country level for a number of years. The feed-borne nature of BSE transmission lent itself to compartmentalisation by production type. In many assessed countries, a stark contrast existed between the dietary protocols for dairy and beef production. Dairy cattle were more prone to BSE exposure than the vast majority of beef animals.
  - Beef cattle raised in extensive husbandry were virtually devoid of BSE risk. The BSE Chapter emphasised that surveillance be targeted at cattle exposed to elevated levels of risk. If a risk assessment validated the negligible risk experienced by a country's extensively husbanded beef cattle, then that sub-population might be dealt with as a separate entity from its dairy component. Surveillance could target the dairy population, based on the points target from Table 1 for that inevitably smaller population size.

However, the natural appeal of this option was subject to a number of key conditions. The OIE would have to affirm the criteria for establishing and validating the epidemiological separation between the dairy and beef compartments. The national identification and surveillance systems would have to be proven capable of accurately identifying and defensibly attributing surveillance points to the correct sub-population of origin. Finally, the OIE would have to endorse the application of the compartmentalisation concept in national BSE accreditation. The Group recognised that the *Terrestrial Code* had not yet evolved to the point of accepting this provision for official BSE risk status recognition.

At such juncture, the concept could be applied and extended beyond delineation by production type to compartmentalisation across all production sectors by birth cohort. The latter option would demand of the applicant Member Country's animal identification and surveillance programmes the same robustness exacted in respect of delineation by production type.

- Points targets could be adopted for countries with adult cattle populations below the current population size range.
  - Alternative 1 (see Appendix III): Adding additional categories to the bottom of Table 1, employing the existing formula for calculating surveillance points targets.

Table 1 did not provide points targets for populations of less than 25,000 adult cattle. In assessments to date of such smaller populations, the Group had extrapolated from the 25,000 – 50,000 category in a manner adherent to the linear relationship originally established by the BSurVE authors. A number of categories could be added at the bottom of Table 1 to formally incorporate this informal approach, with no further modification. The simplicity of the minimal change would extend the appeal already inherent in Table 1.

However, simply formalising the currently tailored process would make it no easier for countries within the added categories to meet the extrapolated points targets. The change would ignore the parallel challenges faced by populations in the range of 100,000 or more head. The change would also ignore the relative inequality wherein the existing categories of Table 1 ask of countries at their lower bound as many surveillance points as those at their upper bound.

- Points targets could be amended for all countries
  - Alternative 2 (see [Appendix III](#)): Adding categories to the bottom of Table 1 as per Alternative 1; further subdividing the number of categories within the existing body of Table 1; retaining the existing formula for calculating surveillance points targets.

The change would benefit countries with smaller adult cattle population but also would extend to those of less than one million head. Increasing the number of categories within Table 1 would yield smaller population ranges within each category. Smaller population ranges would reduce inequality in points targets within a category between its lower and upper extremes. Countries of one million or more head would continue to benefit from a pre-existing, inherent statistical advantage.

Taken to extremes, the number of categories could be increased to the point of virtually eliminating intra-category inequalities. Impracticability would arise as countries found themselves unable to define their adult cattle population sizes within ever-reduced category limits. In the effort to strike a balance between scientific stringency and practicability, the number of categories within Table 1 could be increased in a reasonable manner.

- Alternative 3 (see [Appendix III](#)): Reconfiguring Table 1 as in Alternative 2, but in a more scientifically robust way.

This alternative employed a reconfiguration based on the mid-points of existing categories and logarithmic transformations which restore the original linearity in points targets distribution established by the BSurVE authors. The advantages and considerations were those of Alternative 2, accompanied by a more robust, underlying statistical fairness in the re-distribution of the surveillance points targets by category. The greater degree of divergence from the current approach could require a greater need for explanation to Member Countries.

Selection of any of these three alternatives would not affect the BSE official risk status of the 49 Member Countries already assessed.

Of the countries not yet assessed by the OIE for BSE risk status, approximately fifty would be unaffected irrespective of the new alternative selected. Approximately fifty others would be more favourably or less favourably affected, depending on the choice of alternative 1 versus alternatives 2 or 3. The net impact of change on countries within this latter grouping would depend on their current – arbitrary - positioning within the categories of Table 1. Those at the upper bound of current intra-category ranges would be less favourably affected than those at the lower bound.

The approximately 20 additional countries with the smallest adult cattle populations - the original focus of this study - would be more favourably affected by Alternative 3.

The Group therefore recommended Alternative 3 and supported its introduction (see [Appendix III](#)).

#### 4. Review of the recent literature on atypical BSE

The Group recalled that an OIE *ad hoc* Group first reported on atypical BSE in December 2003. An update was provided on this subject in 2007. The still limited information at that time did not support the derivation of specific guidelines regarding atypical BSE strains. A considerable growth in experimental and empirical evidence during the last five years allowed the current Group to offer additional guidance.

The Group noted that 93 scientific articles had appeared subsequent to the 2007 meeting of the *ad hoc* Group, including a formal review article (Seuberlich T., Heim D. & Zurbriggen A. (2010) – Atypical transmissible spongiform encephalopathies in ruminants: a challenge for disease surveillance and control. *J. Vet. Diag. Invest.*, **22**: 823-842) which had been co-authored by a member of the Group.

The Group further noted that field observations on atypical BSE strains were subject to the limitations inherent within the diagnostic protocols and surveillance regimens from which they had emerged (4, 9, 27, 29)<sup>1</sup>; until the introduction of rapid tests, standard protocols lacked the ability to distinguish the variants; retrospective European reassessments revealed atypical cases initially grouped within the undifferentiated diagnosis of “BSE”; their incidence – both absolute and relative to that of classical BSE - varied among countries.

It was also noted that analysis of less than the composite brain anatomy – the norm in rapid tests – denied the potential detection of variant strains with a predilection to other areas of cerebral anatomy (24, 27, 28); beyond the diagnostics themselves, variability among countries was subject at least in part to the resident bovine age demographic and the relative intensity of surveillance applied across that age spectrum (29); as a result of these and other variables, as in the products of all surveillance programs, one observed the apparent as opposed to the actual incidence of atypical variants.

The Group agreed that within the above mentioned limitations the empirical evidence and knowledge so far available could be summarised as follows:

- Atypical BSE strains were found in both *Bos taurus* and *Bos indicus* (36).
- The apparent incidence of atypical BSE was approximately 1-3 cases per million cattle tested depending upon the age structure and clinical stream under assessment within the target population (4, 29, 30).
- The average age of the limited number (<100) of atypical BSE (L-type and H-type) cases reported to date was approximately twice that of classical cases. The average age of classical BSE cases would increase as countries progress through the tail of the epidemic, altering if not reversing the preceding age differential. For example, EU data for 2011 revealed an average age of 183 months for classical BSE cases as compared to 164 months for atypical cases (10, 17, 28, 29).
- Although it was once emphasised – generating associated hypotheses – that all atypical BSE cases were born before the feed ban, the statement would no longer apply following the isolation in 2012 of an atypical strain in the USA (10, 33).
- The relatively constant rate of occurrence of atypical BSE cases by birth cohort appeared autonomous to that of the characteristic epidemic pattern seen in classical BSE (28, 29, 30, 33).
- The proportional relationship between the reported incidence of classical and atypical BSE cases varied among countries. Within the atypical strains themselves, an approximately one-to-one relationship existed between the incidence of L-type and H-type isolates (4, 11, 17, 28, 29, 38).
- Atypical BSE cases were reported from geographic locations in which diagnostic tests capable of discerning the atypical strains were applied to large numbers of animals (e.g. the EU, Japan and North America) over an extended interval (10, 11, 14, 26, 28, 33, 35, 38).

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<sup>1</sup> See the reference list, below.

- Atypical BSE cases were not reported from geographic locations in which diagnostic tests capable of discerning the atypical strains were introduced later in the international epidemic of classical BSE (e.g. South America and Asia outside Japan), or applied to smaller numbers of animals (e.g. Australia and New Zealand), or both.
- Atypical BSE cases were reported by countries in which indigenous, classical BSE was never found (e.g. Sweden, USA). Within countries with indigenous classical BSE, atypical BSE cases were reported in regions remote from regions expressing indigenous classical BSE (e.g. Canadian province of Manitoba) (10, 12).
- Empirical evidence to date suggested that countries which apply BSE surveillance primarily to the clinical surveillance stream might never disclose the presence of atypical BSE (18, 28, 29, 30, 31, 32).
- Experimental evidence suggested that H-type and L-type atypical BSE strains might represent the origin of the classical BSE epidemic. “Atypical” strains might represent the endemic form of BSE while that which to date had been characterized as “classical” BSE might represent an epidemic expression arising from an imbalance (such as might have occurred in the United Kingdom) among the factors historically governing endemicity (2, 3, 7, 28, 37).
- Experimentation had suggested a relationship between L-type atypical BSE and both sporadic Creutzfeldt-Jakob disease (CJD) and transmissible mink encephalopathy (TME). L-type atypical BSE in downer cattle might have been the origin of TME in 1987 in the State of Wisconsin, USA (3, 20).
- Research in *Bos taurus* identified genetic markers in the prion gene putatively associated with susceptibility to classical BSE. To close the knowledge gap created by a longstanding research focus on *Bos taurus*, researchers had investigated the frequencies of occurrence of the same insertion/deletion polymorphisms in *Bos indicus* and crossbred cattle. Differences in the relative frequencies of two polymorphisms were observed in comparison with *Bos taurus* – one being found more frequently and one less frequently. Consensus was lacking as to the relative degree of classical BSE susceptibility conferred by each of the polymorphisms (5, 6, 15, 19, 23).
- Research conducted on field cases had disclosed no genetic predisposition to atypical BSE, with the exception of a novel mutation E211K revealed in an American H-type BSE case. The mutation had not been previously reported in cattle, but parallels a similar one (E200K) most frequently associated with genetically-induced CJD in humans (11, 13, 31, 32).
- Empirical field observations on the frequency of its diagnosis and geotemporal distribution, limited epidemiological investigations and the composite of genetic research into atypical BSE favoured an hypothesis of spontaneous origin as in sporadic CJD in humans (11, 12, 29, 31, 33, 38).
- Experimental evidence suggested that the L-type atypical BSE strain was more virulent than either the H-type or classical BSE in interspecies transmission (1, 8, 16, 21, 22, 25, 34).

Based on the preceding observations and acknowledged, limited field experience with atypical BSE, the Group agreed to advise the Scientific Commission for Animal Diseases of the following, as preliminary conclusions:

- The possibility that atypical BSE strains are present throughout the world’s cattle population including in countries recognised as having negligible BSE risk cannot be excluded.
- The application of sufficient surveillance intensity, employing diagnostic tests capable of detecting atypical strains, might disclose atypical BSE wherever cattle are raised.
- Experimental evidence supports the hypothesis that the classical BSE strain could have evolved from either an L-type or an H-type BSE strain. Given this evidence and the preceding empirical observations regarding the distribution of the atypical strains, it could be hypothesised that the “seeds” of epidemic classical BSE reside throughout the world’s cattle population.

- Atypical BSE strains represent potential, zoonotic threats of both a direct (interspecies transmission of L-type BSE) and indirect (L-type and H-type transition to classical BSE) nature.
- The ruminant-to-ruminant feed ban which mitigates the risk of classical BSE concurrently reduces the recycling of atypical BSE in the cattle populations of the controlled and negligible BSE risk countries within which it is applied.
- In many countries, surveillance for classical BSE – employing diagnostic protocols capable of discerning atypical BSE – increasingly focus on an age range in which most animals with atypical BSE are identified. In such countries, a progressive emphasis on increasingly older cattle could eventually affect the relative apparent incidence of classical versus atypical strains. The number of atypical BSE cases identified per million animals tested might increase even as the number of classical BSE cases diminishes.
- The disclosure of atypical BSE is a rare event. Empirical evidence suggests that approximately one per million tested animals carried an atypical strain, of which approximately half were of the L-type. Nevertheless, the L-type strain's experimentally demonstrated enhanced ability to cross the species barrier cannot be ignored. *Terrestrial Code* restrictions on certain commodities (SRM) in and from countries of undetermined and controlled BSE risk concurrently reduce human exposure to atypical BSE. However this is not the case in countries with negligible BSE risk.
- The BSE Chapter of the *Terrestrial Code* rewards countries which focus on clinical suspects in a specified age range (4 to 7 years) by granting thousands of times as many points to a clinical surveillance suspect as to a routinely slaughtered animal. As the relative significance of classical BSE decreases, the relative significance of atypical BSE will increase, raising the question as to the eventual relevance of surveillance guidelines as currently applied.
- In addition to the required reporting of BSE incidence to the OIE, several countries employed the BSurvE model to assess its apparent prevalence. Their calculations included atypical cases, inflating estimates of the apparent prevalence of classical BSE in those countries. The global lack of delineation by strain type prior to the evolution of rapid diagnostic tests similarly inflated the apparent incidence of classical BSE in the world, albeit not to the same degree.
- Detection of atypical BSE at an incidence of approximately one per million animals tested demonstrates robust surveillance. The temporal, geographic and demographic distributions of classical versus atypical BSE cases to date tends to refute a direct epidemiological relationship among them. Notwithstanding experimental evidence of a broader aetiological connection, this apparent direct epidemiologic separation suggests that the BSE status of a country is not hampered by the presence of atypical BSE cases. Currently there is no distinction in the BSE Chapter of the *Terrestrial Code* between classical versus atypical BSE cases.

#### **5. Preliminary reading of dossiers received from Member Countries for the evaluation of BSE risk status.**

The Group conducted preliminary reading of dossiers received to date for assessment in 2012 and determined whether applications submitted contained major information gaps to be filled before a formal assessment at the November meeting. The Group agreed to ask the relevant applicant countries to clarify data on surveillance and feed sampling and to follow the submission template as required by the OIE procedure for official recognition of disease status.

#### **6. Other matters**

No other matters were discussed.

## 7. Adoption of the report

The Group reviewed and amended the draft report provided by the rapporteur. The Group agreed that the report would be subject to a period of circulation to the Group for comments and adoption. The report was finalised by correspondence.

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Appendix I

**MEETING OF THE OIE AD HOC GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK  
STATUS EVALUATION OF MEMBER COUNTRIES**

**Paris, 11– 13 September 2012**

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**Agenda**

1. Opening
  2. Adoption of the agenda and appointment of chairperson and rapporteur
  3. BSE surveillance: Options to adjust Member Countries with a small bovine population
    - 3.1 Refinement of the review carried out by the Group on the opinions received from the authors of the BSurvE surveillance model
    - 3.2 Review of current BSE Chapter of the *Terrestrial Code* to accommodate Member Countries with a small bovine population
  4. Review of the recent literature on atypical BSE
  5. Preliminary reading of dossiers received from Member Countries for the evaluation of BSE risk status
  6. Other matters
  7. Adoption of report
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Appendix II

**MEETING OF THE OIE AD HOC GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)  
RISK STATUS EVALUATION OF MEMBERS**

**Paris, 11 – 13 September 2012**

**List of participants**

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## Appendix III

## Surveillance Alternative 1

Points targets for country, zone or compartment		
Adult cattle population size (24 months and older)	Type A surveillance	Type B surveillance
≥1,000,000	300,000	150,000
800,001-1,000,000	240,000	120,000
600,001-800,000	180,000	90,000
400,001-600,000	120,000	60,000
200,001-400,000	60,000	30,000
100,001-200,000	30,000	15,000
50,001-100,000	15,000	7,500
25,001-50,000	7,500	3,750
12,501-25,000	3,800	1,900
6,251-12,500	1,900	950
3,125-6,250	900	450

## Surveillance Alternative 2

Points targets for country, zone or compartment		
Adult cattle population size (24 months and older)	Type A surveillance	Type B surveillance
>1,000,000	300,000	150,000
900,001-1,000,000	270,000	135,000
800,001-900,000	240,000	120,000
700,001-800,000	210,000	105,000
600,001-700,000	180,000	90,000
500,001-600,000	150,000	75,000
400,001-500,000	120,000	60,000
300,001-400,000	90,000	45,000
250,001-300,000	75,000	37,500
200,001-250,000	60,000	30,000
150,001-200,000	45,000	22,500
100,001-150,000	30,000	15,000
75,001-100,000	22,500	11,250
50,001-75,000	15,000	7,500
37,501-50,000	11,300	5,650
25,001-37,500	7,500	3,750
18,751-25,000	5,600	2,800
12,501-18,750	3,800	1,900
9,376-12,500	2,800	1,400
7,813-9,375	2,300	1,150
5,466-7,812	1,600	800
3,125-5,465	900	450

## Surveillance Alternative 3

Points targets for country, zone or compartment		
Adult cattle population size (24 months and older)	Type A surveillance	Type B surveillance
>1,000,000	300,000	150,000
1,000,000	238,400	119,200
900,001–1,000,000	214,600	107,300
800,001–900,000	190,700	95,350
700,001–800,000	166,900	83,450
600,001–700,000	143,000	71,500
500,001–600,000	119,200	59,600
400,001–500,000	95,400	47,700
300,001–400,000	71,500	35,750
200,001–300,000	47,700	23,850
100,001–200,000	22,100	11,500
90,001–100,000	19,900	9,950
80,001–90,000	17,700	8,850
70,001–80,000	15,500	7,750
60,001–70,000	13,300	6,650
50,001–60,000	11,000	5,500
40,001–50,000	8,800	4,400
30,001–40,000	6,600	3,300
20,001–30,000	4,400	2,200
10,001–20,000	2,100	1,050
9,001–10,000	1,900	950
8,001–9,000	1,600	800
7,001–8,000	1,400	700
6,001–7,000	1,200	600
5,001–6,000	1,000	500
4,001–5,000	800	400
3,001–4,000	600	300
2,001–3,000	400	200
1,001–2,000	200	100

**MEETING OF THE OIE AD HOC GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)  
RISK STATUS EVALUATION OF MEMBER COUNTRIES**

**Paris, 27 – 30 November 2012**

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A meeting of the *ad hoc* Group on bovine spongiform encephalopathy (BSE) risk status evaluation of Member Countries (hereafter the Group) was held at the OIE Headquarters from 27 to 30 November 2012.

