



**WORLD ORGANISATION FOR ANIMAL HEALTH**  
*Protecting animals, preserving our future*

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

**Paris, 15-19 September 2014**

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A meeting of the OIE Scientific Commission for Animal Diseases (the Commission) was held at the OIE Headquarters in Paris, France from 15 to 19 September 2014.

Dr Brian Evans, Deputy Director General and Head of the Scientific and Technical Department welcomed the Commission on behalf of Dr Bernard Vallat, Director General of the OIE and commended the members of Commission for their commitment in supporting the OIE activities recognising the notable increase of workload.

Dr Evans informed the Commission of the evolving work in the preparation of the 6<sup>th</sup> Strategic plan (2016-2020) that will be presented to the OIE Council. The next strategic plan envisages the new challenges that would drive the OIE activities in the near future.

The Commission was informed on the development of a specific guide to support the OIE Council in the election of the member of the specialist commission. Dr Evans emphasised the accountability of the Scientific Commission to represent and defend interests of Member Countries and the importance of communication between Commission members and the Member Countries from the regions from where they are coming. Similarly, the OIE is committed to improve the communication among the OIE departments ensuring coordination on horizontal issues and avoiding potential overlapping in the activities commissioned to each of the departments.

The President of the Scientific Commission applauded the appointment of Dr Evans and expressed the support of the Commission to his work. He also referred to the importance of communication and coordination among specialist commissions ensuring that each commission complies with its mandate which in the case of the Commission is addressing scientific-related issues to ensure the OIE scientific excellence in the setting of standards. He highlighted the commitment of the Commission to undertake and support country missions for the recognition and confirmation/withdraw of official disease status. The missions have been highly appreciated by Member Countries as they reinforce the Commission decisions and reflect the transparency and credibility of the process.

The President of the Commission outlined the agenda of the meeting indicating that there were a number of comments from Member Countries to be addressed derived from the General Session. There were also a number of recommendations emanating from *ad hoc* Group meetings held since the last meeting of the Commission in February 2014 that needed to be considered.

The President summarised the most critical aspects in the proposed agenda and outlined to the Commission the priority issues and the work plan for the week.

In his address to the Commission on Monday 15 September, the Director General of the OIE, Dr Bernard Vallat thanked the Commission for its work. Dr Vallat outlined the priorities of the OIE for the coming months which were mainly driven by the Member Country requests during the last General Session. The Director General expressed his intention to convene an *ad hoc* Group to revised and update, when necessary, the criteria for listing diseases. He also informed the Commission of his intention to request the *ad hoc* Group on BSE to revise the latest scientific evidence on the occurrence of atypical BSE as an outcome of intensive surveillance in some countries.

Dr Vallat suggested prioritising the finalisation of the chapter on foot and mouth disease (FMD) envisaging its adoption by Member Countries during the General Session in 2015 as well as the amended chapter on African swine fever. He reminded the Commission of the importance of the adoption of Chapter 4.16. on High health status horse subpopulation during the 2014 General Session indicating the relevance of finalising the certificate and guide to management as requested by some Member Countries.

Dr Vallat drew attention to the significance of the scientific-based procedure for disease status recognition to ensure the objectivity, transparency and credibility of the process among all Member Countries. He expressed his concerns on the recent significant incursion of FMD in countries with OIE endorsed FMD control programmes.

Lastly, Dr Vallat commented on the occurrence of the new impact of certain species of *Theileria* spp. in some Member Countries and the need for considering the amendment of the current chapter of the *Terrestrial Animal Health Code (Terrestrial Code)*.

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

The draft agenda was adopted by the Commission. The meeting was chaired by Dr Gideon Brückner and the OIE secretariat acted as rapporteur. The agenda and list of participants are attached as Annexes 1 and 2 respectively.

## **2. Feedback from the 82<sup>nd</sup> General Session – May 2014**

The President briefly outlined the most important outcomes of the 82nd General Session related to the work of the Commission. He acknowledged with appreciation the support that was received from Member Countries for the work of the Scientific Commission.

## **3. Issues from the last meeting of the Scientific Commission**

### **3.1. Review of *Terrestrial Code* chapters**

#### **a) Chapter 12.10. Infection with *Burkholderia mallei* (Glanders)**

The Commission reviewed the chapter forwarded by the Terrestrial Animal Health Standards Commission (Code Commission).

The Commission made some editorial changes for consistency and clarity.

The title in Article 12.10.7. was modified in line with the opinion of the *ad hoc* Group that considered the necessity to specifically refer to fertilized oocytes and oocytes as, for trade purposes they are different commodities than embryos.

The final draft of the amended chapter together with the rationale for changes was provided to the Code Commission for further processing.

**b) Harmonisation of the *Terrestrial Code* chapters on African horse sickness, bluetongue and epizootic haemorrhagic disease (EHD)**

The President of the Commission recalled that an important work had been provided by the *ad hoc* Group on the harmonisation of *Terrestrial Code* chapters on African horse sickness, bluetongue and epizootic haemorrhagic disease: the meeting report was annexed to the Commission report of September 2013. Based on the *ad hoc* Group revision and on the comments from the Code Commission, the OIE Headquarters proposed a further detailed comparison of the three chapters to both Commissions.

He reminded that the task was only to harmonise, taking into account the specificities of each disease, and not to revise the chapter content. He also recalled that a procedure for official recognition exists for AHS.

The harmonisation proposal was reviewed in detail and endorsed by the Commission. The text of the three chapters together with the rationale for harmonisation or absence of harmonisation were forwarded to the Code Commission. The President of the Commission suggested that for clarity and consistency the three chapters should be revised in parallel. He requested that the working document displaying the three chapters in parallel be sent to Member Countries with the respective three chapters to ease their revision before submitting comments.

The detailed rationale for the Commission's proposed amendments is attached as [Annex 3](#).

**4. *Ad hoc* and Working Groups**

**4.1. Meeting reports for endorsement**

**a) *Ad hoc* Group on foot and mouth disease (FMD): 4-6 February 2014**

Chapter 8.7. on FMD was extensively reviewed by the Commission following several *ad hoc* Group meetings, discussions and additional amendments by the Commission during its September 2013, February 2014 and September 2014 meetings following comments by Member Countries as well as joint discussions between the Scientific and Code Commissions. Prior to the September 2014 meeting of the Scientific Commission, a special meeting was also convened between representatives of the Code and Scientific Commissions to clarify uncertainties. During a final joint meeting between the two Commissions on 20 September 2014, consensus could be reached on a few remaining articles where a difference of opinion existed. The final draft was thus submitted by the Commission to the Code Commission with a complete text together with the rationale for the proposed amendments.

During the 82nd General Session Member Countries were informed of the uncertainties that still exist with some Member Countries in interpreting the requirements of the *Terrestrial Code* chapter on the conditions for the movement of vaccinated animals to a zone free without vaccination. The chapter was amended accordingly to further clarify that once a country or zone is officially recognised as free without vaccination, no introduction of vaccinated animals will be allowed unless for direct slaughter. However, both Commissions realised that in the event of a country or zone free without vaccination, where emergency vaccination has to be applied to contain an outbreak and the vaccinated animals are not slaughtered, such animals might then be excluded to be moved in later years. This aspect would be again discussed between both Commissions in the future to provide an acceptable risk based solution.

The Commission supported and further clarified the request of an effective vaccination programme to guarantee an appropriate vaccination coverage and population immunity to a country or zone applying for freedom from FMD where vaccination is practised (Article 8.7.3.).

The Commission supported the proposal of the *ad hoc* Group regarding Member Countries transiting from the status of a country or zone free with vaccination to the status of a country or zone free without vaccination. The Commission clarified that if the country or zone does not comply, its official status will be withdrawn. The Commission emphasised that the establishment of a containment zone should be approved by the OIE.

During its 2014 February meeting, the Commission took note of the *ad hoc* Group's proposal to help Member Countries with the calibration of locally used tests for measuring population immunity after vaccination. The Commission considered appropriate to suggest to the Biological Standard Commission to consider including in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* a request to vaccine manufacturers to provide on request of the vaccine purchaser post-vaccination sera produced during final product batch testing for potency.

The Commission discussed the proposal of some Member Countries to consider statistical representative sampling of vaccinated population to recover free status where vaccination is not practised after an emergency vaccination-to-live strategy had been implemented. The Commission fully supported the recommendations of the *ad hoc* Group.

The Commission also supported the modifications made in the questionnaires in Chapter 1.6. to request evidence of the progress made by the Member Countries that apply for recognition of status or for the OIE endorsement of their official control programmes. The Commission included the request that the Veterinary Services of applicant Member Countries should demonstrate their capability to maintain all FMD related activities.

The detailed rationale for the Commission's proposed amendments is attached as [Annex 4](#).

The endorsed report of the *ad hoc* Group is attached as [Annex 5](#)

**b) *Ad hoc* Group on tuberculosis: 9-11 April 2013 and 11-13 March 2014**

During its 2013 September meeting the Commission considered the *ad hoc* Group report of April 2013. However, the Commission suggested to the Director General to convey an additional *ad hoc* Group meeting in March 2014 to consider the Commission comments and to finalise the draft chapter before circulation for Member Country comments.

Thus, the *ad hoc* Group met twice to amend the Chapter on tuberculosis using the same pathogen approach as used for the amended Chapter on Brucellosis that was adopted at the 82<sup>nd</sup> General Session in May 2014.

The Commission discussed in detail the report and final recommendations of the *ad hoc* Group and made some further changes to the proposed amended chapter. The final draft of the amended chapter together with the rationale for changes and the reports of the *ad hoc* Group were provided to the Code Commission for further processing.

The detailed rationale for the Commission's proposed amendments is attached as [Annex 6](#).

The endorsed reports of the *ad hoc* Group are attached as [Annex 7](#) and [Annex 8](#).

**c) *Ad hoc* Group on African swine fever: 23-25 April 2014**

The Commission considered the report of the *ad hoc* Group which was tasked to update and harmonise chapter 15.1 on African swine fever with chapter 15.2 on Classical swine fever adopted at the 81<sup>st</sup> General Session in May 2013.

The Commission after detailed discussion suggested further changes to the amended chapter. The amended chapter together with the rationale for changes and the report of the *ad hoc* Group were provided to the Code Commission for further processing.

The detailed rationale for the Commission's proposed amendments is attached as [Annex 9](#).

The endorsed report of the *ad hoc* Group is attached as [Annex 10](#)

**d) *Ad hoc* Group on the international movement of horses for equestrian sport (4th meeting): 2-4 June 2014**

The Commission considered the report of the *ad hoc* Group on international movement of horses that met for the fourth time with the main purpose of describing the practical implementation of the concept approved by the World Assembly of Delegates during the 82nd General Session. The Commission took note that the *ad hoc* Group also discussed the development of the concept of an 'equine disease free zone', developed a communication strategy to enhance a better understanding of the concept of high health high performance horses by Member Countries and identified research priorities that can contribute to further increase the application of the concept.