**1. Opening**

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Kazuaki Miyagishima, Deputy Director General and Head of the Scientific and Technical Department, welcomed the Group. Dr Miyagishima congratulated the Group for the important work made at its previous meeting in September 2012 to address the challenges faced by Member Countries with small cattle populations with respect to the current surveillance requirements in the *Terrestrial Animal Health Code (Terrestrial Code)*. He thanked the Group for having considered every single option to address this subject in order to converge on the most scientific, feasible and realistic approach. He requested the Group to propose an amendment to the Chapter of the *Terrestrial Code* accordingly for consideration by the Scientific Commission for Animal Diseases (Scientific Commission) in February 2013.

Dr Miyagishima emphasised that the OIE process for granting official recognition of disease status was under scrutiny by the applicant Member Countries and other OIE partners. In accordance with the OIE Standard Operating Procedures (SOPs) governing official recognition of disease status, he recommended the Group to produce a detailed report in order to give clear understanding to the applicant Member Countries on possible information gaps and/or specific areas that should be addressed in the future. Dr Miyagishima acknowledged that the Group had always found a consensus in the past when evaluating applications. Should a consensus not be reached for a given dossier, the Group should record in its report all views and opinions with detailed rationale behind. Dr Miyagishima reminded the Group that the Scientific Commission was responsible to undertake, on behalf of the World Assembly of the OIE, the assessment of OIE Member Countries applications by considering the report of the Group, including analysis of the dossiers, findings and recommendations.

Dr Miyagishima also informed the Group that for this meeting the OIE had allowed a Member Country to dispatch its experts at the OIE Headquarters to clarify issues relating to the evaluation of its dossier in case the Group considered that a face-to-face interaction with the applicant Member Country would be necessary. In this respect, he reminded the Group that as a matter of principle, the presence of experts from applicant Member Countries at the OIE Headquarters was not actively sought and the request and provision of information through telecommunication was the approach preferred by the OIE. Nevertheless a physical meeting between the Group and the representatives of an applicant Member Country could be considered on a case by case basis, after consultation of the Director General of the OIE.

Finally, the Group was reminded of the standing OIE policy concerning declaration of interest and confidentiality of information statements, noting that the members of the Group had already signed and were bound by confidentiality undertaking. Dr Miyagishima invited experts who were in the situation of a potential conflict of interest to voluntarily withdraw from the discussion on specific dossiers in question.

## 2. Adoption of the agenda and appointment of chairperson and rapporteur

The Group adopted its agenda of the meeting. Dr John Kellar was appointed Chair of the meeting and Dr Martial Plantady acted as rapporteur.

The agenda and list of participants are provided as Appendices I and II, respectively.

## 3. Review of current BSE Chapter of the Terrestrial Code to accommodate Member Countries with a small bovine population according to the conclusion reached at the September meeting

Based on the conclusion reached at its September 2012 meeting, the Group amended Article 11.5.22. of the *Terrestrial Code* in order to accommodate Member Countries with a small bovine population..

## 4. Evaluation of requests from Member Countries for the evaluation of BSE risk status

Experts of the Group, in pairs, had accepted to conduct a preliminary analysis of the dossiers of individual applicant Member Countries (as allocated by the OIE Headquarters) prior to the meeting. The experts presented their key findings to the plenary, which proceeded with in-depth discussion, dossier by dossier, on the applicant Member Country's compliance with the provisions on BSE risk status in the *Terrestrial Code*. Where necessary, messages were sent electronically to the applicants requesting missing information. All contacted Member Countries provided requested information to the Group in time. In addition, the Group held a face-to-face meeting with representatives of one applicant Member Country to seek clarification on a number of points.

### 4.1. Bulgaria

In February 2012 Bulgaria submitted a dossier seeking a 'controlled BSE risk' status and an update in October 2012. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code*.

Points specifically noted by the Group were summarised in the following discussion.

#### a) *Section 1: Risk Assessment — Article 11.5.2. point 1*

- *Risk assessment for introduction of the BSE agent*

The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered Bulgaria during the interval covered by the assessment was not negligible.

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

The Group considered that the conclusion of the exposure assessment was that there was a negligible risk of recycling and amplification of the BSE agent if it were present in Bulgaria's cattle population during the interval covered by the assessment.

#### b) *Surveillance according to Articles 11.5.20.-11.5.22.*

The Group noted that the surveillance undertaken exceeded the minimum requirements of type A surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*.

**c) Other requirements — Article 11.5.2. points 2–4**

▪ *Awareness programme*

The Group determined that the awareness programme met the requirements of the *Terrestrial Code*.

▪ *Compulsory notification and investigation*

The Group noted that BSE was declared a notifiable disease under relevant legislation since 1998 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

▪ *Laboratory examination*

The Group determined that the arrangements for laboratory examination met the requirements of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)*.

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

The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

**d) BSE history in the country**

No BSE case had been recorded in Bulgaria.

**e) Compliance with conditions for ‘controlled BSE risk’ status - Article 11.5.4.**

Based on the information provided, the Group accepted Bulgaria’s request for ‘controlled BSE risk status’. Additionally, the Group noted that Bulgaria has also met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as ‘negligible BSE risk’.

**f) Conclusions**

▪ *Recommended message to be conveyed to the Member Country by the Director General*

- Status

‘Controlled BSE risk’ or ‘negligible BSE risk’

**4.2. Costa Rica**

In October 2012, Costa Rica submitted a dossier seeking a BSE risk status. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code*.

Points specifically noted by the Group were summarised in the following discussion.

**a) Section 1: Risk Assessment — Article 11.5.2. point 1**

▪ *Risk assessment for introduction of the BSE agent*

The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered Costa Rica during the interval covered by the assessment was not negligible.

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

The Group considered that the conclusion of the exposure assessment was that the risk of recycling and amplification of the BSE agent if it were present in Costa Rica's cattle population during the interval covered by the assessment was not negligible.

**b) *Surveillance according to Articles 11.5.20.-11.5.22.***

The Group noted that the surveillance undertaken exceeded the minimum requirements of type A surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*. The Group noted in 2011 and 2012 a considerable increase in the number of surveillance samples attributed to the clinical suspect stream, while accessions in the other streams remained within the ranges established in preceding years.

**c) *Other requirements — Article 11.5.2. points 2–4***

- *Awareness programme*

The Group determined that the awareness programme met the requirements of the *Terrestrial Code*.

- *Compulsory notification and investigation*

The Group noted that BSE was declared a notifiable disease under relevant legislation since 2001 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- *Laboratory examination*

The Group determined that the arrangements for laboratory examination met the requirements of the OIE *Terrestrial Manual* including the 2011 introduction of immunohistochemistry.

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

The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

**d) *BSE history in the country***

No BSE case had been recorded in Costa Rica.

**e) *Compliance with conditions for 'controlled BSE risk' status - Article 11.5.4.***

Based on the information provided, the Group recommended that Costa Rica be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'controlled BSE risk'.

**f) *Conclusions***

- *Recommended message to be conveyed to the Member Country by the Director General*

- Status

'Controlled BSE risk'

The Group acknowledged improvements recently accomplished and under way in the areas of surveillance, specific risk materials (SRM) removal, feed mill line dedication and laboratory diagnostics. These improvements had contributed to acquisition of controlled BSE risk status.

The Group noted a considerable increase in the number of accessions attributable to the clinical suspect surveillance stream in 2011 and 2012, in the absence of a parallel increase in other streams. While the focus on clinical suspects was in keeping with guidance in the *Terrestrial Code* Chapter, in the absence of a parallel increase in other streams it could signify less than adequate specificity in the attribution of accessions by surveillance stream. The Group recommended that Costa Rica review the criteria whereby accessions were attributable to the clinical suspect stream.

The Group noted a considerable concentration of accessions in the 4 to 7 years age category which commanded the greatest number of surveillance points per accession. This could signify less than adequate specificity in the attribution of accessions by age. The Group recommended that Costa Rica also review the criteria whereby the age of tested animals was established.

#### 4.3. Israel

In September 2012, Israel submitted a dossier seeking a 'negligible' or 'controlled' BSE risk status and an update in October 2012. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code*.

Points specifically noted by the Group were summarised in the following discussion.

##### a) *Section 1: Risk Assessment — Article 11.5.2. point 1*

- *Risk assessment for introduction of the BSE agent*

The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered Israel during the interval covered by the assessment was negligible.

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

The Group considered that the conclusion of the exposure assessment was that the risk of recycling and amplification of the BSE agent if it were present in Israel's cattle population during the interval covered by the assessment was negligible.

##### b) *Surveillance according to Articles 11.5.20.-11.5.22.*

The Group noted that the surveillance undertaken exceeded the minimum requirements of type A surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*.

##### c) *Other requirements — Article 11.5.2. points 2-4*

- *Awareness programme*

The Group determined that the awareness programme met the requirements of the *Terrestrial Code*.

- *Compulsory notification and investigation*

The Group noted that BSE was declared a notifiable disease under relevant legislation since 1992 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- *Laboratory examination*

The Group determined that the arrangements for laboratory examination met the requirements of the OIE *Terrestrial Manual*.

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

The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

**d) *BSE history in the country***

The Group noted that Israel had so far one case of BSE born in September 1992. The indigenous case was born more than 11 years preceding the submission of the dossier. Therefore, Israel had met the provisions of Article 11.5.3. point 3 b). All cattle which were reared with the BSE case during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country, were completely destroyed.

**e) *Compliance with conditions for ‘negligible BSE risk’ status - Article 11.5.3.***

Based on the information provided, the Group recommended that Israel be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as ‘negligible BSE risk’.

**f) *Conclusions***

- *Recommended message to be conveyed to the Member Country by the Director General*

- Status

‘Negligible risk’

**4.4. Italy**

In accordance with the established procedures, the participating expert from Italy withdrew from the meeting during the discussions on the Italy’s dossier by the Group.

The Group recalled that in 2007 the OIE received a dossier from Italy to evaluate the BSE risk status of its cattle population in accordance with the *Terrestrial Code*. The recommendation of the Group at that time was that Italy should be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as ‘controlled BSE risk’. Italy had been listed as a Member Country having a ‘controlled BSE risk’ status since May 2008.

In October 2012, Italy submitted a dossier seeking a negligible BSE risk status. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code*.

Points specifically noted by the Group were summarised in the following discussion.

**a) *Section 1: Risk Assessment — Article 11.5.2. point 1***

- *Risk assessment for introduction of the BSE agent*

The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered Italy during the interval covered by the assessment was not negligible.

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

The Group considered that the conclusion of the exposure assessment was that there was a negligible risk of recycling and amplification of the BSE agent if it were present in Italy’s cattle population during the interval covered by the assessment.

**b) Surveillance according to Articles 11.5.20.-11.5.22.**

The Group noted that the surveillance undertaken exceeded the minimum requirements of type B surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*.

**c) Other requirements — Article 11.5.2. points 2–4**

- *Awareness programme*

The Group determined that the awareness programme met the requirements of the *Terrestrial Code*.

- *Compulsory notification and investigation*

The Group noted that BSE was declared a notifiable disease under relevant legislation since 1992 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- *Laboratory examination*

The Group determined that the arrangements for laboratory examination met the requirements of the *Terrestrial Manual*.

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

The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

**d) BSE history in the country**

The Group noted that Italy had so far 145 cases of BSE. The youngest birth cohort reported as affected by BSE was born in 2001, meaning that all indigenous cases were born more than 11 years preceding the submission of the dossier. Therefore, Italy had met the provisions of Article 11.5.3. point 3 b). All cattle which were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country, were completely destroyed.

**e) Compliance with conditions for ‘negligible BSE risk’ status - Article 11.5.3.**

Based on the information provided, the Group recommended that Italy be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as ‘negligible BSE risk’.

**f) Conclusions**

- *Recommended message to be conveyed to the Member Country by the Director General*

- Status

‘Negligible BSE risk’

**4.5. Japan**

In accordance with the established procedures, the participating expert from Japan withdrew from the meeting during the discussions on Japan’s dossier by the Group.

The Group recalled that in December 2008 the OIE received a dossier from Japan to evaluate the BSE risk status of its cattle population in accordance with the *Terrestrial Code*. The recommendation of the Group was at that time that Japan should be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as ‘controlled BSE risk’. Japan had been listed as a Member Country having a ‘controlled BSE risk’ status since May 2009.

In September 2012, Japan submitted a dossier seeking a negligible BSE risk status. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code*.

Points specifically noted by the Group were summarised in the following discussion.

**a) Section 1: Risk Assessment — Article 11.5.2. point 1**

▪ *Risk assessment for introduction of the BSE agent*

The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered Japan during the interval covered by the assessment was negligible.

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

The Group considered that the conclusion of the exposure assessment was that there was a negligible risk of recycling and amplification of the BSE agent if it were present in Japan’s cattle population during the interval covered by the assessment.

**b) Surveillance according to Articles 11.5.20.-11.5.22.**

The Group noted that the surveillance undertaken exceeded the minimum requirements of type B surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*.

**c) Other requirements — Article 11.5.2. points 2–4**

▪ *Awareness programme*

The Group determined that the awareness programme met the requirements of the *Terrestrial Code*.

▪ *Compulsory notification and investigation*

The Group noted that BSE was declared a notifiable disease under relevant legislation since 1996 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

▪ *Laboratory examination*

The Group determined that the arrangements for laboratory examination met the requirements of the *Terrestrial Manual*.

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

The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

**d) BSE history in the country**

The Group noted that Japan had so far 36 cases of BSE. The youngest birth cohort reported as affected by BSE was born in January 2002, meaning that all indigenous cases would have been born more than 11 years prior to May 2013. Therefore, Japan would have met the provisions of Article 11.5.3. point 3 b) in May 2013 when the final decision would be made by the World Assembly. All cattle which were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country, were completely destroyed.

**e) Compliance with conditions for 'negligible BSE risk' status - Article 11.5.3.**

Based on the information provided, the Group recommended that Japan be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'negligible BSE risk'.

**f) Conclusions**

- *Recommended message to be conveyed to the Member Country by the Director General*
  - Status
  - 'Negligible BSE risk'

**4.6. The Netherlands**

The Group recalled that in February 2007 the OIE received a dossier from the Netherlands to evaluate the BSE risk status of its cattle population in accordance with the *Terrestrial Code*. The recommendation of the Group was at that time that the Netherlands should be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'controlled BSE risk'. The Netherlands had been listed as a Member Country having a 'controlled BSE risk' status since May 2008.

In February 2012, the Netherlands submitted a dossier seeking a 'negligible BSE risk status' followed by an update in October 2012. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code*.

Points specifically noted by the Group were summarised in the following discussion.

**a) Section 1: Risk Assessment — Article 11.5.2. point 1**

- *Risk assessment for introduction of the BSE agent*

The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered the Netherlands during the interval covered by the assessment was not negligible.

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

The Group considered that the conclusion of the exposure assessment was that there was a negligible risk of recycling and amplification of the BSE agent if it were present in the Netherlands' cattle population during the interval covered by the assessment.

**b) Surveillance according to Articles 11.5.20.-11.5.22.**

The Group noted that the surveillance undertaken exceeded the minimum requirements of type B surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*.

**c) Other requirements — Article 11.5.2. points 2–4**

- *Awareness programme*

The Group determined that the awareness programme met the requirements of the *Terrestrial Code*.

- *Compulsory notification and investigation*

The Group noted that BSE was declared a notifiable disease under relevant legislation since 1990 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- *Laboratory examination*

The Group determined that the arrangements for laboratory examination met the requirements of the *Terrestrial Manual*.

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

The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

**d) BSE history in the country**

The Group noted that the Netherlands had so far 95 cases of BSE. The youngest birth cohort reported as affected by BSE was born in February 2001, meaning that all indigenous cases were born more than 11 years preceding the submission of the dossier. Therefore, the Netherlands had met the provisions of Article 11.5.3. point 3 b). All cattle which were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country, were completely destroyed.

**e) Compliance with conditions for ‘negligible BSE risk’ status - Article 11.5.3.**

Based on the information provided, the Group recommended that the Netherlands be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as ‘negligible BSE risk’.

**f) Conclusions**

- *Recommended message to be conveyed to the Member Country by the Director General*

- Status

‘Negligible BSE risk’

**4.7. Slovenia**

The Group recalled that in 2007 the OIE received a dossier from Slovenia to evaluate the BSE risk status of its cattle population in accordance with the *Terrestrial Code*. The recommendation of the Group was at that time that Slovenia should be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as ‘controlled BSE risk’. Slovenia had been listed as a Member Country having a ‘controlled BSE risk’ status since May 2008.

In September 2012 Slovenia submitted a new dossier seeking a negligible BSE risk status. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code*.

Points specifically noted by the Group were summarised in the following discussion.

**a) Section 1: Risk Assessment — Article 11.5.2. point 1**

- *Risk assessment for introduction of the BSE agent*

The Group considered that the conclusion of the release assessment was that the risk that the BSE agent could have entered Slovenia during the interval covered by the assessment was not negligible.

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

The Group considered that the conclusion of the exposure assessment was that there was a negligible risk of recycling and amplification of the BSE agent if it were present in Slovenia's cattle population during the interval covered by the assessment.

**b) Surveillance according to Articles 11.5.20.-11.5.22.**

The Group noted that the surveillance undertaken exceeded the minimum requirements of type B surveillance according to Article 11.5.22. on surveillance for BSE in the *Terrestrial Code*.

**c) Other requirements — Article 11.5.2. points 2–4**

- *Awareness programme*

The Group determined that the awareness programme met the requirements of the *Terrestrial Code*.

- *Compulsory notification and investigation*

The Group noted that BSE was declared a notifiable disease under relevant legislation since 1995 and determined that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

- *Laboratory examination*

The Group determined that the arrangements for laboratory examination met the requirements of the *Terrestrial Manual*.

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

The Group noted that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least 8 years.

**d) BSE history in the country:**

The Group noted that Slovenia had so far 8 cases of BSE. The youngest birth cohort reported as affected by BSE was December 2000, meaning that all indigenous cases were born more than 11 years preceding the submission of the dossier. Therefore, Slovenia had met the provisions of Article 11.5.3. point 3 b). All cattle which were reared with the BSE cases during their first year of life, and which investigation showed consumed the same potentially contaminated feed during that period, if alive in the country, were completely destroyed.

**e) Compliance with conditions for 'negligible BSE risk' status - Article 11.5.3.**

Based on the information provided, the Group recommended that Slovenia be regarded as having met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'negligible BSE risk'.

*f) Conclusions*

- *Recommended message to be conveyed to the Member Country by the Director General*
  - Status
    - ‘Negligible BSE risk’

**4.8. United States of America**

In 2006 the OIE received a dossier from the United States of America (USA) to evaluate the BSE risk status of the cattle population of the USA in accordance with the *Terrestrial Code*. The Group recommended that the USA should be regarded as having met the requirements for recognition as complying with the *Terrestrial Code* as a Member Country with ‘controlled BSE risk’. The USA had been listed accordingly since May 2007.

In July 2012, the USA submitted a new dossier seeking a negligible BSE risk status. The Group agreed that the submission conformed to the guidelines circulated for Member Countries wishing to make a formal evaluation of their BSE risk status according to the requirements of the *Terrestrial Code*.

Points specifically noted by the Group were summarised in the following discussion.

*a) Section 1: Risk Assessment — Article 11.5.2. point 1*

The Group considered that the national risk assessment conducted in 2006, updated in 2009 and 2010 on a national basis and in 2012 on a regional basis, was robust and comprehensive, taking into account all known pathways of BSE exposure in accordance with the criteria specified in Article 11.5.2. of the *Terrestrial Code*.

- *Risk assessment for introduction of the BSE agent*

The Group acknowledged that 7 years and 8 years had lapsed, respectively, since the USA introduced mitigation measures against import risk associated with live cattle and bovine material from Canada. The Group noted the robust national risk assessments associated with those mitigation measures and the recent regional assessment. The Group agreed that while the USA permitted live cattle imports for slaughter and breeding from birth cohorts starting in 1999, in fact, imports for slaughter had been born in 2003 or later and imports for breeding had been born in 2005 or later. The Group noted that 4 cases of BSE had been detected (one imported from Canada; three indigenous atypical cases) since 2003. The year of birth of the last indigenous case was 2001. The Group could not reach a consensus on the interpretation of this information.

Several members of the Group were of the view that the release risk during the interval of the assessment, while very low, was not negligible. They questioned the results of the BSurVE assessment whereby the BSE prevalence by birth cohort was established for Canadian cattle. They also questioned the integrity of the importation process, considering that live cattle imports could violate the rules governing their disposition by virtue of inadequate identification, age determination and oversight. These members of the Group agreed that the import conditions for imported cattle from controlled BSE risk countries were not following Article 11.5.8. of the *Terrestrial Code* (cattle selected for export were born after the date from which the ban on the feeding of ruminants with MBM and greaves derived from ruminants was effectively enforced). Citing the 2007 meeting report of the Group on atypical BSE, these members of the Group considered the atypical BSE case diagnosed in 2012 as a continuing indigenous BSE challenge to an imperfect feed ban.

Other members of the Group held the view that the release risk was negligible. These members of the Group considered that more than 8 statutory years had lapsed since ruminant MBM was imported from Canada with minimal BSE scrutiny and more than 7 statutory years had lapsed since live cattle had been imported from Canada with minimal BSE scrutiny. They credited the phased reintroduction of imports from Canada as reflecting mitigation measures commensurate with their assessed risk, in accordance with Article 2.1.5. of the *Terrestrial Code*. They reminded the Group that Member Countries lacking adequate national identification systems (such as Brazil, New Zealand, Argentina) at the time of assessment had been approved by the OIE as negligible BSE risk. The same Member Countries determined the age of animals using dentition instead of national identification. In their view, the Group should apply consistency in respect of these facts.

These members of the Group considered the atypical BSE case diagnosed in 2012 as epidemiologically unrelated to the classical BSE epidemic against which the USA feed ban was directed. They further considered that atypical BSE was a naturally occurring transmissible spongiform encephalopathy of rare prevalence and did not constitute a significant threat to the control of classical BSE, based on the report provided to the Scientific Commission by the Group in September 2012. The members considered furthermore that, given the age (born in 2001) of the 2012 case, even if the report provided to the Scientific Commission in September 2012 was not taken into consideration because of it not yet having been endorsed by the Scientific Commission, the 2012 BSE case was not a consideration by virtue of the fact that cattle infected by the BSE agent but born more than 11 years before should not be considered in the release risk assessment (Article 11.5.3. of the *Terrestrial Code*).

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

The Group agreed that since 1997 the USA had prohibited the use of MBM (except poultry origin and pure porcine or equine MBM) in ruminant feed. The Group acknowledged the introduction in April 2009 of a prohibition on the use of certain SRM (achieving a 1-log reduction in BSE infectivity via removal of brain and spinal cord of animals over 30 months of age) for animal feed. The Group acknowledged the exclusion of 77 % of fallen stock from rendering; the industry's estimation that 99 % of MBM production occurred in dedicated facilities; an average of 2-log reduction in BSE infectivity in rendering; the diversion of 31 % of MBM to pet food; the processing of livestock feed in dedicated facilities in 98 % of feed mills; the raising of cattle on 80 % of premises without pigs or poultry. The Group acknowledged the conducting of 26,000 tests in the feed chain, 50 % of which tests were applied to feed destined for ruminants.

The Group agreed that the effectiveness of a ruminant-to-ruminant feed ban did not exceed 65 % based on experience in other countries. The Group acknowledged that rendering parameters in the USA were not mandatory in the manner of those applied in the other countries already assessed as negligible risk (several European Union members and Japan for example).

The Group could not reach a consensus on the interpretation of this information.

Several members of the Group considered that 23 % of fallen stock was still being processed in rendering plants. They also considered that the information provided on the relative distribution of rendering parameters among renderers was based on estimation primarily from industry (secondarily from the USA's Food and Drug Administration) and 10 % of the renderers used a 0-1 log reduction-method. These members of the Group considered that until October 2009 SRMs and other inedible offal were rendered for non-ruminant feed. They considered that potentially infective ruminant material (vertebral column, tonsils and ileum) could still be recycled into the feed chain following the imposition of the modified SRM ban at that time. These members of the Group considered that the removal of SRMs in rendering plants seemed difficult due to the diverse number of options and to the absence of an accurate determination of age. They considered that approximately 30 % of MBM domestically produced for feeding

purposes was mixed ruminant/non ruminant MBM. They considered that the effectiveness of the feed ban could therefore be questioned regarding its ability to prevent recycling and amplification of the BSE agent. They considered that on the 20 % of farms where cattle cohabit with swine or poultry or both, there were no preventive measures (other than a warning label on feed bags) applied to prevent ruminants from having access to feed for monogastric animals (which contain SRM). These members of the Group considered that to take the average log reduction for every step was not a realistic worst case assumption; they considered that under realistic worst case assumptions the risk of recycling and amplification is not negligible.

Other members of the Group considered that the efficacy of the feed ban should be commensurate with the assessed release risk (Article 2.1.5. of the *Terrestrial Code*). They acknowledged a feeding system incorporating the removal of 77 % of fallen stock; the dedication of 99 % of rendering plants to only ruminant or only monogastric species; the achievement of a weighted average reduction in BSE infectivity of 2-logs by rendering; and that the diversion of 31 % of MBM production to pet food and the dedication of 99 % of feed mills to only ruminant or to only monogastric species led to a net linear reduction in infectivity exposure of  $7 \times 10^{-7}$  until and including 2008 and with the addition of a partial SRM ban in 2009 a net linear reduction of  $7 \times 10^{-8}$ . These members of the Group considered that this conclusion is supported by: the results of 26,000 tests conducted throughout the feed chain; and a BSurVE model assessment showing a marked decline in BSE prevalence upon the imposition of the 1997 feed ban. These members, referring to the importance of applying consistency, considered that the combination of these measures was no less robust than those of other Member Countries already assessed by the OIE as having negligible BSE risk (such as New Zealand, Australia and many South American countries in which human consumption of SRM had been accepted as a mitigation measure without monitoring).

**b) Surveillance according to Articles 11.5.20.-11.5.22.**

The Group accepted that surveillance on a national basis had been undertaken at a level 20 times higher than the minimum requirements for retained controlled BSE risk status or achievement of negligible BSE risk status. The Group agreed that surveillance on a regional basis directed at 2 regions most exposed to Canadian BSE risk met or exceeded *Terrestrial Code* requirements on a zone basis. The Group agreed that the level of surveillance applied had been sufficient to detect 3 cases of atypical BSE and an imported case of BSE from Canada.

**c) Other requirements — Article 11.5.2. points 2–4**

▪ *Awareness programme*

The Group determined that the awareness programme met the requirements of the *Terrestrial Code*.

▪ *Compulsory notification and investigation*

The Group noted that BSE was declared a notifiable disease under relevant legislation since 1986 and concluded that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

▪ *Laboratory examination*

The Group noted that the arrangements for laboratory examination met the minimum requirements of the *Terrestrial Code*.

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

The Group referred to the findings of the exposure assessment and its interpretation by parts one and two.

**d) BSE history in the country**

The Group noted that the USA had so far 4 cases of BSE. One of them was proven to have been imported from Canada and the others were indigenous, atypical BSE cases. All indigenous cases were born more than 11 years prior to the submission of the dossier. Every effort had been expended in the country to trace all cattle which were reared with the BSE cases during their first years of life. For the last case (atypical BSE case born in 2001), 50 animals among 344 within its birth cohort were sold in 2007 and 2008 but could not be traced.

**e) Compliance with Conditions for 'negligible BSE risk' status - Article 11.5.3.**

Based on the information provided and the nature of bovine husbandry in the USA, the Group reached consensus that birth cohorts born in and since 2009 represented negligible BSE risk. Several members of the Group were of the view that the USA would meet the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'negligible BSE risk' no earlier than 2016, provided that current measures are maintained. Other members of the Group were of the view that the USA currently met the requirements for recognition as complying with the BSE Chapter of the *Terrestrial Code* as 'negligible BSE risk'.

**f) Conclusions**

- *Recommended status*

After extensive deliberation, the Group was not able to reach the consensus on the final recommendation to the Scientific Commission on the dossier of USA. Several members of the Group recommended 'controlled BSE risk', while others recommended 'negligible BSE risk'. Both opinions along with the detailed rationale for each component of the risk assessment would be conveyed to the Scientific Commission for its assessment and final conclusion on the recommendation to bring to the World Assembly of Delegates.

- *Recommended message to be conveyed to the Member Country by the Director General*

- Status

The Director General is referred to the findings above.

**4.9. Other Member Country request**

The Group assessed one additional request of a Member Country for recognition of 'negligible BSE risk' status which did not meet the requirements of the *Terrestrial Code*; the dossier was referred back to the corresponding Member Country.

**5. Other matters**

The Group agreed to bring to the attention of the Scientific Commission the challenges encountered by the Group in interpreting the rendering protocol incorporated in Article 11.5.19. of the *Terrestrial Code*, given the latitude provided by the risk assessment chapter (Chapter 2.1. of the *Terrestrial Code*) in respect of equivalent versus prescribed mitigation measures. Several members of the Group interpreted the provision of the Code as prescription of measures. Other members of the Group believed that within the Code equivalence in measures applied could be accounted for. To date, the Group had, by consensus and with guidance from the Scientific Commission, employed a degree of latitude in interpretation of the Code Chapter on BSE vis-à-vis the provisions of corollary chapters of the Code on surveillance and risk assessment. In this instance, consensus could not be reached within the Group in the approach to be taken.

Dr Miyagishima congratulated the Group for its hard work and recognised that it had employed every single means to reach conclusions based on a consensus. Dedication of the Chair, the rapporteur and all other experts of the Group to examine all data available in detail and interpret them objectively was recognised.

**6. Finalization and adoption of the draft report**

The Group reviewed and amended the draft report provided by the rapporteur. The Group agreed that the report would be subject to a period of circulation to the Group for comments and adoption. The report was finalised by correspondence.

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.../Appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)  
RISK STATUS EVALUATION OF MEMBER COUNTRIES**

**Paris, 27 – 30 November 2012**

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**Agenda**

1. Opening
2. Adoption of the agenda and appointment of chairperson and rapporteur
3. Review of current BSE Chapter of the *Terrestrial Code* to accommodate Member Countries with a small bovine population according to the conclusion reached at the September meeting
4. Evaluation of requests from Member Countries for the evaluation of BSE risk status
5. Other matters
6. Finalization and adoption of the draft report

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Appendix II**MEETING OF THE OIE AD HOC GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)  
RISK STATUS EVALUATION OF MEMBER COUNTRIES**

Paris, 27 – 30 November 2012

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## REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON BRUCELLOSIS

Paris, 9-11 January 2013

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A meeting of the *ad hoc* Group on brucellosis (hereafter the Group) was held at the OIE Headquarters from 9 to 11 January 2013.

### 1. Opening

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Kazuaki Miyagishima, Deputy Director General and Head of the Scientific and Technical Department of the OIE, welcomed the Group and explained the objectives of the meeting. Brucellosis was a very important disease because of its public health impact. It was also important that the *Terrestrial Animal Health Code (Terrestrial Code)* chapters and its on-going revision could guide, and were in phase with, incremental evolution of national legislation in Member Countries.

Following the principles set by the OIE to gradually converting the disease-specific chapters of the *Terrestrial Code* into pathogen-specific chapters, the Group, at its meeting of July 2011, had merged the chapters of the *Terrestrial Code* on bovine brucellosis (Chapter 11.3.), caprine and ovine brucellosis (excluding *Brucella ovis*) (Chapter 14.1.) and porcine brucellosis (Chapter 15.3.) into a new multispecies chapter called "Infection with *Brucella*". After the review by the Scientific Commission for Animal Diseases (Scientific Commission) and the Terrestrial Animal Health Standard Commission (Code Commission), the proposed draft had been circulated for Member Country comments in September 2011.

The number and nature of the comments received resulted in a joint discussion between the OIE Scientific Commission and the Code Commission at their meetings in February 2012, where it was decided that representatives of both Commissions should be present at the Group's subsequent meeting to ensure liaison. Consequently, Dr Sergio Duffy, representative of the Scientific Commission, and Dr Etienne Bonbon, representative of the Code Commission, were present at the present meeting to provide guidance to the Group. Dr Duffy welcomed and thanked the Group on behalf of the Scientific Commission for its excellent work conducted so far. Dr Bonbon commented that the approach followed by the Group at its previous meeting was scientifically sound and appreciated; however, the Group now should consider the comments of the Scientific Commission, the Code Commission and Member Countries to review the structure and content of the new version of the draft chapter.

### 2. Adoption of the agenda, appointment of a chair and rapporteurs

The Group adopted the proposed agenda as agenda for the meeting. The Group was chaired by Dr Bruno Garin-Bastuji, and Drs John Fischer and Ana Maria Nicola acted as rapporteurs.

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

### 3. Revision of the draft updated chapter addressing the comments received

The Group noted that the underlying principles to keep *Brucella abortus*, *B. melitensis* and *B. suis* together in one multispecies chapter (Chapter 8.x.) remained valid on scientific grounds. However, the Group agreed to address the comments from the Member Countries and Specialist Commissions by restructuring the chapter according to the different animal species, where relevant, in order to make it more comprehensive and easily applicable at the national level. The Group drafted provisions regarding disease status which were specific to each animal species as appropriate. For instance, for pigs, the Group noted that there was a dramatic lack of accurate diagnostic tests, serological tests in particular. This prevented the implementation of a regular and periodic testing of large pig populations that might produce many false-positive reactions. Thus, the concept of disease free status in pigs was not considered for the zone or country levels and was limited to the herd level, this being essentially based on the surveillance of clinical signs.

#### Article 8.x.1. - General provisions

The Group accepted the proposals from Member Countries by eliminating the word “isolated” from the definition of *Brucella* infection, assuming that the term “identified” was sufficient as the bacteria could be identified without being isolated (e.g. by PCR).

In addition, the Group excluded vaccine strains from the definition of *Brucella*.

The list of epidemiologically significant animal species was revised for clarification. The use of scientific names in parentheses after the vernacular names of Cervidae species was suggested by the Group to avoid confusion associated with common names, such as “elk,” which referred to different species in Eurasia (*Alces alces*) and in North America (*Cervus elaphus canadensis*). Regarding equids, the Group maintained the same conclusion as it reached at its last meeting: “Equids were considered a dead-end host and therefore the provisions of the chapter on the other animal species were considered sufficient to mitigate the *Brucella* infection risk in equids”. Hares were kept in the list for notification purposes, but the provisions related to their trade were removed (see below).

The Group agreed that any mention of diagnostic techniques and vaccines should be contained in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* rather than in the *Terrestrial Code* chapters.

#### Article 8.x.2. - Safe commodities

The application of the veterinary certificate was removed because these commodities were safe by definition.

#### Articles on disease free status (Articles 8.x.3. to 8.x.12.)

The Group agreed to split the articles on disease free status by relevant species, providing for a free status in a country, zone, herd or flock, with or without vaccination for bovines, sheep and goats; only a free status without vaccination could be considered for camelids and cervids because of the current lack of appropriate vaccines for these species. The provisions for disease free status without vaccination were therefore almost identical for bovines, sheep and goats, camelids and cervids.

In regard to how the *Terrestrial Code* should deal with suspect cases without being too prescriptive, the Group suggested a provision on the implementation of regulatory measures for early detection. Another improvement to the text consisted of clarifying the provisions for testing to first attain and subsequently maintain a free status.

The Group also formulated provisions for a country or zone free with vaccination the status of which was to be converted to freedom without vaccination.

The Group agreed not to use the concept of compartments in this chapter because the free status of herds or flocks would be sufficient to manage the risks posed by *Brucella* – the specific chapter on compartmentalisation in the *Terrestrial Code* could be used if needed.

The Group also discussed the non-infection period required for a herd or flock free without vaccination in a country or zone that was not free from the disease and recommended to adopt a 12-month period considering the presence of potential carriers and the completion of a reproductive cycle of animals.