The Commission was concerned that referring to two different but related concepts: high health status sub-population (HHS) and high health performance sub-population (HHP) might be confusing for some Member Countries and requested that the *ad hoc* Group reconsiders the use of the acronyms HHS and HHP in such a manner that Member Countries fully understand that these are the same horses. The *ad hoc* Group provided a definition that integrates the HHP horse into the high health status subpopulation. The Commission recommended reviewing the definition in view of being very clear regarding these different terms. It was also noted that the terminology used in the proposed health certificate focus much on the high health performance sub-population while the chapter adopted in May 2014, describes mainly the concept related to a high health status sub-population of horses. It was proposed to consider changing the title of the Chapter from high health status sub-population to high health status horse compartment as per definition in the Glossary of the *Terrestrial Code*.

The Commission discussed the need of having an *ad hoc* Group for Surra, considering that this disease is required for certification by many countries in the world and that the OIE does not have any guidelines for trading requirements. The Commission agreed that recommendations for trade may be needed. The Commission recommended requesting to the OIE Director General to convene an *ad hoc* Group on equine trypanosomiasis, without limiting it to Surra to draft a Chapter for the *Terrestrial Code* while considering the outcome of the *ad hoc* Group on Surra convened in 2009.

The Commission endorsed the *ad hoc* Group report that is attached as [Annex 11](#).

**e) Sub-group to the OIE *Ad hoc* Group on international horse movement: 10 – 11 April 2014**

The Commission considered the report of the expert sub-group which was convened to develop biosecurity measures and management practices for the implementation of the HHP concept at the home stable, at the event venues and during transport.

The Commission endorsed the *ad hoc* Group report that is attached as [Annex 12](#).

**f) Sub-group HPP health certificate and subpopulation management: 23-25 July 2014**

The Commission considered the report of this *ad hoc* Group which was convened to finalise the guidelines for management of the high health, high performance horses (HHP) and to revise the HHP certificate taking into consideration the adoption of the new *Terrestrial Code* Chapter 14.6 in May 2014, Member Country comments from the equine industry and particularly comments made by the Regional Commission for Africa during the 82nd General Session.

The Commission noted with appreciation that several categories for certification were now introduced depending on the particular disease risk and that provision has now also been made to allow the incorporation of horses from countries not free from African horse sickness into the concept as requested by the OIE Regional Commission for Africa. In accordance with the revised health certificate, individual HHP horses, selected for their capacity to compete, would now be registered in a database and issued the HHP health certificate, which allows them to travel continuously to multiple destinations for a period of 90 days, before they have to return to the country and establishment of origin.

The Commission considered and endorsed the *ad hoc* Group report, the guide to the management of the high health status equine sub-population and the high health-high performance horses as well as the model veterinary health certificate. The Commission recommended to include into the management guidelines not only a procedure to obtain a 'high health' level but also procedures to maintain the given high health status.

The endorsed *ad hoc* Group report is attached as [Annex 13](#).

**g) Ad hoc Group on porcine epidemic diarrhoea (PED): 19-20 June 2014**

Following discussions at the 82nd General Session during which the World Assembly of OIE Delegates was informed of the first outbreak of this disease in two Member Countries the Director General convened an *ad hoc* Group to assess whether or not the infection with PED virus matches with the criteria of Chapter 1.2. of the *Terrestrial Code* to be included as an OIE Listed Disease.

The Commission also considered the written opinion provided by a Member Country after the meeting of the *ad hoc* Group on the listing of PED and its rationale regarding the impact of the disease.

After considering the scientific evidence available, the Commission supported the recommendation of the *ad hoc* Group who concluded that measuring the available scientific information available at the time of the meeting and the requirements for disease listing, infection with PED virus did not meet the criteria of the *Terrestrial Code* to be included in the OIE List of diseases.

The Commission agreed that PED and transmissible gastroenteritis were comparable in terms of the OIE criteria for listing diseases. However, considering that the OIE is in the process of revising the criteria for listing diseases, their listing could be discussed again, if and when revised criteria become available.

The Commission also considered and endorsed the technical factsheet on PED and recommended that it be made available on the OIE website to support Member Countries, following the same protocol as in the case of technical factsheets of other emerging disease that were not incorporated in the OIE List of diseases.

The endorsed *ad hoc* Group report including the endorsed technical factsheet is attached as [Annex 14](#).

**h) *Ad hoc* Group to develop a global database on the use of antimicrobial agents in animals: 8-9 July 2014**

The Commission was briefed by the Scientific and Technical Department on the involvement of the OIE in the tripartite activities related to antimicrobial resistance.

The Commission noted with appreciation the progress made by the *ad hoc* Group to develop a template for the global database on the use of antimicrobial agents in animals as suggested in its February meeting.

The next *ad hoc* Group meeting is planned for December 2014. The outcome of this meeting will lead to the finalisation of the global database envisaging the endorsement by OIE Member Countries during the 83rd General Session.

The *ad hoc* Group report was endorsed and is attached as [Annex 15](#).

**i) *Ad hoc* Group on Middle East Respiratory Syndrome Coronavirus (MERS-CoV) infection in animals: 15-17 July 2014**

The Commission considered and endorsed the report of the *ad hoc* Group that was convened to review the latest scientific evidence relating to the epidemiology of MERS-CoV, to provide guidance on surveillance in camelids and others animals and to evaluate whether MERS-CoV infection meets the criteria of Chapter 1.2. of the *Terrestrial Code* to be included as an OIE Listed Disease.

The Commission supported the recommendation of the *ad hoc* Group who unanimously concluded that if measured against current scientific information and the requirements for disease listing, infection with MERS-CoV did not meet the criteria to be included in the OIE List of diseases.

The Commission also confirmed its decision that was taken by electronic communication following the meeting of the *ad hoc* Group to endorse the proposed communications strategy that included an update of the Questions and Answers (Q and A) on the OIE website.

The endorsed reported is attached as [Annex 16](#).

**4.2. Re-convening of *ad hoc* Groups**

The Commission reviewed the draft agendas of the following *ad hoc* Groups scheduled until the next Commission meeting in February 2015 and endorsed them with minor modifications.

- a) *Ad hoc* Group on FMD: 30 September- 3 October 2014
- b) *Ad hoc* Group on CBPP: 21-23 October 2014
- c) *Ad hoc* Group on CSF: .3-4 November 2014
- d) Wildlife Working Group: 4-6 November 2014
- e) *Ad hoc* Group on BSE: 25-27 November 2014
- f) *Ad hoc* Group on FMD: 18-20 November 2014
- g) *Ad hoc* Group to develop a global database on the use of antimicrobial agents in animals: 10-12 December 2014
- h) *Ad hoc* Group on PPR: 16-18 December 2014
- i) *Ad hoc* Group on AHS: 12-14 January 2015
- j) *Ad hoc* Group on FMD (*chapter*): 27-29 January 2015

**4.3. Programme and priorities**

The Commission reviewed and updated the working plan and priorities of the Commission for 2014/2015.

## **5. Official disease status**

### **5.1. Missions of the Scientific Commission**

The importance of the Commission to continue with missions to Member Countries was discussed with the Director and Deputy Director General who fully supported this initiative. It was also agreed that for future missions, a member of the OIE Scientific and Technical Department, responsible for country evaluations, should be included in the expert teams visiting Member Countries.

#### **a) Andean countries (including Bolivia): April-May 2014**

The Commission was briefed on the outcome of an expert mission to the Andean Countries to assess the compliance with the requirements of the *Terrestrial Code* for disease status recognition and endorsement of official national control programmes for FMD. The mission followed the signing of an Agreement between some Member Countries and the OIE to collaborate their efforts in a regional context for the control of FMD in the region. A back-to-back mission was conducted in Bolivia to assess compliance with the requirements of the *Terrestrial Code* for a FMD free zone with vaccination.

Two members of the Commission and an expert consultant participated in the mission with support from the OIE Regional Representative for the Americas.

The Commission noted with appreciation the assistance provided by the Member Countries to the experts and the transparency demonstrated in giving the experts access to all the relevant information during discussions and visits to disease related sites.

The Commission supported the recommendations of the experts, including the proposal to conduct a follow-up mission to Bolivia. The Commission endorsed the mission report.

#### **b) Follow-up mission to South Africa: 1-5 December 2014**

Following the outcome of the mission to the southern African countries in 2013, the Commission was informed that the recommended follow-up mission to assess compliance of the Member Country for the maintenance of disease free status is now scheduled to be conducted from 1 to 5 December 2014.

#### **c) Follow-up mission to Mercosur**

The Commission agreed that a mission to the Mercosur countries, other than Bolivia (see point 5.1a) to assess compliance with the requirements for the maintenance of their FMD free status would be appropriate in the Mercosur region and that a date for such a visit will be considered during the next meeting of the Commission, if endorsed by the Director General.

#### **d) Other mission**

The Commission was also briefed on the planned expert mission to a Member Country to assess compliance with the requirements for an OIE endorsed official control programme for FMD.

### **5.2. Consolidated follow-up information provided by Ecuador on their application for the endorsement of its official control programme for FMD**

The Commission acknowledged with appreciation the additional consolidated information provided by the Delegate of Ecuador.

### **5.3. Consideration of endorsed official FMD control programmes**

The Commission reviewed the information provided by the Delegates of Tunisia and Algeria on the outbreaks of FMD experienced in both countries. This information was requested by the Commission to assess the impact of the outbreaks and the management of the events upon the endorsement by the OIE of the official FMD national control programmes.

After a comprehensive consideration of the available information, the Commission unanimously concluded that Tunisia does not fulfil the requirements of the *Terrestrial Code* for the endorsement of an official control programme for FMD and concluded to withdraw the endorsement in accordance with Article 8.7.49. of the *Terrestrial Code*.

The Commission also recommended requesting further information from the Delegate of Algeria to better assess their response to the latest epidemiological events before taking a final decision on the endorsement of its official control programme.

The response of Morocco to the incursion of FMD virus into North Africa was also discussed and the Commission recommended requesting epidemiological information from the Delegate of Morocco on the situation with regards to the endorsed official control programme.

#### **5.4. Atypical BSE and official recognition of BSE risk status**

##### **a) Brazil**

The Commission reviewed electronically prior to its September meeting the report of the epidemiological investigation submitted by Brazil to the OIE following the detection and reporting of a case of atypical bovine spongiform encephalopathy in May 2014. The Commission unanimously concluded that there was no reason to modify the BSE risk status of Brazil and confirmed that Brazil remains officially recognised as having a negligible BSE risk status as adopted through Resolution No 18 by the OIE World Assembly of Delegates during the 82nd General Session.

During this September meeting the Commission reconfirmed its previous decision.

##### **b) BSE surveillance points**

The Commission was informed on the difficulties experienced by a Member Country to reach the requested surveillance points to maintain its BSE official status due mainly to the reduced cattle population and its good health status. The Commission acknowledged the transparency of the Member Country and its effort to fulfil the requirements of the *Terrestrial Code*.

The Commission agreed not to suspend the negligible BSE risk status of this Member Country at present providing that it maintains its efforts to increase the collection of samples.

##### **c) Chapter 11.4. on bovine spongiform encephalopathy (BSE): Consideration of atypical BSE in relation with official risk status recognition**

The Commission reviewed the latest reported events on atypical BSE and the scientific evidence currently available regarding this disease. The Commission acknowledged the different aetiology and the epidemiological particularities of atypical BSE differing from classical BSE. In view of this information and events, the Commission recommended that the *ad hoc* Group consider among others its impact on official disease status recognition during the process of revising chapter 11.4. on BSE during their meeting in November 2014.

##### **d) Updating of the BSurvE model**

The Commission took note of the information provided to the OIE by one of the authors of the BSurvE model. Recognising the need of updating the model parameters to incorporate the changes in the epidemiology of the disease, the Commission suggested forwarding this information to the forthcoming *ad hoc* Group on BSE for further consideration.

### **5.5. Presentation of a project by the OIE Scientific and Technical Department for a web-based tool for annual reconfirmation.**

The Commission was informed on the project to develop a web-based tool for annual status reconfirmation to ease the Member Country reporting and the processing of the information by the OIE staff. The Commission endorsed the proposal and took note of the timeline for its implementation.

### **5.6. Harmonisation of annual reconfirmation forms for official status recognition**

The Commission reviewed the forms for the annual official status reconfirmation.

The Commission was briefed on the difficulties experienced by the OIE Scientific and Technical Department to validate and verify the information provided by Member Countries especially as it relates to requirements for disease surveillance for the maintenance of status.

The Commission noted the requirements of the *Terrestrial Code* for the retention on the List of countries having an official status and interpreted that the “documented evidence” requested could be simplified in the declaration signed and submitted annually by the Delegate of a Member Country. However, the Commission recommended increasing the involvement of the Regional and Sub-regional OIE Representations in the process of verification of the maintenance of status and implementation of endorsed control programmes. The Commission took note and reiterated the need and importance that the maintenance of status and annual reconfirmations should be transparent and a true reflection of compliance with the requirements of the *Terrestrial Code* as they may be subject to legal scrutiny and verification procedures.

The Commission discussed the transition from an OIE endorsed control programme to official status recognition. It was clarified that when an official disease status is granted for the whole territory it would not be necessary to submit the annual reconfirmation for the endorsement of the official control programme. It would be substituted by the annual official status reconfirmation.

## **6. FMD and PPR control strategies**

### **6.1. Peste des petits ruminants (PPR) global control strategy**

The Commission was updated on the activities related to the preparation of the PPR global control strategy which the main principles are endorsed by the FAO and OIE. The Commission was reminded that the global control strategy for PPR would follow a similar structure as the strategy for FMD. The strategy will comprise three components (strengthening veterinary services, PPR and other major small ruminant diseases control) as well as a set of tools which will include a monitoring and assessment tool and a post vaccination monitoring tool.

The Commission was informed of the upcoming meeting and activities related to the PPR global control strategy which include an international conference to be held, if possible, in Abidjan, 30-31 March 2015.

A specific project funded by the Bill and Melinda Gates Foundation on PPR control was explained with its three components (regional vaccine bank, Pan African veterinary Vaccine Centre –PANVAC–strengthening for quality control of vaccines used in Africa and pilot control programme in Ghana and Burkina Faso). The project closure meeting will take place in OIE Paris, 2-3 October and the results will be used during the expert meeting on PPR global control strategy to be held in Rome, 8-10 October 2014.

## **6.2. FMD global control strategy**

The Commission was informed on the progress of the implementation of the FMD global control strategy including the activities under the Global Framework for the progressive control of Transboundary Animal Diseases (GF-TADS). Regional roadmap meetings have been organised in Amman, Jordan for the Middle East and Northern Africa, March 2014 and in Astana, Kazakhstan for WestEurasia, April 2014.

The process for the evaluation and acceptance of the country progressive control pathway (PCP) stage classification is well established now. It started for the first time in Amman and it was used in Astana for. The role of the Regional Advisory Group (RAG) is well recognised and accepted by the participants representing their country at the regional roadmap meeting. The RAG is composed of three Delegates of the relevant region, elected by the country participants from the region, the coordinator of the regional laboratory network and the coordinator of the regional epidemiology network. The members of the GF-TADS Working Group for FMD and other experts particularly from EuFMD (when appropriate) are supporting the RAG to present the assessments of the PCP country stage.

## **6.3. FMD global situation**

The Commission was provided with an update of the current FMD global situation by the OIE FMD reference laboratory at Pirbright. A summary was also provided on the outcome of a vaccine matching test conducted in samples sent to Pirbright. The Commission acknowledged the latest development of a new PCR test to differentiate the Pan Asia strains and the India strain and took note of the recommended strains to be included in vaccine banks.

The Commission expressed its concern on the diversity of circulating virus strains in Asia, Eastern Europe and Middle East and North Africa.

## **7. OIE Collaboration Centres**

No application for OIE Collaboration Centres to be considered by the Commission were received for evaluation.

## **8. Liaison with other Commissions**

### **8.1. Terrestrial Animal Health Standards Commission**

Please, refer to the joint meeting between the two Commissions attached as [Annex 17](#).

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 18](#).

### **8.2. Biological Standards Commission**

#### **a) *Ad hoc* Group on disease of Camelids, 1-3 April 2014**

The Commission acknowledged with appreciation the response of the *ad hoc* Group on diseases of camelids to the questions posed to the Group related to the significance of camelid species in the epidemiology of tuberculosis.

#### **b) FMD serum provision to calibrate diagnostic test**

In response to the Commission's request to vaccine manufactures to provide serum to calibrate test, the Biological Standards Commission sought the advice of the Chair of the OIE *ad hoc* Group on Vaccine Quality related to FMD, who considered the Commission's proposal scientifically sound. However he also expressed his concerns regarding the practicability of the proposal.

The Biological Standards Commission was seeking further expert advice before providing a definitive answer to the Scientific Commission.

**c) Modification of Chapter 8.7. of the *Terrestrial Code* on diagnostic related issues**

At the last meeting, the Biological Standards Commission had proposed that details on diagnostic tests and their use and interpretation should be included in the *Terrestrial Manual* only and not in the *Terrestrial Code*. However, the Biological Standards Commission noted that the schematic representation of laboratory tests for determining evidence of FMD virus infection through or following serological surveys that is included in the chapter on FMD in the *Terrestrial Code* is also part of a surveillance scheme and thus might need to be in the *Terrestrial Code* and the proposed change may need to be reconsidered at its next meeting. The Scientific Commission was reminded that any text to be removed from the *Terrestrial Code* would only be removed once it had been adopted and included in the *Terrestrial Manual*.

**d) *Ad hoc* Group on glanders request of including a case definition and testing regimen in the *Terrestrial Manual* rather than in the *Terrestrial Code***

The Biological Standards Commission agreed with the Commission that text in the draft chapter on glanders for the *Terrestrial Code* that included details of which diagnostic tests to use and how they should be interpreted to define a case of glanders should rather be in the *Terrestrial Manual*. The text had been incorporated by the OIE Reference Laboratory experts into the chapter, defined as a Diagnostic pathway to confirm a case of glanders rather than as a case definition. The draft *Terrestrial Manual* chapter would be circulated to Member Countries for first-round comment and eventual proposal for adoption by the Assembly in May 2015.

**e) Zoonosis transmissible from non-human primates**

The Biological Standards Commission referred a concern on Article 6.11.4. Chapter 6.11. of the *Terrestrial Code* on zoonosis transmissible from non-human primates. The Commission decided to reconsider this during its next meeting and to seek expert advice from the Wildlife Working Group.

**8.3. Common issues related to several Specialist Commissions**

**a) Gaps identification and harmonisation in WAHIS**

The Commission was informed by the STD on the initiative of the OIE Headquarters to harmonise, when possible, the definitions included in the guidelines of the World Animal Health Information System (WAHIS) with the already existing definition adopted in the OIE Codes and Manuals. This harmonisation will aim to facilitate and improve the accuracy of the reporting obligations of Member Countries. It involves a coordination exercise among the STD, Animal Health Information Department and International Trade Department.

**b) *Ad hoc* Group on Disease listing criteria**

The Commission took note of Member Country comments during the 82nd General Session and considered the suggestions of the Director General to convene an *ad hoc* Group to consider if criteria for listing diseases need to be modified. The Commission supported the revision of the listing criteria and reminded that the fact of non-listing a disease does not preclude Member Countries to implement risk mitigations measures but involves notification obligations according to the *Terrestrial Code* provisions.

## 9. Conferences, workshops, meetings

### 9.1. OIE – International Council for Game and Wildlife Conservation (CIC) Joint International Meeting on early detection and prevention of African swine fever and other animal health issues at the wildlife-livestock-human interface. Paris. 30 June – 1 July 2014.

The Commission was updated on the output of this OIE – CIC joint meeting. The recommendations and follow up of the meeting were presented.

### 9.2. International field trials workshop June 2014

The Commission was briefed by the member of the Commission who attended the meeting indicating that the workshop aimed to receive expert advice on the organisation of a field trial of a new FMD vaccine which is being developed in the USA. The vaccine under development is not based on an adenovirus vector. The initial experiments were carried out in biosafety units with promising results.

### 9.3. OIE Reference Laboratories Conference: Republic of Korea 14-16 October 2014

The Commission was updated on the progress with the organisation of the conference where more than 300 OIE experts will participate.

### 9.4. The European Commission for the Control of FMD (EuFMD) Open Session: Croatia 29-31 October 2014

The Commission was informed of the conference organised by the EuFMD that takes place every other year. International experts including researchers, policy makers and stakeholders, would attend the meeting. A member of the Commission would also participate.

### 9.5. Rabies

#### a) 2014 Regional meetings (Tunisia, Thailand, Niger and Japan)

The Commission was updated in the last regional meetings organised by the OIE where counterparts representing WHO and FAO were invited in the context of the Tripartite initiatives. The main objective of the meetings was to contribute to the regional control plan of rabies elimination in dogs. During the meeting both Veterinary Services and Human Health services discussed a joint strategy for rabies elimination.