In the case of pigs, only a free status in a herd, not in a country or zone, could be considered, both because of the lack of accuracy of the diagnostic test in pigs and because of the epidemiological differences in pig production.

Provisions for the recovery of a free status were revised by taking Member Countries' comments into account.

#### **Articles on importation (Articles 8.x.13. to 8.x.20.)**

The Group drafted a new provision (Article 8.x.14.) for the importation of pigs for breeding or rearing. Since for pigs a free country or zone status was not possible, only importations from free herds were considered.

On the provisions for the importation of animals for slaughter (Article 8.x.15.), the Group highlighted that animals that were part of an eradication programme against *Brucella* could not be imported if they originated from a country, zone or herd that was not free from the disease.

At its previous meeting, the Group had drafted an article on recommendations for the importation of captive European hares for restocking. A Member Country requested more precise provisions on the draft article. The Group considered that it could not recommend safer measures and decided to delete the draft article.

Finally, the Group recommended keeping the provisions on importation of *in vivo* bovine-derived embryos in Article 8.x.17. since only *B. abortus* was categorised as Category 1 disease by the International Embryo Transfer Society, while *B. melitensis* and *B. suis* were not.

#### **4. Finalization and adoption of the draft report**

The Group reviewed and amended the draft report provided by the rapporteurs. The Group agreed that the report would be subject to a period of circulation within the Group for comments. The report was finalised by correspondence.

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.../appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON BRUCELLOSIS  
Paris, 9-11 January 2013**

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**Agenda**

1. Opening
2. Adoption of agenda, appointment of chair and rapporteurs
3. Revision of the draft updated chapter addressing the comments received
4. Finalisation and adoption of the draft report

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Appendix II**MEETING OF THE OIE AD HOC GROUP ON BRUCELLOSIS**

Paris, 9-11 January 2013

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**REPORT OF THE OIE AD HOC GROUP ON  
EVALUATION OF CONTAGIOUS BOVINE PLEUROPNEUMONIA STATUS  
OF MEMBERS COUNTRIES**

**Consultation by correspondence, 31 December 2012 - 13 January 2013**

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The *ad hoc* Group on Contagious Bovine Pleuropneumonia (CBPP) (hereafter the Group) was invited to evaluate a request from a Member Country for the recognition of CBPP free status. The Scientific Commission for Animal Diseases (Scientific Commission) agreed that this evaluation could be conducted by correspondence between the experts of the Group. The OIE secretariat facilitated communication amongst the experts, which took place via electronic means.

**1. Appointment of Chairmen and rapporteurs**

The meeting was co-chaired by Dr François Thiaucourt and Dr Herbert Schneider. Both participated in the final preparation of the present report.

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

**2. Evaluation of a request from a Member Country for CBPP free status**

The Group assessed one dossier, the only one received by the deadline for applications.

The Group agreed to keep the application on hold, pending certain verification of facts to be made and additional information collected. In accordance with Resolution No. 25 adopted at the 80th General Session, the Group recommended the Scientific Commission to request the Director General to deploy an expert mission to this country to verify some specific facts contained in its dossier before a decision or recommendation is made on the application of the Member Country.

The Group expressed its willingness to discuss the dossier again, once the expert mission had been completed.

**3. Finalisation and adoption of draft report**

The Group adopted this report on 21 January 2013.

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...Appendices

**OIE AD HOC GROUP ON  
EVALUATION OF CONTAGIOUS BOVINE PLEUROPNEUMONIA STATUS  
OF MEMBER COUNTRIES**

**Consultation by correspondence, 31 December 2012 - 13 January 2013**

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**Agenda**

1. Appointment of Chairmen and rapporteurs
  2. Evaluation of a request from a Member for CBPP free status
  3. Finalisation and adoption of draft report
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Appendix II

**OIE AD HOC GROUP ON  
EVALUATION OF CONTAGIOUS BOVINE PLEUROPNEUMONIA STATUS  
OF MEMBER COUNTRIES**

**Consultation by correspondence, 31 December 2012 - 13 January 2013**

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**OIE AD HOC GROUP ON THE INCLUSION OF CLASSICAL SWINE FEVER  
IN THE LIST OF DISEASES WITH OFFICIAL STATUS  
Paris, 16 – 18 October 2012**

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A meeting of the OIE *ad hoc* Group on the inclusion of classical swine fever (CSF) in the list of diseases with official status (hereafter the Group) was held at the OIE Headquarters, Paris, from 16 to 18 October 2012.

**1. Opening, adoption of agenda and appointment of chairperson and rapporteur**

The Group was welcomed by Dr Kazuaki Miyagishima, Deputy Director General and Head of the Scientific and Technical Department, on behalf of the Director General of the OIE, Dr Bernard Vallat. He informed the participants of recent trends in the OIE activities on official disease status recognition and of requests from Member Countries to expand the current list of diseases by adding CSF or PPR.

He then referred to the difficulties experienced between the Scientific Commission of Animal Diseases (Scientific Commission) and the Terrestrial Animal Health Standards Commission (Code Commission), when the latter considered that the draft revised *Terrestrial Animal Health Code (Terrestrial Code)* chapter on CSF developed by the Group and subsequently endorsed by the Scientific Commission represented a major departure from the approach taken in the current chapter, especially regarding the role of wildlife in determining disease status and also in relation to different categories of status. This led to the meeting between the Presidents of the two Commissions to seek a solution.

Dr Brückner, Representative of the Scientific Commission, informed the Group that both Code and Scientific Commissions had agreed that the incorporation of wildlife into the case definition should be revisited together with the provisions on surveillance and that changes to the chapter should be kept to a minimum given that the original request had been to provide for official recognition of CSF free status based on the principles in the current *Terrestrial Code* chapter. For this reason, the addition of new articles to differentiate free zones and countries with and without vaccination should be abandoned, even though he recognised that the Group had based its first work on the approach adopted for FMD.

The Group recalled that, for the moment, there were no validated means in the chapter on CSF of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* of distinguishing between vaccinated and infected pigs. The Group was informed by the OIE Secretariat that the *ad hoc* Group on CSF vaccines had met in June 2012 and was updating the *Manual* Chapter that would incorporate if relevant DIVA vaccines and tests.

The Group noted, against the above-mentioned background, the objectives of the present meeting, which were to propose a revised chapter including a new case definition as well as to review the articles on surveillance in Chapter 15.2 and review the questionnaire to see whether CSF could be added to the list of diseases with officially recognised status.

The meeting was chaired by Prof. Trevor Drew and the OIE Secretariat assumed the rapporteur functions. The adopted agenda and list of participants are attached as Appendices I and II, respectively.

## 2. Amendments to the *Terrestrial Code* Chapter 15.2

The Group agreed to base its work on the current version in the *Terrestrial Code* chapter on CSF and agreed on the following amendments:

- **Case definition**

The Group inserted a definition of “CSF virus (CSFV) infection” in Article 15.2.1 based on the previously proposed definition with some amendments. The Group simplified the text and harmonised the terminology with the case definition proposed for FMD so that CSF infection was defined from a sample rather than from pigs or pig products.

The Group agreed to retain the requirement for an epidemiological link with a confirmed outbreak when only using molecular detection, such as PCR, for confirmation, to provide additional assurance of the validity of the result.

Dr Bonbon, Representative of the Code Commission, drew the attention of the Group to the need of differentiating a case definition for the purpose of the *Terrestrial Code* and especially for notification purposes, and for the purposes of international trade and status.

The Group considered it was important to include captive wild pigs in the case definition for the purposes of international trade to account for the risk of spread of disease posed by this category of animals. The Group agreed that cases in wild or feral pigs should be notified but would not affect the recognised status of the free country or zone provided that biosecurity measures remained in place.

The Group clarified the use of the wording "field strain of CSFV" in the definition to make sure that the detection of CSF positives was not due to vaccination.

- **Harmonisation of wildlife-related terms**

The recent incorporations to the Glossary of the *Terrestrial Code* of the wildlife-related definitions (captive wild animals, feral animals and wild animals) were taken into account by transposing these definitions into the context of CSF (e.g. the vernacular term “wild boar” was replaced by “wild and feral pigs” throughout the text).

The Group, noting that in some countries the control of wildlife was not always under the responsibilities of Veterinary Services, agreed to use the term “Competent Authority” where appropriate. This choice also provided for encouraging an interactive communication between the involved bodies.

The Group acknowledged the fact that the provisions for historical freedom and 25-year freedom in Article 1.4.6 required the demonstration that infection was not established in wildlife within the last 10 years. However, for CSF, the Group proposed that the official disease status only be affected by infection in domestic and captive wild pigs. For this reason, the Group did not insert any provisions for historical freedom in the chapter and decided to bring this point to the attention of the Scientific and Code Commissions to avoid inconsistencies across the *Terrestrial Code* chapters.

- **Disease freedom recognition**

The Group discussed the usefulness of keeping Article 15.2.2 on the pre-requisites for disease freedom recognition. The Representative of the Code Commission recalled that this approach had been taken from the *Terrestrial Code* chapter on avian influenza as it was dealing with only a specific animal sub-population in the country. The Group agreed not to delete the article and to make reference to it in Article 15.2.3 containing the key requirements to be recognised as disease-free. The Group agreed to change the title of Article 15.2.2 in case the official recognition of CSF status was granted. Similarly, the Group proposed insertion of a cross-reference in Article 15.2.2 to a relevant article (1.6.X) of Chapter 1.6 of the *Terrestrial Code*, where the questionnaire for the official recognition of freedom would be inserted, once adopted.

In relation to compartmentalization, the Group agreed to treat it separately from the provisions for free country or zone as compartmentalization was based on bilateral agreements. A new article (15.2.3.bis) was added to account for CSF free compartments.

### **3. Analysis of the surveillance provisions of the *Terrestrial Code* chapter for CSF to determine whether official recognition of CSF free status is feasible**

Articles 15.2.23 to 15.2.28 on CSF surveillance had been reviewed by the Group at its previous meeting and were taken into account for this point of the agenda. The Group revised the text with the role of feral and wild pigs on the spread of CSF (Article 15.2.23) and reviewed several aspects that should be considered within the surveillance system in Article 15.2.24.

- **Clinical surveillance**

The Group emphasized that clinical manifestations of infection could be missed due to reasons such as low-virulence virus or immunotolerance. The intention of this paragraph in Article 15.2.25 was therefore to highlight that clinical surveillance was very valuable but that serological and virological surveillance were of equal importance.

- **Virological surveillance**

The Group discussed the importance of considering high mortality as a sign of CSF to start virological investigation. The Group acknowledged the importance of sending the isolates to an OIE Reference Laboratory to carry out necessary molecular investigations.

- **Serological surveillance**

The Group added one new point to this section in Article 15.2.25 to the effect that a Member Country should revise the surveillance strategy when there was an increased risk of introduction of CSF virus such as "an increase in the prevalence of CSF in wild or feral pigs".

- **Additional surveillance procedures for disease freedom**

The Group revised Articles 15.2.26 and 15.2.27.

Article 15.2.26 was simplified to include only the additional surveillance procedures to apply for disease freedom by removing redundancy. The Group agreed that the aim of this article was to enable Member Countries to demonstrate absence of infection in domestic and captive wild pigs and to specify the minimum time for which surveillance had been in place for that purpose (12 months). The paragraph dealing with compartmentalization was also deleted, as no provisions were included in this article additional to the requirements laid out in Chapters 4.3 and 4.4.

The purpose of Article 15.2.27 was to target surveillance in high risk areas or populations to provide greater assurance of the absence of infection. The Group also added cross-references to the containment zone.

- **Surveillance in wild and feral pigs**

The Group agreed that the requirements in Article 15.2.28 were challenging but necessary for Member Countries and also added the word "feral" to bring it in line with the categories defined elsewhere in the chapter. The Group also clarified point c) by adding that the degree of interaction with domestic and captive wild pigs had to be taken into account when proposing a free country or zone. The Group also amended point b) to acknowledge the difficulties in obtaining valid data on wild and feral pigs. Another change agreed to by the Group was to replace the wording "wildlife conservation organisation" with "governmental and non-governmental wildlife organisations". Finally, the Group amended the objective of the surveillance in this article to either demonstrate the absence of infection in wild and feral pigs or to estimate the prevalence if known to be present. Monitoring was expanded to include serological and virological testing.

- **Interpretation of diagnostic tests in surveillance**

The Group revised the diagram in Article 15.2.28.bis and deleted the parts relating to DIVA tests.

- **Harmonisation of surveillance terms**

The Group noted that the term ‘targeted surveillance’ was sometimes used without being defined in the *Terrestrial Code* Chapter 1.4, where the term ‘systematic non-random surveillance’ was used instead. The Group requested that this matter be referred to the Scientific Commission.

- **Containment zone**

The Group inserted a draft article on the establishment of containment zone and cross-referenced it to Article 4.3.3 (3) where the necessary requirements were already provided. A new point was added relating to the pattern of movements, density and control measures implemented to avoid dispersion of wild and feral pigs (Point 1b). A containment zone could not be applied in cases of CSFV infection in wild and feral pigs, but surveillance should be adapted in such circumstances.

#### **4. Finalisation of the draft questionnaire for Member Countries submitting applications for official recognition of CSF free status**

The questionnaires for CSF free countries and zones were reviewed and completed.

The Group discussed whether it was possible to merge the questionnaires for country and zone status since there were many common elements in these two. The Group agreed to submit both separate questionnaires and a merged questionnaire for consideration by the Scientific Commission.

#### **5. Adoption of the draft report**

The Group reviewed and agreed on the draft report provided by the secretariat.

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.../Appendices

Appendix I

**OIE AD HOC GROUP ON THE INCLUSION OF CLASSICAL SWINE FEVER  
IN THE LIST OF DISEASES WITH OFFICIAL STATUS**

**Paris, 16-18 October 2012**

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**Agenda**

1. Opening, adoption of agenda, and appointment of chairperson and rapporteur
  2. Amendments to the *Terrestrial Code* chapter
  3. Analysis of the surveillance provisions of the *Terrestrial Code* chapter for CSF to determine whether official recognition of CSF free status is feasible.
  4. Finalisation of the draft questionnaire for Member Countries to support submission of applications for official recognition of CSF free status.
  5. Adoption of the draft report.
-

Appendix II

**OIE AD HOC GROUP ON THE INCLUSION OF CLASSICAL SWINE FEVER  
IN THE LIST OF DISEASES WITH OFFICIAL STATUS**

**Paris, 16-18 October 2012**

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## MEETING OF THE OIE AD HOC GROUP ON EPIDEMIOLOGY

Paris, 2 - 4 October 2012

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The meeting of the OIE *ad hoc* Group on Epidemiology (hereafter the Group) was held at the OIE Headquarters in Paris. On behalf of the Director General of the OIE, Dr Kazuaki Miyagishima welcomed the participants describing the main items laid out in the agenda. He emphasised the importance of finalising both the revision of the surveillance articles of the Chapter 8.5. on Foot and mouth disease (FMD) in the *Terrestrial Animal Health Code (Terrestrial Code)* and the Guide for Terrestrial Animal Health Surveillance.

### 1. Adoption of the agenda and appointment of a rapporteur

The meeting was chaired by Dr Cristóbal Zepeda and Dr Vitor Picão Gonçalves acted as rapporteur. The adopted agenda and list of participants are attached as Appendices I and II, respectively.

### 2. Feedback from the Scientific Commission meeting of 27-31 August 2012

The Group was informed about the decisions of the Scientific Commission for Animal Diseases (Scientific Commission) at its last meeting in August 2012 as they related to the work relevant to this Group.

### 3. Review of the articles on surveillance of *Terrestrial Code* Chapter 8.5

Upon request of the Scientific Commission the Group reviewed the articles on FMD surveillance in the *Terrestrial Code* Chapter 8.5. The Chairman of the *ad hoc* Group on the evaluation of FMD status of Member Countries attended the meeting to ensure consistency in the approach taken in the review of the Chapter.

The Group agreed that the recommendations on FMD surveillance should not be excessively prescriptive, in order to allow countries to adapt the principles laid down in the *Terrestrial Code* to their specific epidemiological conditions.

As the Chapter also dealt with OIE endorsed official control programme for FMD, the Group agreed that an additional article on surveillance applicable in this situation should be included.

The Group agreed that the term “passive surveillance” should be avoided as much as possible throughout the text because the Group realised that it was not an adequate qualifier for these very important surveillance activities, notably in the case of FMD, and that the term was progressively being avoided in the wider community of epidemiologists. In addition, the term “laboratory testing” was replaced by “diagnostic testing” throughout the Chapter with a view to taking pen-side tests into account.

The Group stressed the need to include the concept and definition of risk-based surveillance in the *Terrestrial Code* in order to be in line with the most widely used and accepted terminology, currently used in textbooks and elsewhere in technical and scientific publications. The use of the term “risk-based surveillance” was kept to a minimum because the term was not yet formally approved by the OIE; however the Group found it very difficult to use an alternative term in parts of the text where the concept applied.

In Article 8.5.43 (Surveillance: general principles), the role of wildlife was included as one of the possible risk factors that might be taken into account when designing risk-based surveillance strategies. Although this article already contained a cross-reference to the surveillance strategies in Chapter 1.4, those surveillance strategies other than risk-based ones were also considered and outlined in point 2 of Article 8.5.43 for clarification.

In Article 8.5.44, “strategies” in the title was replaced by “methods”. The introduction section of this article was transferred to and merged with Article 8.5.42, which was entitled “Surveillance: introduction”. The references to monitoring of at-risk populations and to daily mortality were removed because these did not apply to virological surveillance of FMD. In the same article, the rationale for including heterophile serological (cross) reactions in the general context of FMD surveillance was discussed. The lack of specificity of the diagnostic tests used was added by the Group to the list of causes for positive FMDV antibody results. The Group agreed that the question as to whether to keep or remove the point on heterophile reactions should be referred to the *ad hoc* Group on FMD.

The Group noticed that the wording in the beginning of Articles 8.5.45 to 8.5.47 was not harmonized and proposed to start the sentence with “Members...” and favoured “to provide evidence for the existence...” over “to show evidence of...” in relation to a surveillance programme.