#### b) Global Conference on Rabies: Geneva, end 2015 (tentative date)

A global conference on rabies is envisaged as a follow-up of the global conference on rabies control organised by the OIE in Seoul in 2011. The exact dates are yet to be confirmed but it is foreseen to be organised in collaboration with WHO in Geneva (WHO-HQ) at the end of 2015.

### 9.6. Workshop disease status or national control programme recognition: Europe, Americas, Africa (2015)

The Commission welcomed the initiative to organise a series of workshops to support Member Countries in the preparation of dossiers for official disease status or national control programme recognition. The Commission highlighted the importance to include in the agenda the surveillance aspects required for each of the diseases, as well as all the requirements of the *Terrestrial Code*, without limiting it to FMD but also the other diseases for status recognition such as CSF and BSE.

## **10. Disease specific issues**

### **10.1. Update on the Middle East respiratory syndrome (MERS-CoV)**

The Commission was updated on the OIE activities related to MERS-CoV which involved joint activities with FAO and WHO. No significant changes have been observed since the meeting of the *ad hoc* Group.

The Commission highlighted the need for reliable epidemiological data to better understand the role of animals in the epidemiology of the disease.

The Commission was informed of the possible application of one Member Country to become laboratory reference for MERS-CoV. The application would be duly assessed by the Biological Standards Commission.

### **10.2. Feedback on FMD post-vaccination monitoring (PVM)**

The initial PVM document was now in the last stages of finalisation. The Commission maintained the opinion that the guidelines should be published as a joint FAO/OIE venture and in a similar format as the publication on the FMD global control strategy.

### **10.3. Feedback on PPR post-vaccination monitoring (PVM)**

The Commission was informed that the PVM tool for PPR would be one of the tools available for the global strategy for PPR control. The tool would be described in the main document and would be supported by technical annexes.

### **10.4. Review of *Terrestrial Code* chapter on scrapie**

The Commission maintained the review of the Chapter 14.8. on scrapie in the work plan, but it was not considered a priority. The question of the maintenance of scrapie diseases listed by OIE is also to be addressed before undertaking the revision. Therefore, the revision of the chapter should be considered once the disease listing criteria have been revised.

### **10.5. Rinderpest**

The Commission received feedback on the questionnaire sent to Member Countries on the rinderpest virus containing material (RPVM). The participation was very high with 94% of countries answering to the questionnaire without major technical problems. Nevertheless, it is intended to improve the web-based tool used for the questionnaire to be more user-friendly.

The OIE received 5 applications for establishments containing RPVM from four different countries. All the applications were accepted in the initial phase of the process.

The next Joint OIE/FAO Advisory Group meeting is scheduled for November 2014.

## **11. Any other business**

### **11.1. Draft guidelines for declaring areas free from tsetse and tsetse transmitted trypanosomiasis**

The Commission was informed of the initiative and decided to revise the guidelines once they become available

### **11.2. Cooperative platform on wildlife (CPW) fact sheet on ‘Sustainable wildlife management and livestock’**

The Commission was informed on the CPW to manage topics related to wildlife. FAO is acting as secretariat of this platform. The Commission strongly recommended that the OIE should be actively involved in all the activities related to animal health. The Commission agreed that the president of the Wildlife Working Group should be involved electronically in the elaboration of the factsheets.

### **11.3. Disease prioritisation for research programmes on the vaccine manufacturing**

The Commission was informed on the proposal of developing prioritisation criteria to guide research priorities on vaccine manufacturing or other alternatives with the goal of decreasing or preventing use of antimicrobials. The OIE is envisaged to convene an *ad hoc* Group to address this issue in order to assess the feasibility of the creation of relevant vaccines.

The Commission supported the initiative and recommended that the OIE invite one member of the Commission to participate as an observer

### **11.4. Ebola Technical factsheet**

The Commission was requested to endorse a technical factsheet on Ebola virus disease to be published in the OIE website to support Member Countries. Because of lack of time and late transmission of the document, it was agreed that the endorsement would be finalised electronically and then submitted for further processing.

## **12. For the Commission information**

### **12.1. Development scientific criteria for when an emerging disease is no longer emerging**

The Commission considered the importance of this issue for the reporting of diseases and clearer guidance to Member Countries. It was recommended that this issue should be considered in the context of upcoming revision of the disease listing criteria.

### **12.2. Global conference on bio- threat reduction**

The Commission was informed on the progress with organising an OIE global conference on bio-threat reduction. The conference would aim to encourage collaboration between animal and public health and security sector. The Conference would take place at the end of June 2015 in Paris.

## **13. Adoption of the report**

The Commission agreed to circulate the draft report electronically for comments before adoption.

The next meeting of the Scientific Commission is scheduled for 9-13 February 2015.

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.../Annexes



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

**Paris, 15-19 September 2014**

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**Agenda**

- 1. Adoption of the agenda and appointment of rapporteur**
- 2. Feedback from the 82<sup>nd</sup> General Session – May 2014**
- 3. Issues from the last meeting of the Scientific Commission**
  - 3.1. Review of *Terrestrial Code* chapters
    - a) Chapter 12.10. Infection with *Burkholderia mallei* (Glanders)
    - b) Harmonisation of the *Terrestrial Code* chapters on African horse sickness, bluetongue and epizootic haemorrhagic disease (EHD)
- 4. Ad hoc and Working Groups**
  - 4.1. Meeting reports for endorsement
    - a) *Ad hoc* Group on foot and mouth disease (FMD): 4-6 February 2014
    - b) *Ad hoc* Group on tuberculosis: 9-11 April 2013 and 11-13 March 2014
    - c) *Ad hoc* Group on African swine fever: 23-25 April 2014
    - d) *Ad hoc* Group on the international movement of horses for equestrian sport (4th meeting): 2-4 June 2014
    - e) Sub-group to the OIE *Ad hoc* Group on international horse movement: 10 – 11 April 2014
    - f) Sub-group HPP health certificate and subpopulation management: 23-25 July 2014
    - g) *Ad hoc* Group on porcine epidemic diarrhoea (PED): 19-20 June 2014
    - h) *Ad hoc* Group to develop a global database on the use of antimicrobial agents in animals: 8-9 July 2014
    - i) *Ad hoc* Group on Middle East Respiratory Syndrome Coronavirus (MERS-CoV) infection in animals: 15-17 July 2014
  - 4.2. Re-convening of *ad hoc* Groups
  - 4.3. Programme and priorities
- 5. Official disease status**
  - 5.1. Missions of the Scientific Commission
    - a) Andean countries (including Bolivia): April-May 2014
    - b) Follow-up mission to South Africa: 1-5 December 2014
    - c) Follow-up mission to Mercosur
    - d) Other mission
  - 5.2. Consolidated follow-up information provided by Ecuador on their application for the endorsement of its official control programme for FMD
  - 5.3. Consideration of endorsed official FMD control programmes
  - 5.4. Atypical BSE and official recognition of BSE risk status
    - a) Brazil
    - b) BSE surveillance points
    - c) Chapter 11.4. on bovine spongiform encephalopathy (BSE): Consideration of atypical BSE in relation with official risk status recognition
    - d) Updating of the BSurvE model
  - 5.5. Presentation of a project by the OIE Scientific and Technical Department for a web-based tool for annual reconfirmation.
  - 5.6. Harmonisation of annual reconfirmation forms for official status recognition

**6. FMD and PPR control strategies**

- 6.1. Peste des petits ruminants (PPR) global control strategy
- 6.2. FMD global control strategy
- 6.3. FMD global situation

**7. OIE Collaboration Centres**

**8. Liaison with other Commissions**

- 8.1. Terrestrial Animal Health Standards Commission
- 8.2. Biological Standards Commission
  - a) *Ad hoc* Group on disease of Camelids, 1-3 April 2014
  - b) FMD serum provision to calibrate diagnostic test
  - c) Modification of Chapter 8.7. of the Terrestrial Code on diagnostic related issues
  - d) *Ad hoc* Group on glanders request of including a case definition and testing regimen in the *Terrestrial Manual* rather than in the *Terrestrial Code*
  - e) Zoonosis transmissible from non-human primates
- 8.3. Common issues related to several Specialist Commissions
  - a) Gaps identification and harmonisation in WAHIS
  - b) *Ad hoc* Group on Disease listing criteria

**9. Conferences, workshops, meetings**

- 9.1. OIE – International Council for Game and Wildlife Conservation (CIC) Joint International Meeting on early detection and prevention of African swine fever and other animal health issues at the wildlife-livestock-human interface. Paris. 30 June – 1 July 2014.
- 9.2. International field trials workshop June 2014
- 9.3. OIE Reference Laboratories Conference: Republic of Korea 14-16 October 2014
- 9.4. The European Commission for the Control of FMD (EuFMD) Open Session: Croatia 29-31 October 2014
- 9.5. Rabies
  - a) 2014 Regional meetings (Tunisia, Thailand, Niger and Japan)
  - b) Global Conference on Rabies: Geneva, end 2015 (tentative date)
- 9.6. Workshop disease status or national control programme recognition: Europe, Americas, Africa (2015)

**10. Disease specific issues**

- 10.1. Update on the Middle East respiratory syndrome (MERS-CoV)
- 10.2. Feedback on FMD post-vaccination monitoring (PVM)
- 10.3. Feedback on PPR post-vaccination monitoring (PVM)
- 10.4. Review of *Terrestrial Code* chapter on scrapie
- 10.5. Rinderpest

**11. Any other business**

- 11.1. Draft guidelines for declaring areas free from tsetse and tsetse transmitted trypanosomiasis
- 11.2. Cooperative platform on wildlife (CPW) fact sheet on ‘Sustainable wildlife management and livestock’
- 11.3. Disease prioritisation for research programmes on the vaccine manufacturing
- 11.4. Ebola Technical factsheet

**12. For the Commission information**

- 12.1. Development scientific criteria for when an emerging disease is no longer emerging
- 12.2. Global conference on bio- threat reduction

**13. Adoption of the report**

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

**Paris, 15-19 September 2014**

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**Rationale for the harmonisation of:**

**CHAPTER 12.1. INFECTION WITH AFRICAN HORSE SICKNESS VIRUS (AHS)  
CHAPTER 8.3 BLUETONGUE (BT)  
CHAPTER X.X. EPIZOOTIC HAEMORRHAGIC DISEASE (EHD)  
provided by the Scientific Commission**

*To be considered together with the September 2013 Scientific Commission's report*

The Commission confirmed the restriction of the case definition to those BT virus species transmitted only by *Culicoides* vectors. Based on their biological similarities the same should apply to EHD. In contrast, *Culicoides*-independent transmission is not known for AHS.