In Article 8.5.46 (additional surveillance procedures for Members applying for FMD freedom with vaccination) the Group decided to request the Scientific Commission and the *ad hoc* Group on FMD to make it clear whether wildlife was included in the “susceptible population in the last 12 months” or this referred to domestic animals only. The Group agreed that the assessment of the level of herd immunity achieved by the vaccination programme was not relevant for the purpose of granting free status with vaccination, as previously stated in Article 8.5.46, because some Member Countries might be phasing out the vaccination scheme. In addition, at this stage of the Global FMD Control Strategy, the relevant issue was the demonstration of absence of virus circulation.

For Member Countries applying for OIE endorsed official control programme for FMD that used vaccination, the assessment of immunity levels in the vaccinated population was relevant. The Group recognised that Member Countries where such studies were to be conducted should estimate herd-level immunity and within-herd immunity, rather than looking at general proportions of protected animals. It was not possible to provide precise targets for these parameters due to the variable conditions of different epidemiological regions and countries. However, the suggestion of a minimum target of 80% protection of vaccinated animals was kept in the text rather as a programme management tool, aimed at decision-makers, than as a science- or evidence-based parameter to be recommended in field studies. A new Article (8.5.48 Bis) was drafted to include this concept.

The Group updated Article 8.5.47 (additional surveillance procedures for Members re-applying for freedom after an outbreak) with the provision of specific surveillance activities that should be carried out by Member Countries reapplying for recognition of official disease status following an outbreak, in addition to the disease control methods described in the current version of the article.

The Group was asked to outline additional surveillance that would enable the reduction of the period stated in Article 8.5.9. 1c) from 6 to 3 months. Currently, the *Terrestrial Code* recommended a serological survey to demonstrate the absence of infection. Should the period be reduced to 3 months, the Group suggested that all animals in vaccinated herds should be tested for NSP antibodies and the follow-up procedures in Article 8.5.49.1 be applied. The Group suggested that a sentence be added in Article 8.5.49.1 to clarify that these procedures also apply to Member Countries using emergency vaccination. The increase in intensity of surveillance would aim at compensating the difference in the waiting period. The Group recognised the possibility of some infected animals failing to react to NSP tests as well as the lack of information on the frequency of such event and on how it might be influenced by the length of the waiting period. Therefore, no additions to the chapter were proposed and the Group recommended that the *ad hoc* Group on FMD provide an opinion on the matter.

Lastly, some texts were re-arranged amongst the surveillance articles of the Chapter with a view to improving clarity and readability.

**4. Updating on the draft text “Guide for Terrestrial Animal Health Surveillance”**

The Guide was considered ready to be published, after the Group made some minor editorial changes. Chapters 4 and 5 had a very long list of references but all of them were considered valuable and necessary by the Group. The Group was informed that a reviewer had proposed to add terms that had been approved by the international community to the glossary. However, the Group considered that the glossary contained the terms that were used throughout the Guide and did not consider necessary to include additional definitions. The Group also noted that the numbering in the index still needed to be harmonised with the page numbering. The effort of Dr Susanne Munstermann (OIE Scientific and Technical Department) in the development of the final document was recognised and the Group suggested that a section of acknowledgments to the individuals and organisations who contributed to the Guide should be included. A Foreword was also proposed as requested.

**5. Other matters**

Dr Mariner offered to host the next meeting in Kenya.

**6. Adoption of the draft report**

The Group reviewed and approved the draft report provided by the rapporteur.

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.../Appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON EPIDEMIOLOGY**

**Paris, 2 - 4 October 2012**

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**Agenda**

1. Adoption of the agenda and appointment of a rapporteur
  2. Feedback from the Scientific Commission meeting of 27-31 August 2012
  3. Review of the articles on surveillance of *Terrestrial Code* Chapter 8.5
  4. Updating on the draft text “Guide for Terrestrial Animal Health Surveillance”
  5. Other matters
  6. Adoption of the draft report
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## Appendix II

## MEETING OF THE OIE AD HOC GROUP ON EPIDEMIOLOGY

Paris, 2 - 4 October 2012

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**MEETING OF THE OIE AD HOC GROUP ON EPIDEMIOLOGY****Teleconference, 28 January 2013**

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A distance-meeting of the OIE *ad hoc* Group on Epidemiology (hereafter the Group) was held telephonically between the OIE Headquarters and the participants with duration of around 2 hours. The objective of this meeting was the consultation of the articles on surveillance in the draft chapter on Infection with Peste des petits ruminants (PPR) virus of the *Terrestrial Animal Health Code (Terrestrial Code)*. In November 2012, the *ad hoc* Group on PPR had drafted new articles that would allow PPR to be added to the list of diseases for which the OIE officially recognised disease-free status of countries or zones.

**1. Adoption of the agenda and appointment of a rapporteur**

Dr Martinez, the OIE Secretariat, served as rapporteur. The adopted agenda and list of participants are attached as Appendices I and II, respectively.

**2. Review of the draft articles on surveillance of the *Terrestrial Code* Chapter 14.8**

Upon request of the Scientific Commission, the Group reviewed the articles on PPR surveillance as drafted by the *ad hoc* Group on PPR. The Chairman of the *ad hoc* Group on PPR participated in the meeting to ensure consistency in the approach taken in the review of the Chapter of the *Terrestrial Code*.

The Group agreed that the recommendations on surveillance for Member Countries applying for the recognition of PPR freedom should be sufficiently flexible so that an appropriate combination of both random and non-random sampling could be recommended. This way, sampling would be more sustainable, particularly at a low prevalence of infection.

The Group agreed that clinical surveillance was the basis of surveillance and discussed whether the absence of clinical signs would be sufficient to demonstrate freedom. The Group recalled that after two years without vaccination, the susceptible population was expected to be naïve at a turn-over rate of around 75%. The Group concluded that a risk would exist that certain infections remain undetected. Therefore, the recommendation to combine clinical surveillance with other surveillance strategies such as serological surveys was maintained.

The Group suggested three changes to the draft article 14.8.27 on Surveillance strategies:

1. To add several words as follows: “The strategy employed should be based on an appropriate combination of randomised and targeted sampling requiring...”
2. To move the text under “Introduction” to article 14.8.29 on requirements for Member Countries applying for recognition of PPR freedom
3. To delete under point 2. *Clinical surveillance*, the second sentence: “Whereas significant emphasis is placed on the diagnostic value of mass serological screening, surveillance based on clinical inspection should not be underrated” and replace it with “Clinical surveillance and epidemiological investigations are the cornerstone of all surveillance systems and should be supported by additional strategies such as virological and serological surveillance”. To ensure the flow of the text, the Group also suggested the next sentence to start with “Clinical surveillance may...”.

### 3. Other matters

The Group noted that the term “risk-based” had not been adopted yet by the OIE and therefore continued using the term “targeted” for the sampling strategy. The Group agreed that the term “risk-based” would describe more accurately the sampling strategy. The Group emphasised that risk factors should be adequately identified especially in the last stages of disease eradication, to guide risk-based sampling for trade purposes. The Group agreed to recommend to the Scientific Commission to develop, as a horizontal element in Chapter 1.4 of the *Terrestrial Code*, more specific guidelines on risk based sampling and identification of risk factors to support such sampling.

### 4. Adoption of the draft report

The draft report was circulated among the participants and adopted by correspondence.

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.../Appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON EPIDEMIOLOGY**

**Teleconference, 28 January 2013**

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**Agenda**

1. Adoption of the agenda and appointment of chairman and rapporteur
  2. Review of the articles on surveillance of the draft Terrestrial Code chapter on Peste des petits ruminants
  3. Other matters
  4. Adoption of the draft report
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Appendix II

**MEETING OF THE OIE AD HOC GROUP ON EPIDEMIOLOGY**  
**Teleconference, 28 January 2012**

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**MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION  
OF FOOT AND MOUTH DISEASE STATUS OF MEMBER COUNTRIES**

**Paris, 9 – 12 October 2012**

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**1. Opening**

A meeting of the OIE *ad hoc* Group on the Evaluation of Foot and Mouth Disease (FMD) Status of Member Countries (hereafter the Group) was held at the OIE Headquarters, Paris, from 9 – 12 October 2012.

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Kazuaki Miyagishima, Head of the Scientific and Technical Department welcomed the participants. Dr Miyagishima thanked the Group for accepting to participate in four meetings this year that were considered by the OIE necessary to finalise the revision of Chapter 8.5 in the OIE *Terrestrial Animal Health Code (Terrestrial Code)* in addition to addressing the increasing number of applications for endorsement of official control programmes for FMD to be evaluated. He emphasised that the actions of the OIE and Food and Agriculture Organization of the United Nations (FAO) were linked more intimately through the commitment of the two Organisations to collaborate together for advancing the global control of FMD. At the global conference on FMD control held in Bangkok from 27 to 29 June 2012 jointly organised by the OIE and FAO, a global FMD control strategy was endorsed with strong support from some donors to provide funding to control the disease. The conference had created a new dynamism to increase communication with a clear, common message from the OIE and FAO.

Dr Miyagishima reminded the experts on the OIE procedures for protecting the confidentiality of information and for declaring potential conflicts of interest. He also informed the Group on the significant changes brought in the OIE Standard Operating Procedures for official recognition of disease status and for the endorsement of official control programmes of Member Countries for FMD (SOP) based on the experience gained to date. He mentioned that the deadline for submitting the dossier was extended to 45 days prior to the meeting of the relevant *ad hoc* Group compared to 30 days previously to give more time to the experts to study the dossier. In line with this and because the OIE would expect an increase in the number of applications, more experts would be involved to cover sufficiently all the three official languages of the OIE as dossiers could be submitted in any of the OIE official languages. He also informed the Group that the record of evaluations for unsuccessful applications needed to be more detailed so as to improve the communication with the applicant Member Countries, while protecting confidentiality as appropriate. To support the increasing workload, the OIE reinforced the OIE secretariat serving the *ad hoc* Groups relating to official disease status.

Dr Miyagishima clarified that as a matter of principle, an application for endorsement by the OIE of an official control programme should be handled and assessed independently from the presence or absence of zones located in the same country and already officially recognised as free from FMD. However, any evidence submitted from a country could be verified by the Group one against another across the dossiers before drawing a conclusion.

Finally, the Group was informed that the OIE decided to allocate to this meeting all the applications dealing with official control programme for endorsement to ensure consistent approach in the evaluations.

## 2. Adoption of the agenda and appointment of chairperson and rapporteur

The Group was chaired by Dr Alf-Eckbert Füssel and Dr Wilna Vosloo acted as rapporteur. The Group adopted the proposed agenda as agenda for the meeting. Drs Moetapele Letshwenyo and Mehdi El Harrak were absent due to other commitments. One of them provided his comments regarding the evaluation of the official control programmes to be shared with the Group.

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

## 3. Revision of Chapter 8.5.

The Group reviewed mainly the surveillance Articles (8.5.44 – 47 and 49) as amended by the *ad hoc* Group on Epidemiology at its meeting from 2 to 4 October 2012. Owing to lack of time, the Group decided to address the comments provided by the February 2012 meeting of the Scientific Commission at its forthcoming December meeting, building on the discussion so far and all other comments received.

## 4. Evaluation of a request from a Member Country for recovery of FMD free zone status where vaccination is practised

### Turkey

The Group reviewed the dossier submitted by Turkey to apply for recovery of FMD free zone status where vaccination is practised in the Turkish Thrace region. The Group discussed in detail the results of the serological surveillance Turkey conducted in 2012 while analysing the map indicating the random distribution of non-structural proteins (NSP) sero-positive animals detected during the sero-survey carried out in 2012. The follow-up actions put in place by Turkey and described in the dossier to clarify whether these sero-positive animals (e.g. cattle, sheep and water buffalo) were considered as FMDV infection/circulation or as non-specific reactions, were deemed sufficient to rule out FMDV infection/circulation in domestic animals in the Turkish Thrace region. However, the Group regretted that Turkey, instead of conducting more surveillance in wild boar in 2012, mostly made reference to the European Food Safety Authority (EFSA) report in this subject, which, for a significant part, relied upon the surveillance results obtained in Bulgaria, to show that the disease had most likely died out in the area.

The Group agreed to recommend to Turkey - as matter of priority - that Veterinary Services should interact with other relevant bodies in order to carry out surveillance during the hunting seasons to prove the absence of FMD. The Group also agreed to encourage Turkey to continue monitoring the FMD situation in domestic animals and wildlife in the Turkish Thrace region.

The Group considered the surveillance conducted adequate to demonstrate the absence of evidence of virus infection/circulation in the Turkish Thrace region and therefore decided to recommend to the Scientific Commission the reinstatement of FMD free zone where vaccination is practised in the Turkish Thrace region.

## 5. Evaluation of requests from Member Countries for endorsement of official control programme for FMD

The Group noted that the OIE had received a total of five applications for endorsement of official control programme for FMD, to be evaluated at this meeting.

The Group noted that the Article 8.5.48 of the *Terrestrial Code* for endorsement of official control programme for FMD clearly indicated the provisions needed to apply for an OIE endorsed official control programme for FMD but did not refer to the PCP and its five Stages. According to the PCP, Member Countries could submit to the OIE their official control programme for endorsement only when they have reached Stage 3. The Group reiterated the importance for a country to carefully consider the most appropriate timing to submit its official control programmes to the OIE in the light of the progress made by the country. The Group noted that although the use of the PCP was not obligatory, it could be used by countries to self-evaluate their state of progress.

The Group noted that three on the five applicant Member Countries were at the very early stages of the implementation of their national control programme for FMD and had put into practice few measures in accordance with Article 8.5.48. The assessment carried out by the Group concluded that the progress in their control strategy did not meet the requirement for endorsement. It was therefore considered premature for the three applicants to submit their official control programme for endorsement. In addition, the Group noted that although the applicants followed the structure of the questionnaire in their submissions, the documentation given was not enough detailed for conducting an appropriate assessment of the dossiers in accordance with the relevant articles of the *Terrestrial Code*. For these applications, the Group agreed that instead of providing general or specific feedback on each point in the documentation, the OIE should draw the attention of the applicant countries to all the necessary references in the *Terrestrial Code* and any relevant additional documentation which the countries needed to fully comply with. These countries would then be requested to review their status objectively and holistically before re-submitting an application in several years' time.

The Group recommended that the OIE encourage the three applicant Member Countries to provide, in future, more detailed and complete information to enable the OIE to conduct a thorough assessment of dossiers in accordance with the requirements laid out in Article 8.5.48. through the use of the questionnaire provided in Article 1.6.8 of the *Terrestrial Code*. The Group also agreed that all applicant Member Countries should be made aware that they could seek advice/assistance from the OIE Regional/Sub-regional Representations regarding the preparation and submission of dossiers.

As regards the two remaining applications, the Group decided to request supplementary information so that it can complete its assessment at its December meeting.

## 6. Other matters

The Group requested that all dossiers submitted in French or Spanish languages be translated (not only the executive summary part but at least the main body of application) into the main working language of the Group so that decisions would be based on the inputs from all members of the Group. Noting the financial implications of this process to the OIE, the Group agreed that Member Countries were welcome to supply translation on a voluntary basis together with the original dossier.

The Group expressed the need to extend the meeting planned in December 2012 to a five-day meeting to allow for the finalisation on the *Terrestrial Code* Chapter and the assessment of the Member Country applications.

## 7. Adoption of report

The *ad hoc* Group reviewed and amended the draft report provided by the rapporteur. The Group agreed that the report captured the discussions but should be circulated to the entire Group for final comments.

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.../Appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION  
OF FOOT AND MOUTH DISEASE STATUS OF MEMBER COUNTRIES**

**Paris, 9 – 12 October 2012**

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**Agenda**

1. Opening
  2. Adoption of the agenda and appointment of chairperson and rapporteur
  3. Revision of Chapter 8.5.
  4. Evaluation of a request from a Member Country for recovery of FMD free status where vaccination is practised
  5. Evaluation of requests from Member Countries for endorsement of official control programme for FMD
  6. Other matters
  7. Adoption of report
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## Appendix II

**MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION  
OF FOOT AND MOUTH DISEASE STATUS OF MEMBER COUNTRIES**

**Paris, 9 – 12 October 2012**

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**MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION  
OF FOOT AND MOUTH DISEASE STATUS OF MEMBER COUNTRIES**

**Paris, 10 – 14 December 2012**

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A meeting of the OIE *ad hoc* Group on the Evaluation of Foot and Mouth Disease (FMD) Status of Member Countries (hereafter the Group) was held at the OIE Headquarters from 10 to 14 December 2012.

**1. Opening**

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Elisabeth Erlacher-Vindel, Deputy Head of the Scientific and Technical Department, welcomed the Group. Dr Erlacher-Vindel reminded the Group of the importance of the OIE policy concerning declaration of interest and confidentiality undertaking.

Dr Erlacher-Vindel supported the use of a common template for pre-evaluation recently provided to the Group members by the OIE secretariat in order to give clear structure and transparency to the process of assessment. The Group was requested to discuss the format and provide inputs on its use for future meetings.

Dr Erlacher-Vindel congratulated the Group for the important work so far done to revise the Chapter of the *Terrestrial Animal Health Code (Terrestrial Code)* and emphasised the finalisation of this revision as a matter of priority for this meeting.

Dr Erlacher-Vindel welcomed the two experts that were attending a meeting with the Group for the first time. She stressed that while the OIE was reinforcing the capacity of the Group to handle French and Spanish languages, Member Countries must always follow the format provided in Chapter 1.6. of the *Terrestrial Code* and observe the Standard Operating Procedures for official recognition of disease status to facilitate timely translation and evaluation of dossiers.

The Group was reminded of the key aspects of the FMD Progressive Control Pathway (PCP). The use of the PCP was not obligatory for countries and could be used by them to self-evaluate their state of progress. But as this tool was not part of the *Terrestrial Code*, the non-use of the PCP could not constitute a reason for not endorsing an official control programme for FMD. The Group was informed that OIE regional and sub-regional representations had been tasked to provide technical support to Member Countries willing to apply for the endorsement of their official control programme. The Group welcomed this information and emphasised the need that Member Countries received substantial help before submitting an application for the endorsement of official control programme, in order to evaluating the most appropriate timing for sending an application and avoiding to do it in a premature stage.

**2. Adoption of the agenda and appointment of chairperson and rapporteur**

The Group was chaired by Dr Alf-Eckbert Füssel and Dr Wilna Vosloo acted as rapporteur. The Group endorsed the proposed agenda.

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

### 3. Final revision of Chapter 8.5. to improve consistency in line with comments received from Member Countries

Chapter 8.5. of the *Terrestrial Code* was fully reviewed by considering the comments submitted by Member Countries and to discuss the surveillance Articles (8.5.44. to 8.5.47 and 8.5.49).

#### Article 8.5.1.

Ruminants were moved up in the listing of the third paragraph, considering that they were more important than tylopods in the epidemiology of FMD.

In the previously amended definition of *infection* the phrase ‘epidemiologically linked’ had been removed in the case where the virus/RNA was identified, to avoid a country refuting a result because of the absence of obvious epidemiological link. The possibility of obtaining false positive results has always to be considered due to laboratory contamination for example. The Group view was that all positive laboratory results whether from PCR or any other test need to be confirmed within the laboratory and after consultation with the field investigation teams. Taking this into account, the Group decided to further simplify the definition by removing reference to specific tests, details of which can be found in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)*.

Further to the new definition of infection, the definition of circulation was revised to refer to ‘recent’ infection. This would then exclude carriers.

#### Article 8.5.X. (merged article between Articles 8.5.2. and 8.5.4. which would be removed)

The Group worked on a merged version of the previous Articles 8.5.2. and 8.5.4., respectively about country and zonal FMD-freedom without vaccination, to create an Article on country/zonal freedom without vaccination.

The introduction was rewritten and clarified. The text was adjusted considering that a Member Country could not have a free status for the whole country and a zone of a different status within the territory. The reference to ‘protection from neighbouring countries’ was removed as the animals in a country or zone should be protected from more than just neighbours. However, the reference to neighbours was included when referring to borders. The Group wondered if containment zone should also be mentioned but finally agreed that the definition of a zone was including the containment zone.

Point 4 c) of this Article was changed as this point referred not only to animals but products such as semen. Consequently, the reference to Article 8.5.10. was moved to point 4 d).

Regarding the comment received from the Scientific Commission on point 4 d), the Group recognised that all 5 sub-points under point 4 should be maintained at all times after gaining freedom and could not see a reason why point 4 d) should specifically be linked to a time line. Retention of official disease status also required that countries/zones already having official status submit their confirmation of compliance every year. However, it was necessary to state the time period before recognition of freedom as at least 12 months for points 3 and 4. Articles 8.5.10., 8.5.11. and 8.5.14. were included as those regulations should demonstrably be followed.

Point 4 e) was clarified, changed to refer to both a country and zone, and reference to Article 8.5.11. was added. The Group identified various historical pathways for Member Countries/zone applying for freedom from FMD without vaccination for the first time. Prior to the application, there could be a history of outbreaks in the absence of vaccination or a history of vaccination. In these circumstances, there would be animals present in the country that were sero-positive due to exposure either to vaccine or infection more than 12 months before. This article was adjusted accordingly.

Regarding provision related to emergency vaccination in zoological collections the Group felt it should not be prescriptive as to which animals should be vaccinated; this should be the decision of the Member Country. Defining *zoological collection* was difficult, and sub-points a) to c) also aimed to define what should be seen as a zoological collection. Point a) was adjusted by adding additional information on what the collection was for (to exhibit animals and preserve rare species). The degree of captivity was difficult to define but at a minimum the collection should be registered.

The Group wished to provide guidance about how to manage a situation where there was more than one zone in a country, especially where the zones shared borders with each other and were of the same status. The Group noted that a resolution was adopted at the recent General Session that clearly outlined this and was used as guidance to put into this *Terrestrial Code* Chapter. This text was also provided for FMD free zones where vaccination is practiced.

**Article 8.5.Y. (merged article between Articles 8.5.3. and 8.5.5. which would be removed)**

The Group worked on a merged version of the previous Articles 8.5.3. and 8.5.5, respectively about country and zone free with vaccination to create an article on country/zone freedom with vaccination.

The introduction was rewritten and clarified, in accordance with the merged article for country/zone freedom without vaccination.

The Group agreed that a country could be recognised as an FMD free country with vaccination with a part of the country where vaccination is practised and other parts of the country where vaccination actually is not practiced. The sub-population described in this article could be, for example, only cattle or a geographically linked sub-population.

The Group agreed that a defined target population was by definition a sub-population. However, the Group looked at all the points where the term “target population” was used and agreed to change “target population” to “sub-population” in this article, but not in other articles where the term ‘target population’ was preferred because considered more descriptive.

If a country or zone that had already been recognised as free with vaccination was to change its status to FMD free without vaccination, it was required to have ceased vaccination at least 12 months before, and shown evidence that there was no infection during the past 12 months in accordance with Article 8.5.2. The Group discussed whether a country/zone should demonstrate the absence of infection since the beginning or at the end of the transitional period. The Group decided the *Terrestrial Code* should not be too prescriptive. The Group preferred that surveillance data be gathered at the end of the transitional period (that could then include the unvaccinated animals), just before the compilation of the dossier, with the understanding that dossiers would be evaluated according to the reasoning used by the applicant country/zone. The Group also clarified that the change of status should be approved by the OIE.

However, the Group suggested that this country/zone could maintain its status of “free with vaccination” until it was granted the new status, with a time limit of 24 months by the end of which the new dossier submitted by the country/zone should be evaluated by the OIE or its status would be lost. The length of 24 months was chosen as it might be difficult to obtain a new status within 12 months due to the current cycle of the OIE meetings. However, this length of time was a proposal and could be reviewed by the Scientific Commission.

**Article 8.5.6.**

Point 1) was clarified. There was some debate about the requirements for surveillance in a compartment which were equivalent to those for the endorsement of an official control programme and the recognition of an official status (Articles 8.5.42. to 8.5.47. and Articles 8.5.49.). If a country/zone could demonstrate freedom from infection, there should not be a need for establishing a compartment. On the other hand, a compartment should not be allowed in a country/zone without any disease control. This was the reason why there was a reference to the surveillance articles. Compartments should have been established at a time when there was no active disease, but the surveillance needed to ensure there was no disease close to the compartment. In the case where vaccination was used within a compartment, surveillance would also help to ensure the vaccines used in the compartment contained the correct strains. The Group changed this Article to consider only Articles 8.5.42 to 8.5.44.

Regarding point 2 c) I, for consistency, the Group copied the wording from the merged Articles for this Article on compartment, with necessary adjustments.

The Group linked point 2 e) indicating that compartment should have surveillance in operation for FMDV infection, with point 2 b) where absence of infection has to be proven to establish a compartment.

The Group specified that the traceability and animal identification in point 2 g) did not refer to the whole country /zone but only to the compartment.

Point 3 was adjusted to ensure countries provide sufficient information to address the risks from outside the compartment.

#### **Article 8.5.8.**

The rationale for the replacement of “case” by “outbreak” was linked to the definition of an epidemiological unit which referred more to livestock than wildlife. Therefore the Group decided that the introduction did not need reference to domestic animals in particular. A case outside the containment zone could then refer to wildlife and so cover the event of finding any infected species outside the containment zone.

The Group did not agree that the incubation period should be used in a similar way for all diseases as diseases differ, especially in terms of transmission. However, there was significant discussion previously on the waiting period, and since the containment zone was a very special situation, with very strict guidelines, it was decided that a minimum of one incubation period for FMD was sufficient. The Group was of the opinion that this period should be discussed for each disease separately.

In case of a new outbreak/case found after the establishment of a containment zone, it was decided to distinguish the locations of this outbreak/case: A case found outside the containment zone would make the disease-free status suspended. A case found within the containment zone would lead to suspension of the status if FMDV circulation is proved.

#### **Article 8.5.9.**

Flow charts were developed to facilitate the understanding of the different options for recovery of disease free status after an outbreak. The Group emphasised that these charts should be considered as summaries and should not be interpreted as specifying types of surveillance to be implemented. A note was added to the charts to indicate intense surveillance was required along all the options in the flow charts.

#### **Article 8.5.12.**

The Scientific Commission had requested the Group to revise the provisions on the ten-kilometre radius of safeguard, especially on the borders of countries, which were putting at disadvantage the farmers close to the borders with an infected neighbouring country. The Group kept the ten-kilometre radius for the establishment of compartments as this was a different situation.

The Group maintained the requirement for extra assurance that animals were protected from potential infection when close to a border of a country/zone with different disease status. The period was shortened from three months to 30 days in line with EU legislation and to cover two incubation periods. The ten-kilometre radius was based on the evidence that the risk of infection decreased significantly the further away one moved from a source of infection, also considering air-borne infection. When the animals originated from an area close to the border with an infected neighbouring country, the exact distribution of the outbreaks was not always available. So proof must be provided that the animals were well protected from the neighbouring countries. However, the ten-kilometre radius was kept for countries with several zones of different status. Proof was needed that within the same country, the animals had not originated within ten kilometres of a possible infection.

The Group considered the possible case of a Member Country newly recognised as free from FMD with recent history of outbreaks. The country may have seropositive animals one year later (animals with a history of infection but not detected because of absence of clinical evidence), despite application of modified stamping-out. The absence of requirement in Chapter 8.5.12. to refuse the importation of seropositive animals due to infection was addressed.

#### **Article 8.5.13.**

The wording about the ten-kilometre radius was changed, consistent with the discussion on Article 8.5.12.

The question arose as to whether there should be stipulations addressing the situation where animals were moved between two countries free with vaccination, especially when countries were vaccinating against different serotypes/strains. The *Terrestrial Code* mentioned disease-free status but not serotype-free status. Therefore, point 3 was adjusted to prevent movement of animals that have been vaccinated with serotypes different from those used in the importing country/zone.

**Article 8.5.14.**

This article addressed only animal movement to countries with higher status and the Group considered whether it should also consider the requirements to be applied in the trade between infected countries. Infected countries could have different serotypes or strains that should be prevented from introduction as this could impact on vaccines and other control measures. The Group concluded that this should be left to bilateral agreements between countries which should exchange information on the virus serotypes and strains present.

The Group decided to keep the ten-kilometre safeguard in point 4 of this article as this was movement from an infected country to free countries/zones and to allow movement, strict regulations were needed even if the ten-kilometre distance referred to neighbouring countries.

**Article 8.5.15.**

The Group added a point to ensure that donor bulls had not been infected at any point before semen collection.

**Article 8.5.17.**

In other articles the status of the country/zone was in the title and repeated in the text. The Group considered that countries could use the requirements of the article as an attestation when they negotiated trade conditions, and in that case, the repetition of language was needed to ensure that the requirements were easily understood.

**Articles 8.5.22. and 8.5.23.**

The Group recalled that the ten-kilometre radius had been brought in, based on the perceived risk of the movement (animals and their products). Since meat was of lower risk, the Group decided not to bring in extra mitigation steps such as the ten-kilometre radius.

**Article 8.5.25.**

The Group clarified that the 'official control programme' mentioned in this Article did not refer to the OIE endorsed programme as stated in Article 8.5.48..

The article made reference to establishments that did not address the epidemiological unit within the communal context. According to the glossary, an 'establishment' referred to 'premises in which animals are kept'. The Group discussed the replacement of 'establishment' by 'epidemiological unit'. Such a change would imply that the animals could be kept in a village with contacts from anywhere, while these animals should be kept together for 30 days with no contact with other animals. So the Group decided to keep the term 'establishment' as it was.

**Article 8.5.27.**

The Group agreed that when products are used for animal feeding, they should be treated, regardless of the origin, as there is always a risk that the disease might have been present at the time of collection of products. The article was changed, distinguishing products of animal origin depending on their use.

The current Article 8.5.27 did not require any treatment of raw milk intended for human consumption and of products of animal origin (from FMD susceptible animals) intended for feeding to animals, not excluding FMD susceptible animals, agricultural or industrial uses when originating from countries or zones free with or without vaccination.

The current Article 8.5.28 required for milk and dairy products from infected countries with a control programme that the milk, regardless of the intended use, was produced in disease free herds, subjected to inactivating processing and protected from recontamination. In this case precautionary measures were applied to prevent any FMDV introduction through imports of milk and dairy products.

The Group considered that milk could represent a risk, since virus is present in milk before clinical disease is seen. The risk of infected milk was therefore comparable for milk produced in FMD free countries or zones with or without vaccination. Consequently, milk from FMD susceptible animals intended for feeding to FMD susceptible animals should be treated to inactivate possible FMD virus.

**Article 8.5.41. bis. (former Article 8.5.48.)**

The Group noted that this Article was placed in between surveillance articles and recommended moving it before Article 8.5.42, so that the Chapter would be better organised in the order of introduction/ freedom/ trade recommendations depending on status/ endorsement of control programme/ surveillance.

The introduction was changed to indicate that the programme is applicable to the entire country.

The Group clarified that implementation of a control plan was required, and not just surveillance and plan on paper

**Article 8.5.42.**

The word 'reestablishment' was changed to 'recovery' to stay consistent with terms used elsewhere in the Chapter.

The Group added a paragraph to address the specific needs for both endorsed programmes (see comments on Article 8.5.48.Bis) and establishment and maintenance of compartments.

The Group considered circumstances where the prevalence was very low, and where targeted or risk based surveillance would be more effective. The article was changed to emphasize this.

**Article 8.5.43.**

The Group noted that the term 'risk-based' still needed clarification in the OIE system and agreed to keep 'targeted surveillance'. The term 'risk based surveillance' previously proposed in point 2 b) was replaced with 'targeted surveillance' (now point 3a). Furthermore, the Group was of the view that the identification of risk factors should determine which ones should be included in the surveillance system. The article was changed accordingly.

**Article 8.5.44.**

The Group recognised the active role of veterinary para-professionals in detection of clinical signs and adjusted the article accordingly.

The Group removed the reference to antigens in serological tests as this was fully described in Article 8.5.49.

The Group noted the emphasis on clinical surveillance, but realised it would be of less value in extensive farming systems than in intensive systems where farmers have regular, close contact with the animals. The article was changed to highlight the role of farmers as first component of early warning system, followed by close clinical inspection by trained people.

Regarding virological surveillance, the Group discussed the possibility and usefulness of swabbing at risk populations and looking for virus as was done in the United Kingdom during 2007. The Group considered that not all countries would use virological surveillance to monitor at-risk populations and this point was moved to the end of the list.

The Group increased consistency in the provisions related to serological surveillance to make them in line with virological surveillance. Part of the previous text was moved to Article 8.5.49. as it dealt with interpretation of serological tests.

**Article 8.5.45.**

The *ad hoc* Group on Epidemiology had wondered if wildlife should also be tested to prove absence of disease. The Group amended the text to consider risk-based and targeted surveillance in wildlife if deemed a risk.

Despite its title, the current article did not provide additional procedures on surveillance. The Group felt it was important to emphasise the requirement to prove absence of FMDV infection during the past 12 months after either vaccination or infection. The main discussion focused on the follow-up to be given on NSP positive animals. According to the definition of 'infection', such animals were infected and should be removed from the population. However, that should not be necessary if there had not been recent virus circulation. The text was adjusted to address this issue by requiring tests on young animals only.

**Article 8.5.46.**

The Group removed the information that did not deal with surveillance from this article. Information on population immunity surveillance, such as age of target population and ways to calculate population immunity, was provided.

The *ad hoc* Group on Epidemiology had noted that Member Countries with FMD free status with vaccination may be phasing out the vaccination scheme. The Group agreed to address this issue by requiring effectiveness of the vaccination programme and adequate level of vaccination coverage rather than a specific figure, such as 80% herd immunity.

**Article 8.5.47.**

The Group noticed that the current article repeated parts of Article 8.5.42. and addressed few additional procedures on surveillance. The Group considered that this article should be the one to provide surveillance provisions to shorten the waiting period required for recovery of status, from 6 to 3 months, when a country previously free without vaccination had an outbreak and used emergency vaccination not followed by the slaughtering of all vaccinated animals (cf. Article 8.5.9.).

The Group had asked the *ad hoc* Group on Epidemiology to provide specific feedback to allow for enhanced surveillance to shorten the waiting period when regaining freedom in Article 8.5.9. 1 c) from 6 to 3 months.

The Group noted that to prove the absence of infection in a vaccinated population, NSP tests should be performed. But taking into consideration the lower sensitivity of the test in vaccinated population, a large number of animals should be sampled to ensure there was no virus circulation.

The Group agreed that, to reach a sufficiently high confidence rate that there was no more infection all the vaccinated herds should be tested. The recommendation that all ruminants within the herd should be tested was accepted, but with a qualification for other species. Testing all vaccinated ruminants would provide information on both carriers and possible virus circulation. Regarding the testing of pigs, the Group considered that due to numbers of animals, it would not be possible to test all of them. Moreover, pigs did not become carriers. The Group agreed that a representative number of animals, based on an acceptable level of confidence, should be tested rather than all of them.

In case a positive animal was found, the requirements of Article 8.5.49. should be followed. However, if the number of positives exceeded a certain level, then it might indicate infection/virus circulation and further action would be needed.

**Article 8.5.48**

The Group moved this article before Article 8.5.42 to give a better structure to the chapter.

**Article 8.5.48.Bis.**

The Group agreed that the article proposed and drafted by the *ad hoc* Group on Epidemiology to address additional surveillance procedures for Member Countries seeking endorsement of their official control programme for FMD, was a repetition of Article 8.5.48. and surveillance articles, and should be deleted. However, the discussion highlighted that Article 8.5.42. did not consider official control programmes for endorsement and needed adjustment. Article 8.5.42. was modified accordingly.

**Article 8.5.49.**

The Group removed the information already provided in the *Terrestrial Manual* and restructured the article.

The Group expanded the article to consider Member Countries seeking for the recovery of their free status without vaccination.

The introduction was improved to provide more background, particularly on the difference between structural and non-structural proteins (SP and NSP) tests and their use. Parts from Article 8.5.44. were incorporated into the text.

The Group added a paragraph to list the possible causes for positive serological test results and provided guidance on the procedure to follow when sero-positive animals were found during post-outbreak surveillance. Paired serology and the use of sentinels were detailed.