The Commission acknowledged that milk and milk products, meat and meat products, hides and skins from horses could be safely traded and this may be of interest for some Member Countries. However, it was decided not to include an article for safe commodities in the AHS chapter at this stage of the harmonisation. Nevertheless, it recommended that such an article should be considered in a future revision of the chapter. According to the International Embryo Transfer Society, there is not enough scientific information regarding the role of embryos and oocytes in the epidemiology of EHD, prompting the commission to decide not to include embryos and oocytes as safe commodity in the EHD chapter.

Demonstration of freedom from disease

The Commission agreed in harmonising the requirements to demonstrate freedom from disease regarding the importation of commodities in the three chapters. The Commission observed that surveillance requirements to demonstrate freedom of disease cannot be totally harmonised considering the different impact of the three diseases. The Commission also emphasised that the demonstration of AHS freedom should not only be based on the absence of the vector.

Seasonal freedom

The Commission acknowledged the challenge to substantiate seasonal freedom, although recognising the reduction of risk during periods of low vector activity. Thus, considering the impact and geographical distribution of AHS as well as official status recognition, the Commission confirmed that requirements for seasonal freedom should not be included. Concerning BT and EHD, their impact, the trade practised in some part of the World and freedom of disease based on self-declaration, the Commission accepted to keep these requirements.

Recommendations for importation from free countries or zones

The Commission noted the differences in the three chapters related to the recommendations for importation from free countries or zones. However, it was decided not to harmonise these recommendations due to the different impact of the three diseases. Similarly, it was not considered appropriate to harmonise the recommendations for importation from infected countries or zones because vector protected environment was not 100% reliable and could not guarantee the appropriate risk mitigation the Commission considered necessary in the case of AHS. Thus it was decided for AHS to maintain the requirements of isolation plus vaccination.

The differences in the Chapter on AHS concerning recommendations for the importation of in vivo derived equine embryos or oocytes were justified by the fact that, at present, the technology in embryos of horses is only possible in vivo. Once it becomes technically feasible for in vitro manipulation of equine embryos harmonisation could be considered.

The provision for transport by air was incorporated in the BT and EHD chapters to harmonize with the AHS chapter. The Commission acknowledged that this type of transport of ruminants susceptible to BT and EHD may be used in certain Member Countries.

The Commission acknowledged the differences in the surveillance articles which referred to the detection of virus infection or transmission. It was decided at present not to modify the text as it was beyond the scope of harmonisation. However, it was recognised that this issue should be addressed in a future revision of the Chapters.

References to specific levels of risk was eliminated from the AHS chapter admitting that each Member Country can determine the levels of risk as they consider appropriate.

The requirements for non-vaccinated sentinel animals were harmonised in the three chapters.

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**Rationale for the amendments to:**

**CHAPTER 8.7. INFECTION WITH FOOT AND MOUTH DISEASE VIRUS  
provided by the scientific commission**

*To be considered together with the ad hoc Group report (Annex 5)*

Article 8.7.1.

Definition of transmission: The Commission thoroughly discussed the definition of FMDV transmission by highlighting that it is mainly referred to vaccinated population. The Commission clarified that it implies a change in the proportion or strength of seropositive reactors, however the text was not amended as the Commission could not find a more suitable definition than the proposed one.

Articles 8.7.2. and 8.7.3. to demonstrate freedom from infection in a country or zone where the vaccination is or is not practised

The Commission clarified that the surveillance should be implemented to detect clinical signs of FMD, as well as to prove the absence of FMD infection in non-vaccinated animals and FMDV transmission in previously vaccinated animals, to declare a free country or zone, regardless the vaccination status. The Commission reiterated that clinical surveillance is a key component of a FMD control or eradication programme, and clarified the wording accordingly.

Definition of emergency/systematic vaccination

The Commission agreed with the *ad hoc* Group proposal of developing in the Glossary of the *Terrestrial Code* a definition for vaccination, including systematic vaccination.

Article 8.7.4. Free compartment where vaccination is practised

The Commission acknowledged that compartment implies the highest biosecurity measures. However, it stressed that the establishment of a compartment is not related to the OIE procedure for official recognition of disease status and that the trade from compartment will only be based on bilateral agreement.

The Commission was of the opinion that the concept of compartment was developed to facilitate trade, including in infected countries. Thus, compartment free with vaccination should be seen as a mechanism to facilitate trade, should partners reach an agreement. The Commission maintained its proposal of providing requirements for a compartment free with vaccination to give Member Countries the opportunity to take the decision.

Article 8.7.7. Recovery of free status

The Commission clarified that for recovering its FMD free status, a country or zone where vaccination is practised that have not conducted emergency vaccination would apply for reinstatement in accordance with Article 8.7.3. on the recognition of a free country or zone where vaccination is practised.

The Commission further clarified that in the specific situation where a country detects a FMD introduction just before the launch of its vaccination campaign, emergency vaccination would not necessarily be requested for the recovery.

Article 8.7.8. Direct transfer of FMD susceptible animals from an infected zone for slaughter in a free zone where vaccination either is or is not practised

Introduction of previously vaccinated animals into country or zone free where vaccination is not practised.

In response to Member Country comments during the last General Session, and further field consideration during missions conducted to assess maintenance of disease status, the Scientific Commission discussed in details the possibility of introducing previously vaccinated animals into country or zone free where vaccination is not practised. Several scenarios were thoroughly discussed. However, the Commission concluded that a country or zone where vaccination is not practised should not import any vaccinated animal except for slaughter, to mitigate the risk of introducing FMDV and to avoid introducing vaccinated animals in a free country or zone where vaccination is not practiced. The importation should fulfil the provisions of Article 8.7.2. and all along the *Terrestrial Code*.

The last paragraph of Article 8.7.8. was removed to clarify that animals from infected countries should not be traded except for direct slaughter.

Article 8.7.22. Recommendations for importation from FMD infected countries or zones, where an official control programme for FMD, including compulsory systematic vaccination exists

The Commission addressed a Member Country comment on the recommendations from importation from infected countries in the case where a previously FMD free country or zone would experience an FMD incursion.

The Commission emphasised the differences between an official control programme and the OIE endorsed official control programme for the purpose of the *Terrestrial Code*. An official control programme, as defined in the Glossary of the *Terrestrial Code* and mentioned in Article 8.7.22., is seen as an important management tool for countries, but it is not linked to the OIE procedure published in the *Terrestrial Code* for the endorsement of official control programme. Thus, infected Member Country having an official control programme for FMD could trade under the conditions stated in Article 8.7.22. without needing an OIE endorsement.

In addition, free countries are supposed to have management tools in place such as contingency plans that in case of incursion could be considered as an official control programme. Therefore, a country previously free and experiencing an incursion of FMD, may be in a position to trade if it fulfils all the requirements of Article 8.7.22.

Finally, the Commission invited previously FMD free countries or zones experiencing a FMD incursion to consider the other possibilities to facilitate trade such as the establishment of a containment zone or a short-term recovery, in accordance with Articles 8.7.8. and 8.7.9., respectively.

Article 8.7.31 Procedures for the inactivation of FMDV in meat and meat products

The Commission amended the text to clarify that a visual inspection of meat can determine that the requested temperature has been reached.

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**MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION  
OF FOOT AND MOUTH DISEASE STATUS OF MEMBER COUNTRIES  
Paris, 4 - 6 February 2014**

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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 4 to 6 February 2014.

**1. Opening**

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Elisabeth Erlacher-Vindel, Acting Head of the Scientific and Technical Department, welcomed and thanked the Group for being available for this additional meeting.

Dr Erlacher-Vindel informed the Group that the objective of this meeting was to finalise the consideration of comments received on Chapter 8.6. on FMD of the *Terrestrial Animal Health Code (Terrestrial Code)* from the OIE Member Countries and from the specialist Commissions. To help the Group in the process of reviewing the comments, she reminded that if time was lacking the Terrestrial Animal Health Code Commission had proposed that the Group only provide the scientific rationale to decisions rather than to focus on specific wording.

**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. Chapter 8.6. of the *Terrestrial Animal Health Code* on FMD: review of the comments from Member Countries and Specialist Commissions**

The Group reviewed Chapter 8.6. of the *Terrestrial Code* on FMD in detail by considering the comments submitted by Member Countries as well as questions referred from the OIE specialist Commissions. The Group accepted, where appropriate, amendments proposed by Member Countries. The following gives the rationale of noteworthy decisions taken to address Member Country comments.

**General comments**

Recognising that absolute proof of absence cannot be achieved, the Group agreed that the term “to substantiate absence” was a more appropriate term than “to demonstrate absence” However, the definition given in Article 1.4.6. point 5 explains that for the purpose of the *Terrestrial Code* “demonstrate” is not an absolute term. Therefore the Group agreed not to change the wording.

The Group considered the comments on the prescriptive three-month waiting period and the ten-kilometre distance. The Group reiterated that the elapsed time and increased distance were clearly related to lowering the risk of spread and proposed in the *Terrestrial Code* for several years as a practical guideline in the FMD chapter to establish a compartment or to import from an FMD infected country or zone. The Group stressed the principle of equivalence in the WTO Sanitary and Phytosanitary Measures (SPS Agreement) and indicated

that Member Countries may, for trade issues, set different measures but must justify and demonstrate that those measures comply with the requirements of the *Terrestrial Code*. The Group considered that the *Terrestrial Code* gives standards for international trade and that these prescriptive measures provide an essential basis. Regarding the ten-kilometre distance, the Group reiterated that this figure was based on the risk related to spread<sup>1,2</sup>. This topic was relevant and discussed for many articles, including Articles 8.6.4, 8.6.8 and 8.6.22.

For consistency and harmonisation of terminology, the Group agreed to use the term “transmission” instead of “circulation” throughout Chapter 8.6.

In response to several Member Countries comments, the Group did not support the addition of a definition for emergency vaccination as this already exists in Chapter 1.1.10 of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)*. The Group felt that it was unnecessary to link emergency vaccination to a specific potency of the vaccine since effective vaccination is also reliant on other control measures and countries use different formulations during their vaccination campaigns. The Group would rather emphasise that the vaccine should comply with the *Terrestrial Manual* with regard to vaccine potency, purity and strain matching, throughout the chapter for harmonisation.

#### **Article 8.6.1.**

The Group considered it counterproductive to include for the purpose of international trade additional species susceptible to FMD (e.g. including other camelids), because they do not play a significant role neither in the epidemiology of the disease nor in international trade, even if they can be infected. Trade in animals not listed in this article could still proceed, subject to bilateral agreements.

In response to the comment from a Member Country to define FMD as an infection with viruses of the genus Aphthovirus, the Group acknowledged this fact but concluded that there was no need, as it is not current practice, to detail virus taxonomy in the *Terrestrial Code*. The Group did not support another comment proposing to add that consequences of infection may or may not be clinically apparent as it was implicit in the Glossary definition of infection and was also elaborated in point 6 of this article.

The Group extensively discussed the definition of infection and recommended to keep a shorter and simpler definition. The Group proposed to differentiate the indication of FMDV infection through positive laboratory results and the confirmation (or exclusion) of FMDV infection through the consideration of other information, such as clinical signs, the number of animals positive to the tests and epidemiological links. The Group was of the opinion that it is the responsibility and competence of the Veterinary Authorities to conclude whether or not infection is present based on a combination of laboratory and field data rather than on laboratory data alone.

The Group proposed to improve the definition of “transmission” to take into account the comments from several Member Countries by focusing on the change of virological or serological status rather than on a recent infection. The Group clarified that “change” can be from a supposed free status and does not necessarily require previous testing.

In response to a Member Country’s comment and on request of the Scientific Commission, the Group defined a “carrier” in point 6 of this article and clarified that only African buffalo (*Syncerus caffer*) carriers have been shown to transmit FMDV. The Group decided that the period during which FMDV could persist in a carrier animal was too variable to be mentioned in the chapter and indications are contained in Chapter 2.1.5. of the *Terrestrial Manual*.

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<sup>1</sup> Keeling MJ, Woolhouse ME, Shaw DJ, Matthews L, Chase-Topping M, Haydon DT, Cornell SJ, Kappey J, Wilesmith J, Grenfell BT. (2001). Dynamics of the 2001 UK foot and mouth epidemic: stochastic dispersal in a heterogeneous landscape. *Science* 294(5543):813-7

<sup>2</sup> Wilesmith JW, Stevenson MA, King CB, Morris RS. (2003). Spatio-temporal epidemiology of foot-and-mouth disease in two counties of Great Britain in 2001. *Prev Vet Med.* 61(3):157-70

**Article 8.6.2. FMD free country or zone where vaccination is not practised**

The Group incorporated specific surveillance requirements in this article, for a country or zone changing its official status from FMD free with vaccination to FMD free without vaccination, which were previously found in surveillance articles of this chapter.

In response to a Member Country's concern on the documentation to be submitted annually to the OIE in order to maintain the official FMD status, the Group clarified that the requirements for the retention on the List had not been changed. In addition, the Group recalled that a specific form for annual reconfirmation was provided by the OIE to assist Member Countries in reconfirming their status. An update on the surveillance, and if relevant, explanations on the changes in the FMD situation or in the mitigation measures should be submitted with the annual reconfirmation form.

Regarding provisions related to zoological collections in point 7 of this article, the Group:

- did not support the comment of a Member Country that proposed to remove these provisions considering that an officially free country or zone should lose its status as soon as a clear threat of FMD was identified;
- reiterated that in the absence of a definition of a zoological collection in the glossary, the first points should give details on what is considered as collection for the purpose of this chapter of the *Terrestrial Code*
- emphasised that, to avoid unjustified vaccination due to an excessive consideration of risk assessment, the FMD threat should have been identified by the Veterinary Authorities.
- added the requirement that animal movements should be traceable (point c));
- agreed that surveillance should not be limited to clinical and active surveillance (Point f))

This paragraph was adjusted accordingly.

**Article 8.6.3. FMD free country or zone where vaccination is practised**

In response to a Member Country's comment on the distinction between the absence of outbreaks during two years and the absence of transmission during 12 months (point 2 of this article), the Group explained that the two requirements were complementary: Two years without outbreaks indicate that the vaccination is sufficient to prevent any clinical disease, which is the main source of virus shedding. The required 12 months without transmission indicate that there are no subclinical infections.

The Group clarified the requirements for surveillance in point 3 a) but considered that the duration for the surveillance requirement was implicit with regard to the previous requirements (point 2).

The Group also clarified a Member Country's question about the 24 months transition period for a country or zone to change the official FMD status from free with vaccination, where vaccination has been discontinued, to free without vaccination in comparison with the 12 months without vaccination in Article 8.6.2.. This transition period would allow a Member Country or zone to go through all the requirements and procedures to be recognised as FMD free without vaccination, but would avoid having a Member Country or zone officially recognised as FMD free with vaccination which discontinued vaccination. If a Member Country or zone officially recognised as FMD free with vaccination discontinues vaccination for more than 24 months, it will no longer be compliant with the requirements for a free country with vaccination, notably the requirement: "routine vaccination is carried out for the purpose of the prevention of FMD".

**Article 8.6.4. FMD free compartment**

The Group reiterated its support for compartments free from FMDV infection where vaccination is practised.

The Group recalled that implementation of a compartment, which has no official recognition by the OIE, is based on biosecurity measures rather than geographical or administrative boundaries as is the case for official recognition of an FMD free country or zone. Moreover, compartments are smaller and it is more feasible to detect infection even if vaccination is practised.

The Group agreed that the restriction of a three-month period before establishing a compartment could be removed because the animals would anyway not be traded before three months have elapsed as stated in the articles related to trade provisions (i.e. Article 8.6.11.). In addition, in contrast to the past where a compartment could only be implemented within a free country or zone, it can now be implemented within an infected country or zone (e.g. in Article 8.6.12.). Considering the risk of spread and the rationale explained above, the Group kept the ten-kilometre distance to decrease the risk of contamination.

The Group recalled that the procedure should be stricter during the period of establishing a compartment, compared to the period of maintenance of the status of the compartment, when biosecurity measures are already embedded. The Group took note of a comment on the risk from infected African buffalo within ten kilometres of the compartment. However, the Group was concerned that if there were livestock mingled with buffalo within the ten-kilometre area, this would represent an unacceptable risk, therefore the Group recommended not changing the text.

#### **Article 8.6.6. Establishment of a containment zone within an FMD free country or zone**

The Group reconsidered the time required before the establishment of a containment zone and followed the Directive from the European Union stating that two incubation periods were the minimum for lifting restrictions in the surveillance zone. The Group thus agreed to go back to two incubation periods as a prerequisite to establish a containment zone.

The Group could not support a Member Country's comment to detail specific surveillance measures, as they were already provided in Chapter 1.4. and in the surveillance articles of this chapter.

The Group reiterated that the detection of a new case within the containment zone should lead to withdrawal of the containment zone only if FMDV transmission was proved, because an infection can be linked to the presence of carriers or to a transmission that occurred prior to the establishment of the containment zone but detected during a sero-survey.

The Group clarified that once a containment zone has been withdrawn, the reinstatement of the status of the country or zone should follow the classical procedure for a recovery (Article 8.6.7.).

#### **Article 8.6.7. Recovery of free status (see Figure 1)**

The Group extensively discussed the time requirements to regain an official status after its suspension and recalled that time was an important factor to increase confidence in the observation and declaration that the disease has not spread.

Points 1 a) and 1 b): The Group removed the limitation to "serological" surveillance considering that other kinds of surveillance could be implemented depending on the context.

To regain a free status, two incubation periods (one month for FMD) after cleansing and disinfection allow time for disclosure of cases that could arise from undetected outbreaks. In addition, serological surveillance should only start 21 days after the eradication of the last case (reference to EU directive<sup>3</sup>). However, the Group flagged that such a short period would leave no margin for error. Therefore, three months were considered to be a sensible compromise. The commenting Member Country was invited to provide evidence in support of further reduction to this time period.

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<sup>3</sup> Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (OJ L 306, 22.11.2003, p. 1)

Point 1 c): The Group understood that four Member Countries would like to reduce the waiting period from six months to three months when emergency vaccination-to-live was conducted but also to restrict the burden of serological surveys by sampling a statistical group of animals rather than the entire vaccinated population. The lengthy discussion on this topic is recorded under the section 8.6.45 of the present report. The Group finally incorporated the requirement for surveillance directly in Article 8.6.7. point 1 c) of this chapter.

Point 2: Regarding the waiting period for a country previously free without vaccination wishing to recover the status free with vaccination, the Group agreed that it could be limited to three months and specified the surveillance to be conducted directly in Article 8.6.7. point 2. The Group also corrected a reference to Article 8.6.3.

Point 3 a): The Group considered the residual risk of FMD infection after stamping out, comparing the situation in an initially free country/zone without vaccination to that of a country/zone initially free with vaccination and concluded that, in the latter case, the risk of undetected cases and consequently missed outbreaks could be greater. Therefore, the waiting period should remain as six months.

Point 3 b): The Group considered the extra risk of residual infection without the implementation of stamping out policy. When the source of FMD is not removed, the virus can still be transmitted in the population. The Group recommended that there should be at least one generation of sentinel calves that have lost their maternal/colostral immunity introduced to this population. Considering that an extra (emergency) vaccination has been implemented, the Group proposed to reduce the waiting period to 12 months.

**Article 8.6.8. Direct transfer of FMD susceptible animals from an infected zone for slaughter in a free zone (where vaccination either is or is not practised)**

The Group kept the ten-kilometre requirements. However, the Group agreed to reduce the waiting period to four weeks (two incubation periods) with reference to Mark Stevenson, 2003<sup>4</sup> as these animals are going for slaughter. Conversely in other articles, the animals are not necessarily slaughtered; therefore a longer waiting period would be required.

**Article 8.6.10. Recommendations for importation from FMD free countries, zones or compartments where vaccination is not practised**

In response to a Member Country's comment, the Group agreed that previously vaccinated animals from a country or zone free without vaccination could be exported to a country or zone free with vaccination. The article was adapted accordingly.

**Article 8.6.11. Recommendations for importation from FMD free countries, zones or compartments where vaccination is practised**

A Member Country suggested that a period in which animals were not vaccinated for trade to a country or zone free without vaccination should be provided. The Group recalled that the intention was that the animals destined to a country or zone free without vaccination should have never been vaccinated. Indeed, the requirements for introduction into a free country or zone without vaccination stated that no vaccinated animals have been introduced since the cessation of the vaccination (reference to Article 8.6.2.).

**Article 8.6.12. Recommendations for importation from FMD infected countries or zones**

In response to a Member Country comment to include nucleic acid detection as an alternative testing method, the Group disagreed as nucleic acid detection is a method of virus detection, which is different from virus isolation. However, the Group agreed to change the terminology from "detection" to "identification" to be compliant with the *Terrestrial Manual*.

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<sup>4</sup> Mark Stevenson 2003, PhD Thesis, Spatio-temporal epidemiology of BSE and FMD in Great Britain, p208

In response to a question from the Scientific Commission whether to propose requirements on importation of wild animals from infected countries or zones, the Group suggested that this should remain as a bilateral agreement between trading countries as there were a number of uncertainties that makes recommendations difficult. These include lack of validation of diagnostic tests, difficulty of sampling and lack of validation of sampling methods, lack of information regarding susceptibility and excretion of the virus for these species, as well as lack of information on the procedure to follow for the import. In addition, the Group confirmed that, even for wildlife, the scope of this chapter would be limited to *Ruminantia*, pigs and *Camelus bactrianus*.