The Group agreed to discourage excessive retesting after having found NSP-positive animals in absence of virus circulation and recommended removing the reactors. A positive result might be due to virus circulation, acute infection followed by recovery, acute infection followed by the development of the carrier state, or false positive test result(s).

The Group discussed the use of repeat and confirmatory tests, considering that the specificity was increased and sensitivity decreased when retesting only the samples that scored positive after the first round. Retesting with the same method should reduce the rate of false positive results. The Group insisted that both sensibility and specificity should be considered for the test system and not for the individual tests. The more samples were tested, the higher the specificity was required for the test system. The Group stressed that the choice of the confirmatory test should consider its concordance with the first test.

Finally, the current flow chart on laboratory tests was checked and minor changes suggested.

#### **4. Finalisation of the evaluation of requests from Member Countries for endorsement of official control programme for FMD**

##### **4.1. Bolivia**

The Group assessed the dossier for the endorsement of Bolivian official control programme. The reference to the 2011-2015 hemispheric plan was very general, and lacked details on specific actions and plans to reach FMD free status (with and/or without vaccination) for the whole country. The Group requested Bolivia to indicate their progress against the 2011-2015 hemispheric plan and whether any adjustments had been needed in terms of actions and timelines since 2011. The Group highlighted the importance of vaccination associated with testing of herd immunity as well as surveillance of virus circulation to plan and prioritise future actions in regions that were still not free from FMD.

The Group received from Bolivia the requested additional information. In addition to the official control programme submitted for endorsement, Bolivia sent a clear outline showing the plan for future control measures. In particular, Bolivia was aiming at obtaining official FMD free status for Santa Cruz y Pailon in 2013 and was submitting an application of FMD free status in Chaco and Valles for evaluation at this meeting. During the first semester of 2013, Bolivia would conduct a survey to look at population immunity and, with the assistance of several neighbouring countries, to apply for more FMD free zones with vaccination. Bolivia was also planning to define higher risk areas to focus active surveillance and perform longitudinal studies.

**Conclusion:**

The Group was satisfied with the additional information submitted by Bolivia and agreed to recommend the Scientific Commission that the official control programme of Bolivia for FMD be endorsed.

**4.2. Other Member Country request**

The Group assessed the request of another Member Country for endorsement of its official control programme for FMD which did not meet the requirements; the dossier was referred back to the corresponding Member Country.

**5. Evaluation of requests from Member Countries for recognition of FMD free zones****5.1. Requests for recognition of FMD free zone where vaccination is not practised****5.1.1. Argentina**

Argentina had submitted a dossier for the recognition of the summer pasture in the province of San Juan in April 2011. When assessed in June 2011, the Group asked specific questions mostly about the legislation of movement control of the animals between Argentina and Chile and management of animals once pasturing in the proposed zone. Argentina provided an answer in November 2012. The Group was satisfied with the additional information provided and recommended that the summer pasture in the province of San Juan be recognised as FMD free where vaccination is not practised.

**5.1.2. Peru**

The Group recalled that Peru had one FMD free zone where vaccination is not practised already recognised by the OIE: this zone consisted of two merged zones as designated in two documents submitted in December 2004 and in January 2007.

Peru had submitted a new dossier for the recognition of a new FMD free zone where vaccination is not practised along the coast.

The Group asked Peru to clarify if the proposed free zone without vaccination was to be merged with the current free zone without vaccination, considering that if the zones were to be merged, an outbreak in that merged zone would suspend the status of the whole zone, and if the zones were to be kept separated, Peru should demonstrate adequate movement control between the two zones having the same status. Peru indicated that the proposed free zone would be merged with the current free zone having already the FMD free status without vaccination.

The Group noted that the identification system with radio frequency was being implemented gradually in the country. The identification system would cover the proposed free zone without vaccination by June 2013.

Additional information was received on the animal movements into the proposed free zone.

The Group noted that results of the serological survey conducted in 2012 were provided but requested Peru to provide a summary of the results of the serological survey conducted in previous years. The Group was satisfied with the additional information received.

**Conclusions:**

The Group agreed to recommend that the proposed free zone along the coast of Peru be recognised as FMD free where vaccination is not practised.

### 5.1.3. Other Member Country request

The Group assessed the request of another Member Country for recognition of an FMD free zone where vaccination is not practised which did not meet the requirements; the dossier was referred back to the corresponding Member Country.

## 5.2. Requests for recognition of FMD free zone where vaccination is practised

### 5.2.1. Bolivia – Chaco and part of Valles regions

The Group recalled that Bolivia had three FMD-free zones already recognised by the OIE: an FMD-free zone without vaccination (Macro-Region of the Altiplano) and two FMD-free zones with vaccination (Chiquitania and the area adjacent to the east of Chiquitania). This new application proposed a new FMD-free zone with vaccination in Chaco and part of Valles regions.

Following the review of the dossier, the Group requested and received additional information from Bolivia, as follows:

Bolivia was requested to send an updated map that clearly indicated the different zones as already recognised or to be proposed for recognition by the OIE. The provided map indicated that the proposed free zone would share a border with the Chiquitania recognised zone. Bolivia clarified that these two free zones with the same status (the proposed zone and Chiquitania) were to be kept separate and not merge in a bigger zone. The Group wondered how Bolivia would ensure that there was strict and traceable movement control across the borders of the proposed zone with the already recognised free zone. Bolivia submitted additional and satisfactory information to explain the situation

Cattle identification, where applied, was mainly per group and not per animal, except in the previous high surveillance zone bordering Paraguay. Bolivia provided the Group with a plan showing that the group identification was implemented in the proposed free zone except in its Altiplano part where it would be implemented within 2 years.

Vaccination coverage seemed acceptable. Cattle younger than 24 months were vaccinated twice per year. In some areas within the proposed free zone, vaccination was only once per year based on risk analysis. However, data on population immunity were not up-to-date for the proposed free zone. The dossier mentioned that samples taken in June-July 2012 had been submitted for testing. At the Group's request, Bolivia sent those results to allow a comparison with the previous surveys. Bolivia was encouraged to continue performing these surveys to ensure the herd immunity was at acceptable levels.

The number of positive animals in serological surveillance was very low and there was no reason to believe there have been virus circulation. The Group agreed to encourage Bolivia to schedule surveys to ensure it would remain free of virus circulation in the future.

The Group wondered if the Bolivian laboratory (Laboratorio de Diagnóstico Veterinario) participated in proficiency tests rounds/inter-laboratory tests. Bolivia provided the results of its last participation in proficiency tests. Bolivia was encouraged to participate in proficiency tests rounds to safeguard the validity of its results.

In response to a request of the Group on additional information on the last outbreaks in Santa Cruz that happened in 2007, Bolivia provided detailed information during the meeting. Although they fell outside the proposed zone, the Group considered it was of importance especially investigation regarding the possible point of introduction.

The Group noted some gaps in the contingency plans such as disinfection and slaughter, but not sufficient to warrant an action from the Group.

The Group appreciated the quality of the serological surveillance but felt that it had been driven by the FMD official status application. Bolivia was strongly encouraged to extend their surveillance to cover the whole country.

The Group had significant difficulty understanding some tables in the dossier as there were no headings for every column and an asterisk seemed to indicate two different meanings. Bolivia was requested to ensure all future submissions were clear and that all pages, figures and tables were numbered.

**Conclusions:**

The Group recommended that the zone of Chaco and part of Valles be recognised as FMD free where vaccination is practised as separate from the zones previously granted with the same status.

**5.2.2. Peru**

The Group noted that Peru had submitted dossier for the recognition of a FMD free zone where vaccination is practised in the north along the border.

The Group requested additional information and received clarification from Peru.

The Group noted that the identification system with radio frequency was fully implemented in the proposed free zone with vaccination and was being implemented gradually in the remaining part of the country.

Peru provided additional information on the animal movements into the proposed free zone with vaccination, including on the prevention of illegal movement from neighbouring countries.

**Conclusions:**

The Group agreed to recommend that the proposed free zone in the north of Peru be recognised as FMD free where vaccination is practised. This would result in the entire territory of Peru be recognised as free, with two zones of different status, one larger zone free without vaccination (including the new proposed free zone and the existing free zone as recognised in 2005 and 2007, which would be merged together) and a smaller zone, free with vaccination acting as a protection zone along the border with its neighbouring country.

**5.2.3. Other Member Country request**

The Group assessed the request of another Member Country for recognition of an FMD free zone where vaccination is practised which did not meet the requirements; the dossier was referred back to the corresponding Member Country.

**6. Clarification of the need for regular notification to the OIE to obtain an official status. Consideration of changes in the questionnaire**

According to the *Terrestrial Code*, all Member Countries should report regularly to the OIE on their animal health status. The Group discussed whether this notification should be more explicitly stated as a requirement for granting and maintaining official status in the relevant Articles. The opinion of the Group was that the *Terrestrial Code* was clear enough that status could not be granted if the obligation of notification was not fulfilled.

**7. Other matters**

The Group requested the OIE secretariat to make it clear to applicant countries that appendices, tables and figures must be clearly numbered and referenced in all submitted documents. Documents (including appendices) that constitute a dossier must have page numbers to allow easy reference while reviewing the documents or communicating back to the countries. The Group emphasised the importance of an executive summary, which must be included in every single dossier. The Group also stressed that dossiers for the endorsement of an official control programme must not only summarise the current situation, but analyse what needed to be improved and provide a step-by-step plan that clearly showed how and when these goals would be attained.

Dr Paton provided feedback on a talk by Dr Angus Cameron given at a recent EuFMD meeting. Dr Cameron was developing an on-line tool to estimate the value of different surveillance activities in evaluating the probability of disease freedom over time. For example, the tool could reinforce the low sensitivity of serological surveillance dealing with a large number of animals by quantifying other measures, such as passive surveillance and slaughter-house surveillance. The tool would help assign values to measures such as data from slaughter houses, expert opinion or clinical surveillance. This would allow the addition of confidence limits to the estimates of each activity and to work on the overall probability that each activity would add.

The Group noted this new development and would consider the possible application of these principles within the OIE activities once the techniques became clearly established.

Dr Letshwenyo announced that he would be standing down from the Group due to other responsibilities he had to attend to. The Group thanked him for his contribution and would miss his inputs and presence sorely.

## **8. Adoption of report**

The *ad hoc* Group reviewed and amended the draft report provided by the rapporteur. The Group agreed that the report captured the discussions but should be circulated to the entire Group for final comments.

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.../Appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION  
OF FOOT AND MOUTH DISEASE STATUS OF MEMBER COUNTRIES  
Paris, 10-14 December 2012**

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**Agenda**

1. Opening
  2. Adoption of the agenda and appointment of chairperson and rapporteur
  3. Final revision of Chapter 8.5. to improve consistency in line with comments received from Member Countries.
  4. Finalisation of the evaluation of requests from Member Countries for endorsement of official control programme for FMD
  5. Evaluation of requests from Member Countries for recognition of FMD free zones
  6. Clarification of the need for regular notification to the OIE to obtain an official status. Consideration of changes in the questionnaire
  7. Other matters
  8. Adoption of report
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Appendix II

**MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION  
OF FOOT AND MOUTH DISEASE STATUS OF MEMBER COUNTRIES  
Paris, 10-14 December 2012**

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**REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON PESTE DES PETITS RUMINANTS**  
**Paris, 27–29 November 2012**

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The OIE *Ad hoc* Group on Peste des Petits Ruminants (the Group) met at the OIE headquarters from 27 to 29 November 2012.

On behalf of Dr Vallat, Director General of the OIE, Dr Miyagishima, the Deputy Director-General of the OIE, welcomed and thanked the participants for their contribution to OIE activities. He emphasised the strategic importance for the OIE of this meeting as the issue of official disease status recognition by the OIE on peste des petits ruminants (PPR) was receiving a lot of attention. Dr Miyagishima reminded the Group that there were currently four active diseases listed by the OIE for official disease recognition (African horse sickness, Foot and mouth disease (FMD), Contagious bovine pleuropneumonia, Bovine spongiform encephalitis) and there was the possibility of adding PPR as the fifth, especially following the momentum created by the eradication of rinderpest and the similarities between rinderpest and PPR in terms of availability of vaccines and the epidemiology of the disease. He observed that it might be possible to achieve the eradication of PPR in the medium term, if all countries take concerted action. He emphasised the need to combine the eradication efforts with the OIE's diseases freedom recognition mechanism in order to achieve verifiable eradication of the disease. Dr Miyagishima indicated that a possible target was to have the *Terrestrial Animal Health Code* chapter on PPR with provisions for official status recognition adopted by the OIE World Assembly in May 2014.

The representatives of the Scientific Commission for Animal Diseases (Scientific Commission) and the Terrestrial Animal Health Standards Commission (Code Commission) provided guidance to the Group reiterating the need for the articles in the revised chapter on PPR to take into account the principles of the *Terrestrial Code* chapters on surveillance and risk analysis. The sanitary measures for inclusion in the chapter should have clear scientific justifications and should not impose unnecessary burdens on countries while still ensuring safe trade in animal commodities. They urged the Group to critically review the available evidence and revise the *Terrestrial Code* chapter on PPR accordingly.

Those participants who had not attended the previous meeting signed a confidentiality undertaking, in line with the OIE procedures adopted at the 79<sup>th</sup> General Session of the World Assembly of Delegates to the OIE.

### **Adoption of the agenda and appointment of a chair and rapporteur**

The Group nominated Dr Adama Diallo as chair and Dr Wamwayi as rapporteur. The adopted agenda and list of participants are attached to this report as [Appendices I](#) and [II](#), respectively.

#### **1. Modification of the *Terrestrial Code* chapter on PPR following Member Country, Scientific and Code Commission comments**

The Group reviewed Chapter 14.8 of the *Terrestrial Code* on PPR taking into account the comments and proposals for amendment received from OIE Member Countries as well as the requests for additional information for scientific justification by the OIE Scientific and Code Commissions.

These concerned mainly the Group's previous inclusion in the draft *Terrestrial Code* chapter, of cattle, camels, buffaloes and wild ruminants as susceptible species for PPR and the introduction of sanitary measures for commodities from those species and for meat and meat products.

Following discussions on the available evidence for the involvement of cattle, camels, buffaloes and wild ruminants in the epidemiology of PPR, the Group agreed that the reported outbreaks involving these species appeared to be exceptional cases and the risks involved were not scientifically evident to the extent that warrants, at this stage, the inclusion of these species in sanitary measures for trade purposes. The Group considered that, although sheep, goats, cattle, camels, buffaloes and some wild ruminants were susceptible to infection with PPR virus, the available evidence suggested that only sheep and goats were epidemiologically significant in the spread of PPR. In light of this, the Group agreed that the commodities from cattle, camels, buffaloes and some wild ruminants should not be considered to pose a risk. Accordingly, the Group accepted the proposals from several Member Countries to exclude sanitary measures for PPR relating to commodities from cattle, camels, buffaloes and some wild ruminants. The Group also noted that when additional knowledge on the role of cattle, camels, buffaloes and some wildlife species in PPR would become available, it could guide future amendment of the *Terrestrial Code* chapter, if appropriate.

With regard to sheep and goats, the Group agreed with the concerns raised by Member Countries relating to the sanitary measures proposed for deboned skeletal muscle meat from sheep and goats. While there was a possibility of virus persisting in meat from these species, there was no evidence to support a risk that sheep and goats would be exposed in a non-experimental way to virus in the raw meat from these species. The Group took note of a publication<sup>1</sup> cited by New Zealand, which had concluded that the risk of transmission of PPR virus through meat was very low and did not warrant the imposition of the sanitary measures. The Group agreed that fresh meat and meat products from animals that had passed ante and post-mortem inspections were safe commodities with respect to PPR.

The Group observed that semen from sheep and goats was processed and stored in a manner that would enhance the preservation of the virus and there was need to apply sanitary measures for trade in this commodity. Sanitary measures were also retained for products including raw milk and milk products, raw hides, skins, wool and hair from sheep and goats.

The Group reviewed all the articles in the chapter making appropriate changes to give more clarity to and reduce of risks of different interpretations. For instance, in several articles, where reference was made to "...were kept in a quarantine station for 21 days prior to shipment", the Group suggested that this be amended to read "...were kept in a quarantine station for at least the 21 days prior to shipment"). The Group observed that the equivalent or similar text appeared throughout the *Code* and recommended that the Code Commission consider a review of the relevant chapters to harmonise these sentences.

Under Article 14.8.7, the Group considered the requirement for the serological testing of animals following vaccination with a live attenuated vaccine as unnecessarily severe and proposed the deletion of this requirement.

## 2. Elements for official disease status recognition

The Group worked on the articles that would allow PPR to become a disease with official status, for consideration by the Scientific Commission and the Code Commission in February 2013, so that sufficient time would be allocated for a review by Member Countries, with a view to final adoption at the General Session in May 2014, as had been proposed by the Director General of the OIE.

The Group agreed to discuss electronically the articles related to the endorsement of an official control programme for PPR in the PPR *Terrestrial Code* chapter and provided a proposal to the OIE.

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<sup>1</sup> MacDiarmid SC, Thompson EJ (1997), The potential risk to animal health from imported sheep and goat meat (*Rev. sci. tech. Off. Int. Epiz.*, **16**(1), 45-56)

The Group reviewed both the rinderpest and FMD questionnaires that were in the current *Terrestrial Code* and agreed that while the FMD questionnaire was a good and updated model, the rinderpest questionnaire (Chapter 8.12.) was a model better suited to PPR. While reviewing the rinderpest chapter during preparation of a PPR questionnaire, the Group realised that the revised chapter on PPR described the attainment of disease freedom without sufficiently defining conditions. Consequently, the Group made amendments to include articles relating to the declaration of freedom, criteria for historical freedom in accordance with Article 1.4.6. and a requirement that, for the recognition of a PPR free country or zone, vaccination has not been used for two years and the country or zone have not imported vaccinated animals in the past two years. Three additional new articles, on compartments, containment zones and infected countries, were adapted from the chapter on FMD. The Group also identified the need to develop a tool to monitor the progress of PPR control.