**Article 8.6.15. Recommendations for importation from FMD free countries, zones or compartments where vaccination is practised**

The Group agreed to a Member Country comment that, to import frozen semen from domestic ruminants and pigs from a country or zone free with vaccination, no more than six months (rather than twelve months) could have elapsed since the last vaccination of the donor, unless duration of immunity greater than six months can be demonstrated for FMD vaccination. The Group considered that this proposal should be also copied to Articles 8.6.16., 8.6.19. and 8.6.22.

**Article 8.6.21. Recommendations for importation from FMD free countries, zones or compartments where vaccination is practised**

In response to a Member Country comment, the Group noted that the meat of all ruminants should be considered in the same manner. The Group also disagreed that the restriction on the feet, head and viscera presented in Article 8.6.22. should be applied to the current article, as the two articles describe different Member Country status.

The Group confirmed that the head and specified organs of all ruminants should be excluded to take into account the risk of carriers but not those of pigs, as pigs cannot be carriers.

**Article 8.6.22. Recommendations for importation from FMD infected countries or zones, where an official control programme for FMD, involving compulsory systematic vaccination exists**

In response to a comment from the Scientific Commission for a clear distinction between an official control programme and an OIE endorsed programme, the Group referred the decision back to the Scientific Commission but indicated that the requirements for trade from infected countries should be kept.

In response to a Member Country comment the Group clarified that this article could not be extended to the fresh meat of sheep and pigs, because it relates to an infected country with an official control programme where vaccination exists and in which outbreaks continue to occur and therefore where the overall virus load is dampened by vaccination. In addition, sheep are not often vaccinated and do not show clinical signs.

**Article 8.6.23. Recommendations for importation from FMD infected countries or zones**

The Group disagreed to a proposal from a Member Country to add a new article on imports of fresh meat from infected countries or zones, because the proposed article did not link the meat to the holding of origin, including no physical or temporal separation from infected animals, and did not stipulate an official vaccination programme to mitigate the residual risk.

**Article 8.6.29. Recommendations for importation from FMD free countries zones (where vaccination either is or is not practised)**

The Group agreed that this article should not be limited to wild animals but should also consider captive wild animals and feral animals and therefore introduced the word “wildlife” defined in the Glossary. This was also changed in Article 8.6.30. In addition, the Group proposed to extend this article to compartments (e.g. game parks).

**Article 8.6.31. Procedures for the inactivation of the FMD virus in meat and meat products**

The Group considered a Member Country comment and amended the text to include “70°C throughout the meat” with reference to EU legislation<sup>5,6</sup>. This would allow a visual assessment, as a temperature of 70°C is sufficient to modify the internal muscle fibre structure and so that the cut surface shows that the product no longer has the characteristics of fresh meat. The Group stated that the requirements were there for a long time, heating to 70°C causes 10<sup>5</sup> reduction in FMDV titre. Whether or not this inactivates all virus in a product depends on the extent to which the temperature has been reached throughout the product. This justifies the approach of requiring a discoloration of the meat as it signifies heating throughout substance in direct function of the size and weight of the meat cut subjected to the heat treatment<sup>7</sup>.

**Article 8.6.39. OIE endorsed official control programme for FMD**

Based on the experience of evaluation of Member Country applications for an OIE endorsed official control programme, the Group agreed to clarify the article and the questionnaire by addressing the following points to better assist Member Countries in the preparation of their dossiers:

- Clarification that the OIE PVS Pathway is one way of providing evidence on the capacity of the Veterinary Services to control FMD (Article 8.6.39. point 2);
- Requirement of a description of the progress made (Article 8.6.39. point 4 a));
- Requirement of evidence of the current FMD situation (text incorporated in Article 1.6.10.)

These additional points were made to provide a clearer framework on the expectations to be met by Member Countries to achieve an OIE endorsed official control programme.

**Articles on surveillance:**

The Group discussed the articles on surveillance extensively while considering Member Country comments relevant under each article. The Group revised and reorganised Articles 8.6.40 to 8.6.46. in order to improve the flow and to clarify the text in the following manner:

- The most general guidelines from articles 8.6.41, 8.6.43. to 8.6.45. were moved to 8.6.40.
- Other parts were redistributed while retaining the content under the relevant articles 8.6.2., 8.6.3. and 8.6.7.
- Others were removed when already covered elsewhere in this chapter or in Chapter 1.4.

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<sup>5</sup> Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)

<sup>6</sup> Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (OJ L 18, 23.1.2003, p. 11)

<sup>7</sup> Foot and Mouth Disease Virus Concentrations in Products of Animal Origin, E. Ryan, D. Mackay and A. Donaldson, *Transboundary and emerging diseases*, 55 (2008) 89-98

Essentially, the articles on surveillance were reorganised into three articles: Article 8.6.40. as a general principles, Article 8.6.41. to address the different surveillance methods (previously 8.6.42.), and Article 8.6.42. to cover the interpretation of serological tests (previously 8.6.46.).

Rationale is provided in this report when the essence of the requirements have been modified.

The Group wondered if each paragraph could be numbered for ease of reference.

#### **Article 8.6.40. Surveillance: introduction**

The Group considered a comment that suggested that a single FMD prevalence rate derived over a period of time could misrepresent the current understating of contagious disease dynamics. The Group indicated that establishing a prevalence of infection can be useful, in particular to monitor the progress in FMD control.

The Group agreed that the performance of confirmatory tests should also be taken into account in the surveillance system.

The Group confirmed a Member Country comment that occurrence of false negatives were taken into account by incorporating test sensitivity into the survey design.

#### **Article 8.6.41. Surveillance: general principles – Article removed**

Relevant content incorporated in 8.6.40.

#### **Article 8.6.42. Surveillance: methods (now 8.6.41.)**

The Group clarified the content. In response to a Member Country comment that no specific guidance in wildlife was provided in cases where clinical surveillance may be insufficient, the Group mentioned the challenge to provide specific guidelines for wildlife but added that hunting, capture and non-invasive sampling methods can be used to obtain diagnostic specimens from wildlife. The Group recalled that the *Terrestrial Code* provides general guidelines.

#### **Article 8.6.43. Members applying for recognition of freedom from FMD for a country, zone or compartment where vaccination is not practised: additional surveillance procedures – Article removed**

The Group clarified the requirements for the two different populations, non-vaccinated and vaccinated populations. Especially for Member Countries transitioning from a status free with vaccination to free without vaccination status, because it is logistically difficult to demonstrate absence of FMDV infection in a large regularly vaccinated population. In addition, a country already recognised to be free with vaccination would have been monitoring the absence of circulation for a while, therefore a requirement to demonstrate absence of FMDV infection in the whole population would be excessive in proportion to the risk. The substance of this article was mainly moved to Article 8.6.2. point 3 a).

#### **Article 8.6.44. Members applying for recognition of freedom from FMD for a country, zone or compartment where vaccination is practised: additional surveillance procedures – Article removed**

Based on the experience in evaluation of dossiers from Member Countries for official recognition of FMD free status, the Group could not support a comment that the focus of surveillance should only be on demonstrating freedom from FMD, and not also on estimating population immunity. Furthermore, given the limitations in proving absence of infection or transmission, the Group noted the importance of providing adequate evidence of vaccine quality and effectiveness of the implemented vaccination programme.

The Group disagreed to add excessive details on reference of statistical figures with regard to describing the significance of different antigenic properties between field and vaccine virus. The content of this article was mainly moved to Article 8.6.40.

**Article 8.6.45. Members re-applying for recognition of freedom from FMD for a country, zone or compartment where vaccination is either practised or not practised, following an outbreak: additional surveillance procedures – Article removed**

The Member Countries comments related to this article were all referring to the additional surveillance to be conducted for countries/zones wishing to recover their FMD free status without vaccination after having implemented a vaccination-to-live strategy.

The Group acknowledged that census surveillance was prescriptive and therefore considered that the three-month option would only be practicable for outbreaks in a limited zone where emergency vaccination was carried out. The Group could accept that the risk related to animal products would be limited; however the Group identified a risk in trade of live non-vaccinated animals due to the fact that the non-vaccinated population could be mixed with a vaccinated population within the country where the emergency vaccination had been carried out.

The Group recognised that if vaccination was conducted effectively, the FMDV transmission would stop. Therefore, the Group highlighted that more emphasis should be given to provide evidence of effective vaccination (e.g. population immunity) as this would give additional confidence in demonstrating the absence of infection. The Group agreed to incorporate this point under Article 8.6.40., because it was not limited to routine vaccination in countries free with vaccination but also applies to emergency vaccination in countries free without vaccination.

The Group agreed that, in theory, a lower level of surveillance could be recommended to make sure the lowest level of possible transmission would be found. However, in practice, the Group was not aware of documented information on the minimum level of transmission for virus persistence or the sensitivity of the non-structural proteins (NSP) test to detect a low level of transmission and proposed the Member Country to provide evidence to support alternative approaches.

The essence of this article was mainly moved to Article 8.6.7. point 1 c).

**Article 8.6.46. The used and interpretation of serological tests (see Figure 2) (now 8.6.42.)**

In response to a Member Country comment, the Group agreed that NSP tests detect infection but considered that they could also help proving transmission.

The Group agreed to a Member Country comment and clarified that the 30-day period post-vaccination for NSP testing should consider the vaccination area to allow a progressive control of the disease. In response to a Member Country comment, the Group clarified the text on the procedure in case of positive test results, especially on the interpretation of the proportion and strength of sero reactors.

In the paragraph on the possible causes for positive FMD antibody test, the Group agreed to combine the non-specific reactivity of the serum (point d) and the lack of the specificity of the diagnostic tests (point e) as they are indistinguishable in a laboratory setting.

Even after the retesting has been done, the status of a herd can remain undetermined. The follow-up measures that were proposed should be related to the risk.

The Group incorporated another Member Country comment to clarify the situation where a Member Country was trying to establish or re-establish the status of an FMD free country or zone where vaccination is not practiced.

**Figure 1: Schematic representation of the minimum waiting periods and pathways for recovery of FMD free status**

Figure 1 was divided in Figure 1 and Figure 2. Both titles were clarified.

The Group removed the colour codes and updated the figures in accordance with the proposed revision of the chapter. In response to a Member Country remark, the Group explained that the compliance with Article 8.6.2. required 12 months without infection but acknowledged that in the absence of control measures, reaching the absence of infection would likely take much longer. The footnote was amended for further clarification that if there are multiple waiting periods due to different control measures, the longer pathway for recovery would apply.