The Group developed two questionnaires for PPR as follows:

- i) Questionnaire on PPR free country: to be used by a Member Country which applies for recognition of status under chapter 14.8 of the *Terrestrial Code* as a PPR free country
- ii) Questionnaire on PPR free zone: to be used by a Member Country which applies for recognition of status under chapter 14.8 of the *Terrestrial Code* as a PPR free zone.

The questionnaire on a PPR free zone was adapted from relevant sections of the questionnaires on FMD.

The Group included incentives for reporting relevant information on surveillance in the questionnaire, and recommended that the questionnaires for other diseases in the *Terrestrial Code* would also include this proposal, rather than just considering penalties for non-reporting the disease to national authorities. The Group also noted that Article 1.6.6 mentioned a footnote (point 5b) that appeared only in the web version but not in the hardcopy version of the *Terrestrial Code*.

### 3. Advice on the steps to be taken to develop a Global PPR Control Strategy

The Group was informed that the GF-TADs<sup>2</sup> Global Steering Committee had decided to establish a PPR Working Group to develop a global PPR control strategy and that the global PPR situation was attracting an increasing interest of partners and donors. The PPR Working Group would follow the model of the FMD Working Group established in 2010. The steps for the preparation of the Global PPR Control Strategy were outlined as follows:

- a) FAO and OIE establish a PPR Working Group under the GF-TADs with specialists from FAO and OIE, modelled after the GF-TADs Working Group established for FMD.
- b) The PPR Working Group starts meeting in January 2013, initially to determine the need to complement the expertise within the Working Group. More experts from outside FAO and OIE would be invited as necessary.
- c) The President of the Scientific Commission reports to the OIE World Assembly in May 2013 about the actions being taken.
- d) The initial draft strategy document is peer reviewed by selected experts not involved in its preparation. It would also be reviewed by the OIE Scientific Commission and by the Global GF-TADs Management Committee.
- e) A representative of the GF-TADs Working Group on PPR would regularly attend the meetings of the OIE Scientific Commission and the relevant *ad hoc* groups to brief them on the activities of the Working Group and invite them to provide comments.

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<sup>2</sup> Global Framework for the progressive control of Transboundary Animal Diseases

- f) A draft Global PPR control Strategy becomes ready by December 2013.
- g) An international conference on PPR may be convened at a later date.

Following the presentation above, comments were invited from the representatives of FAO, AU-IBAR<sup>3</sup> and ILRI<sup>4</sup>. Dr Martin from FAO informed the meeting that the FAO had received an official mandate from the 37<sup>th</sup> FAO Conference to develop a Global PPR Control Strategy as soon as possible. In addition, FAO was dealing with a number of countries on PPR control and was currently developing a framework to guide the countries. The Working Group under the GF-TAFDs umbrella would need to take this FAO work into account when developing a joint OIE FAO Global Strategy to guide on-going initiatives. FAO would share with the Working Group documents already prepared. He indicated that it was necessary for OIE and FAO to agree on the appropriate budget for convening the Working Group.

Dr Wamwayi informed the Group that AU-IBAR, together with ILRI, had prepared and published a strategy for the progressive control of PPR in Africa. The strategy document had also been shared with the Group. The strategy recognised the need to fit within a Global Strategy and could be revised to ensure this in areas that may be at variance with the Global Strategy, once the latter had been developed. AU-IBAR was willing to participate in and share experiences with the GF-TADs Working Group for the development of a Global PPR Control Strategy.

Dr Mariner from ILRI informed the Group that the PPR Alliance was planning its next meeting in early 2013 and was ready to contribute towards the development of the Global PPR Control Strategy.

#### 4. Advice on the selection of vaccines used against PPR

The Group was informed that the diagnosis section of the *Terrestrial Manual* chapter on PPR had been adopted by the World Assembly in May 2012. The vaccine section would be presented for adoption at the next General Session in May 2013, and had been sent to the Member Countries for comment. It was however clarified that there was still an opportunity for the Group comments to be considered by the Biological Standards Commission meeting in February 2013.

The presentation of the vaccine section to the World Assembly had been delayed due to the suggestion made by the Group at its 2011 meeting to identify an alternative challenge system to replace the use of LD<sub>50</sub> for PPR, currently recommended in the *Terrestrial Manual*. The Group suggested that there may be need to consider a challenge on a working seed (tested at the highest recommended passage) and a certain level of the virus cell passage level and to consider that the final product produced within this parameter may not require live animal challenge for efficacy testing.

The attenuated Nigeria 75/1 was the only strain currently mentioned in the *Terrestrial Manual*. A strain developed in India had also been introduced for use but no particular vaccine was quoted in the revised *Terrestrial Manual* that would be presented for adoption in 2013. The Group noted that both vaccines were available commercially now, and it is up to users to select which one to use.

To enhance clarity several amendments were made to sections of the chapter on: serological tests, the method of manufacture, freeze drying, final product batch tests for target host safety testing, batch potency (removal of redundancy), and in-process controls. The Group noted that the paragraph on minimum dose should be placed under the section on batch potency.

The Group agreed on the need to determine the potency by virus titration of batches for each vaccine virus strain. Normally the minimum immunising dose was the lowest dose of vaccine virus that is able to induce 50 % protection plus 2 logs. In the case of the attenuated Nigeria 75/1 strain, the required minimum titre per dose had been demonstrated to be 10<sup>0.5</sup> TCID<sub>50</sub> for domestic small ruminants; therefore the recommended vaccination was 10<sup>2.5</sup> TCID<sub>50</sub> for those species. The Group agreed that the minimum immunising dose for other vaccine strains needed to be determined through challenge in domestic small ruminants.

<sup>3</sup> African Union Interafrican Bureau for Animal Resources

<sup>4</sup> International Livestock Research Institute

The Group proposed deletion of the reference to the possible use of PPR attenuated vaccines in other animal species.

The Group also proposed that the duration of immunity should be determined for each vaccine strain in animal trials. For the attenuated Nigeria 75/1 vaccine strain, this had been shown to be at least 3 years.

## 5. Review of the recent research developments and research initiatives on PPR

### Vaccines:

Dr Mariner briefed the Group on the work on-going at ILRI on the development of a thermostable vaccine for PPR based on the live attenuated Nigeria 75/1 vaccine strain. Comparisons carried out between trehalose-stabilised and sucrose-stabilised vaccines had shown that sucrose provides equivalent stabilisation of PPR virus as trehalose. The work at ILRI had demonstrated that the vaccine virus freeze-dried with 5% lactalbumin hydrolysate and sucrose was stable at 37°C for 155 days and these results were similar to those achieved for the thermostable rinderpest vaccine. On the other hand, the testing of Xerovac had shown that the shelf life of a 25 dose vial was 22.2 days at 37°C.

The Group welcomed the encouraging results from the work at ILRI. The Group observed that the information would not be considered by the Biological Standards Commission before publication in the scientific literature. The Group encouraged additional work to provide further evidence of the effects of the stabilisers in conferring thermostability to the vaccine virus and for the selection of the most appropriate method for thermostabilisation of PPR vaccine virus. These included the need for:

- comparison of freeze drying data with and without additives
- joint comparative studies between ILRI and PANVAC on the thermovax and Xerovac techniques for PPR vaccine.
- sharing available data on Xerovac as there seems to be no additional data generated since the initial publication (2001).

The Group also noted that there were currently on-going investments on the Xerovac technology transfer.

Dr Mariner also briefed the Group on the field component of the thermostable vaccine development that was testing new institutional models for delivering PPR control services. The work was being carried out in Sudan and Uganda under the coordination of AU-IBAR. The field component was examining incentives for participation in vaccination due to the need for more effective and efficient vaccinations given the large numbers of vaccines that would be needed to control PPR. He outlined the complexity and interrelationships of the animal health systems and institutions and emphasised the need to identify incentives, also mobilising a social science perspective, that enhance the participation of the different actors in disease control programmes. He concluded that there was a need for appropriate institutional set-up to ensure effectiveness and cooperation of the actors in PPR control programmes as was done in the final phase of rinderpest eradication.

Dr Domenech emphasized that the work on delivery systems was very important and the results of the AU-IBAR/ILRI study would inform approaches for the Global PPR Control/Eradication Strategy. He further noted that delivery systems would need to have a flexible mixture of public and private sector actors including professionals and community animal health workers.

Dr Diallo informed the Group of on-going research on the development of DIVA vaccines. He indicated that the proof of concept for DIVA vaccines using PPR virus Nigeria 75/1 infectious cDNA clones was now available from the Pirbright Institute (UK), CIRAD (France) and China, as discussed in an earlier meeting in London on the possibility to establish a PPR Alliance. The DIVA vaccines were based on recombinant products and other delivery systems. At the Pirbright Institute, work was on-going both on the removal of epitopes from a vaccine strain of PPRV as well as on the development of DIVA vaccines using adenovirus expression systems. In China, vector-based delivery systems were under development using capripoxvirus and canine adenovirus vectors.

**Serological tests:**

Dr Libeau informed the Group of research activities undertaken by CIRAD. There was no further progress to report on the development of new serological tests for PPR. Dr Libeau briefed the Group on on-going work on the role of camels and cattle in PPR epidemiology (maintenance and transmission) in Pakistan and Sudan, where prevalence of PPR antibodies of up to 30% in unvaccinated cattle and camels were being detected. However, testing of camel sera using the N-based cELISA N test showed negative results due to the properties of the camel immunoglobulin which clumped together and did not allow for competition in the cELISA. Alternative testing of the camel sera would be carried out.

Dr Baron informed the meeting that the H-based PPR cELISA was commercially available. PPR pen-side tests developed at the Pirbright Institute were working well but needed field testing in areas with active PPR. He also informed the Group that there had been no new developments on the detection of PPR virus nucleic acid using real-time PCR.

The Group noted that a new tool, using loop isothermal amplification (LAMP) technology had been developed for PPRV nucleic acid detection.

**6. Assessment of the need to develop PPR specific surveillance guidance**

The Group identified the need to develop PPR specific surveillance guidance and, with the collaboration of the representative of the *ad hoc* Group in Epidemiology, drafted new articles on PPR surveillance for Chapter 14.8 of the *Terrestrial Code*, using elements from the current rinderpest articles of the *Terrestrial Code*.

New articles covered: surveillance strategies; wildlife surveillance; Member Countries applying for recognition of freedom from PPR; Member Countries re-applying for recognition of freedom from PPR following an outbreak; the use and interpretation of serological tests for serosurveillance of PPR.

The Group agreed that key wildlife populations and other susceptible domestic species should be included in the design of the PPR surveillance strategy to establish disease freedom. The requirements for the PPR surveillance programme should include: an early warning system that entailed the reporting and investigation of all significant epidemiological events consistent with PPR, and regular and frequent clinical inspection and serological testing of high risk groups of animals.

The Group debated the need for randomised surveys for determining freedom from infection given the costs involved and the expected outcomes. The Group agreed that surveillance strategies that included randomised sampling were appropriate for demonstrating the absence of PPR virus infection with an acceptable level of statistical confidence while risk-based approaches might be appropriate to refine the surveillance strategy. Risk factors for the presence of PPR included: historical disease patterns, critical population size, livestock husbandry and farming systems, movement and contact patterns, transmission parameters and the demography of susceptible wildlife and other species. The Group agreed on the need for Member Countries to justify the choice of design, assumed minimum prevalence and confidence levels based on the objectives of the surveillance and the epidemiological situation. They proposed that this issue be further explored by the *ad hoc* group on Epidemiology.

**7. Update on the current situation of PPR in the world**

Reports were provided on the current global situation of PPR. Dr Diallo and Dr Libeau pointed out the fact that, while PPR virus lineage IV was the only PPR virus lineage so far circulating in Asia, there was a change in the geographical distribution of PPR virus lineages in Africa. In West Africa, samples collected from outbreaks in the region during the past couple of years showed that PPR virus lineage II was the most prevalent and lineage I appeared to be no longer circulating in the region (Mauritania, Senegal, Mali, Gambia, Sierra Leone, Côte d'Ivoire, Ghana, Burkina Faso and Benin). At the same time, in Central African countries, from the Central Africa Republic to Angola, PPR virus lineage IV was the only identified lineage at present. It was the lineage present in North Africa and it seemed to be replacing lineage III in Sudan and Ethiopia.

The Group observed that PPR was progressing towards Southern Africa with very severe recent outbreaks in Democratic Republic of Congo and Angola involving PPR virus of the lineage IV. In addition, Kenya reported outbreaks of PPR up to September 2012.

Sero-conversions had been detected in sheep and goats in Northern Zambia. A virus of lineage III was isolated from samples collected in this country.

In Asia, PPR virus was isolated from wildlife in China and the full genome data showed that this virus was the same as that isolated from goats in 2011. Similarly, in Sudan, the virus identified in camels using F and N gene sequences was the same as that identified in sheep and goat outbreaks in the country.

It was also noted that the presence of PPR virus lineage IV was identified in a scientific publication on PPR in wildlife in Iraq.

The Group noted that work was on-going to establish epidemiological linkages between the distribution of PPR virus lineages and the movement of animals through transhumance, trade etc.

#### **8. Any other business**

There was no other business.

#### **9. Adoption of the draft report**

The Group reviewed and amended the draft report at the end of the meeting. The Group agreed to circulate the report by email for final adoption. The chairman thanked the rapporteur and all participants in the Group for their active participation and productive discussions.

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.../Appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON PESTE DES PETITS RUMINANTS**

**Paris, 27-29 November 2012**

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**Agenda**

Adoption of the agenda, appointment of chair and rapporteur

1. Modification of the Terrestrial Code chapter on PPR following Member Country, Scientific and Code Commission comments
  2. Elements for official disease status recognition
  3. Advice on the steps to be taken to develop a global PPR control strategy
  4. Advice on the selection of vaccines used against PPR
  5. Review of the recent research developments and research initiatives on PPR
  6. Assessment of the need for developing PPR specific surveillance guidelines
  7. Update on the current situation of PPR in the world
  8. Any other business
  9. Adoption of the report
-

## Appendix II

## MEETING OF THE OIE AD HOC GROUP ON PESTE DES PETITS RUMINANTS

Paris, 27-29 November 2012

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### Summary of Commission Decisions on *Terrestrial Code* Chapters

Chapter	Status before SCAD meeting	Commission Decision
User's guide	New text proposed by TAHSC	Amendments proposed and forwarded to TAHSC
Glossary (risk-based surveillance)	Wait until jointly discussed with TAHSC	Next meeting agenda, to be jointly discussed with TAHSC
Glossary (emerging diseases)	New item	Opinion given. Deeper discussions between both Commissions needed.
6.7. Antimicrobial resistance (AMR) surveillance	Adopted at 80GS. MC comments (TAHSC to SCAD)	No time to see these comments
6.9 Antimicrobial agents	MC comments (TAHSC to SCAD)	Too many comments to see them in detail. Suggested TAHSC to comment first and to send to SCAD the comments that need scientific input.
6.10 AMR risk assessment	AHG address MC	Endorsed and shared with TAHSC, together with reports of the AHG
8.x. Brucellosis	AHG draft	Endorsed and shared with TAHSC, together with reports of the AHG
8.3 Bluetongue (BT)	MC comments (TAHSC to SCAD)	Some comments addressed, other forwarded to an AHG. Shared with TAHSC. New AHG on harmonisation of AHS, BT and EHD to be convened.
8.5 Foot and Mouth Disease (FMD)	AHG draft	Endorsed with changes and shared with TAHSC together with reports of the AHG on FMD and on Epidemiology. Circulate for Member Country comments
8.10 Article on rabies	New article drafted by TAHSC	Based on previous SCAD recommendations, text amended and forwarded to TAHSC
8.11. Rift Valley Fever	Wait until SCAD Feb13	New AHG to be convened. Shared info with TAHSC
8.12 Rinderpest	MC comments (TAHSC to SCAD)	Comments addressed and shared with TAHSC
8.15 Vesicular stomatitis	Wait MC comments on listing diseases	No action
9.1-9.6 Bee diseases	MC comments (TAHSC to SCAD)	AHG being consulted electronically
11.5 Bovine Spongiform Encephalitis (BSE)	MC comments addressed by AHG	Endorsed and shared with TAHSC, together with the AHG reports
11.6-11.7. Tuberculosis	Wait until SCAD Feb13	New AHG to be convened, ToR and agenda endorsed. Shared info with <i>Code</i> and request that a TAHSC representative be present.
12.1-12.11 Equine diseases	Wait until FEI opinion	New AHG to be convened. Endorsed ToR and agenda. Shared AHG with other Specialist Commissions
12.1 African Horse Sickness (AHS)	MC comments (TAHSC to SCAD)	Endorsed with changes and shared with TAHSC. New AHG on harmonisation of AHS, BT and EHD to be convened. Circulate for MC comments
12.9 Equine viral arteritis	MC comment forwarded for expert opinion	Endorsed and shared with TAHSC

Annex 15 (contd)

12.10 Glanders	Wait until SCAD Feb13	Expert opinion sought to find out if addition to diseases with official status still stood
14.8 and 1.6.x.Peste des petits ruminants (PPR)	AHG draft	Endorsed with changes and shared with TAHSC, together with reports of the AHG on PPR and on Epidemiology. Circulate for MC comments
15.8.and 1.6.x. Classical Swine Fever (CSF)	AHG draft	Endorsed with changes and shared with TAHSC. Circulate for MC comments
15.14.Swine vesicular disease	Wait MC comments on listing diseases	No action
X.X. New Chapter on Epizootic Haemorrhagic Disease (EHD)	MC comments (TAHSC to SCAD)	Some comments addressed, other forwarded to an AHG. New AHG on harmonisation of AHS, BT and EHD to be convened. Shared with TAHSC. Circulate for MC comments
X.X. New Chapter on Disease Control	MC comments (SCAD to TAHSC)	Comments addressed and shared with TAHSC. . Circulate for MC comments
X.X. New Chapter on PRRS	Expert opinion sought	Chapter development by an ad hoc Group to be convened. ToR and agenda endorsed. Shared with Code for information

AHG = *Ad hoc* Group

FEI = Fédération Equestre Internationale

MC = Member Country

SCAD = Scientific Commission for Animal Diseases

TAHSC = Terrestrial Animal Health Standards Commission

ToR = Terms of Reference

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