**Figure 2 Schematic representation of laboratory tests for determining evidence of FMDV infection through or following serological surveys (now Figure 3)**

The Group agreed to delete the unnecessary repetition of terms to address Member Country comments to revise the NSP conf. test EITB in accordance with the relevant (previous) Article 8.6.46.

**Questionnaires on FMD, Article 1.6.5.**

The Group considered the comments from a Member Country on Article 1.6.5. of the *Terrestrial Code* related to the four questionnaires to apply for an FMD official status. The Group agreed that most of these comments clarified the information that was requested to evaluate the applications from Member Countries and accepted them.

2. Veterinary System

Section 2. b) used to refer to Chapter 1.1.3. of the *Terrestrial Manual*. It was corrected to Article 1.1.3 of the *Terrestrial Code* as this Article refers to the notification of diseases by the Veterinary Authority to the OIE which is a pre-requisite to any application for an official disease status. In addition, applicant Member Countries are already requested to provide evidence of their compliance with the provisions of Chapter 1.1.3. of the *Terrestrial Manual* in section 4.

The Group emphasised that this should also be corrected in Articles 1.6.4, 1.6.6., 1.6.7., 1.6.8., 1.6.9. 1.6.10. and 1.6.11.

3. FMD eradication

The Group acknowledged the importance of the fate of previously vaccinated animals in countries or zones applying for freedom without vaccination and included it into the questionnaire.

The Group agreed to require more specific information about animal identification and movement controls while addressing both legal and illegal movements.

The Group supported that the vaccine should comply with the requirements in the *Terrestrial Manual*, and clarified this point in the questionnaires for country and zone applying for freedom with vaccination.

4. FMD diagnosis

The Group took note of a Member Country comment to provide further detail on the overview of the capabilities of the FMD approved laboratories as it would assist in evaluating the diagnostic and surveillance data from an applicant Member Country.

#### 5. FMD surveillance

The Group agreed to reflect that serological surveillance activities have been complete and not on-going (point b). In addition, the Group considered that point e) should include events at which FMD susceptible livestock may gather because it would be an important component in understanding the epidemiology of FMD in the applicant Member Country.

#### 6. FMD prevention

The Group acknowledged the potential entry pathways, particularly sourcing of stock feed and bedding, and the biosecurity practices of farmers and animal workers travelling, which could act as a direct high risk pathway.

The Group considered the importance of the corrective actions that have been undertaken in response to a previous disease incursion which would help to demonstrate the ability of an applicant country in describing the epidemiology of the outbreak as well as the ability to reduce the likelihood of future incursions.

#### 7. Control measures and contingency planning

The Group emphasised the contingency planning and outbreak response planning and for more specific information about control and eradication procedures to be submitted by applicant Member Countries. In addition, the Group modified point c) iii. to include information on the access to antigen and vaccine banks due to its sensitivity.

### **4. Other matters**

The Group suggested that the text in Chapter 8.6.42 and Figure 3 be incorporated in the *Terrestrial Manual*.

The Group put more emphasis on the population immunity in the Article 8.6.40 on surveillance. However, the Group is aware that there are difficulties in practise in establishing threshold for acceptance. The Group proposed a solution to this problem by recommending a change to the *Terrestrial Manual* so that vaccine manufacturers provide on request of the vaccine purchaser, post-vaccination sera produced during final product batch testing for potency. This could be used to calibrate the locally used tests for measuring population immunity.

### **5. 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.

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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, 4 - 6 February 2014**

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**Agenda**

1. Opening
  2. Adoption of the agenda and appointment of chairperson and rapporteur
  3. Chapter 8.6. of the *Terrestrial Animal Health Code* on FMD: finalise review of the comments from Member Countries and specialist Commissions
  4. Other matters
  5. 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, 4 - 6 February 2014**

**List of participants**

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**Rationale for the amendments to:**

**CHAPTER 8.X. INFECTION WITH MYCOBACTERIUM TUBERCULOSIS COMPLEX  
provided by the Scientific Commission**

*To be considered together with the ad hoc Group report (annex 7 and annex 8)*

Article 8.X.1. General provisions

The Commission discussed the importance of certain wild animal species and proposed the word ‘reservoir’ to be consistent with the terminology of the *Terrestrial Code*.

The Commission considered the opinion of the *ad hoc* Group on Camelids on the inclusion of camelids as significant susceptible species for tuberculosis. While noting that South American camelids play a significant role in the epidemiology of tuberculosis, the Commission took note of the *ad hoc* Group concern about the absence of validated test methods in New World camelids. The Commission decided to further investigate the test methods used in New World camelids, by seeking the expertise of the Wildlife Working Group. The Commission recommended to include New World camelids in the list of epidemiology significant species in the Chapter with the mention “under study” and amended the chapter accordingly.

The Commission had a similar discussion on goats for which no validated tests exist. Considering the potential zoonotic impact of tuberculosis in goats, the Commission maintained the recommendations related to goats throughout the tuberculosis chapter.

Article 8.x.2. Safe commodities

The Commission agreed that ante and post-mortem inspections were enough to ensure the safety of the fresh meat while requesting the general inspection that always apply to fresh meat. Thus, the Commission recommended that fresh meat be considered as a safe commodity.

Article 8.x.3. Historical freedom

The Commission considered that point 1 and 2 on the notifiability and the early detection were already covered in point 3 making reference to Point 1 of Article 1.4.6., and deleted both of them.

In addition, the Commission discussed the deletion of this Article as horizontal chapters, such as Chapter 1.4., prevail. Historical freedom should apply except in specified otherwise in the disease-specific chapter. The Commission referred this question to the Code Commission.

Article on free compartment

The Commission reminded that the tuberculosis chapter was updated in accordance with the recently adopted Brucellosis chapter. Therefore, and considering the existence of a specific article of herd freedom, the compartment article was not considered as needed. The Commission also referred its decision to the discussions on that topic during previous General Sessions.

Article 8.x.8. Importation of goats for breeding or rearing

The Commission considered the absence of diagnostic validated test for goats. The Commission suggested that this article, as well as Article 8.x.14. (Importation of milk and milk product of goats) remained as amended by the *ad hoc* Group. These articles should be revised once a validated test becomes available.

Article 8.x.12 importation of embryos and oocytes

The Commission deleted Point 1 to be consistent with the other articles.



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

Paris, 9-11 April 2013

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

### 1. Opening, adoption of the agenda, appointment of chairperson and rapporteur

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Elisabeth Erlacher-Vindel, Deputy and Acting Head of the Scientific and Technical Department of the OIE, welcomed the Group and explained the objectives of the meeting. The pathogen approach undertaken in the revision of the *Terrestrial Animal Health Code (Terrestrial Code)* chapters was on-going and could act as a useful guide to the revision of the tuberculosis chapters, namely Chapter 11.6 on bovine tuberculosis and Chapter 11.7 on bovine tuberculosis of farmed *Cervidae*. The chapters on brucellosis had been recently reviewed and merged into a single multispecies chapter with management options per species affected. Following the endorsement of the Scientific Commission for Animal Diseases (Scientific Commission) and the Terrestrial Animal Health Standard Commission (Code Commission), the proposed draft chapter on brucellosis was undergoing circulation for Member Country comments that would be reviewed by both Commissions at their respective September 2013 meetings. It was recommended to the Group that if it was scientifically justified they could follow the same approach for tuberculosis. Other items to be discussed were the implication of wildlife species for tuberculosis management in domestic and captive wild susceptible animals, the use of gamma-interferon tests in surveillance and the use of vaccination as a control option.

The Group adopted the proposed agenda for the meeting. The Group was chaired by Dr Francisco Reviriego Gordejo, and Prof Glyn Hewinson acted as rapporteur.

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

### 2. Revision of the Terrestrial Code chapters on tuberculosis

The Group agreed to follow the same approach as used for the chapters on brucellosis using the same underlying scientific grounds, including differing management practices by species. The approach was modified, where appropriate, to reflect species specific issues related to the control of tuberculosis.

#### Title

The Group named the chapter “Infection with *Mycobacterium tuberculosis* complex” since the susceptible animal populations could be infected by members of the *M. tuberculosis* complex other than *M. bovis*.

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

### Case and infection definitions

Definitions of "case" and "infection" were drafted by the Group taking the draft brucellosis chapter as a model. In addition to merging the provisions under the current *Terrestrial Code* Chapters 11.6 and 11.7, the Group discussed the relevance of each *Mycobacterium* species for the animal species considered in the *Terrestrial Code* for tuberculosis.

The Group discussed which species of the *Mycobacterium tuberculosis* complex should be included in the definition of infection. *M. bovis*, *M. caprae*, *M. tuberculosis*, *M. africanum*, *M. microti* and *M. pinnipedii* have all zoonotic potential, however infections with *M. africanum*, *M. microti* and *M. pinnipedii* have so far been sporadic and opportunistic in the animal hosts considered susceptible for the purposes of the *Terrestrial Code* and thus the Group concluded that there was insufficient evidence to include them in the *M. tuberculosis* complex. However, there is good evidence that *M. caprae* infects and is maintained in cattle, goats, and wildlife in continental Europe.

The Group discussed the increasing reports of *M. tuberculosis* infection in cattle and proposed to include it in the *M. tuberculosis* complex due to its zoonotic potential and to the fact that current diagnostic tests do not distinguish between any of the members of the *M. tuberculosis* complex. Further studies are needed to clarify whether the disease is self-limiting in cattle and whether cattle can act as a reservoir for *M. tuberculosis* in humans.

Vaccine strains were excluded from the definition of the *M. tuberculosis* complex.

### Epidemiologically significant hosts

The Group extensively discussed and revised the epidemiologically significant animal species. *M. tuberculosis* complex bacteria can infect many mammals, but not all species act as maintenance hosts and reservoirs for infection of livestock. Spill-over incidents are very common in a wide range of species.

The OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* Chapter on tuberculosis, the scientific review on tuberculosis in wildlife in the EU published by European Food Safety Authority (EFSA) (2009)<sup>1</sup>, as well as an article published by Cousins and Florisson (2005)<sup>2</sup>, were used for reference by the Group. In addition, the representative of the Working Group on Wildlife Diseases made a presentation on tuberculosis in free ranging wildlife in Africa.

The Group recognised the epidemiological role played by free-ranging badgers, possums, deer, wild boar, buffalo, kudu, lechwe and warthogs in certain ecosystems but for the purpose of this chapter, only domestic and captive wild animal populations would be considered. This is because the epidemiological significance of the wildlife reservoir depends upon local conditions and cannot be considered in a global manner. Factors that determine the significance of the wildlife reservoir include the degree of susceptibility to the pathogen and its pathogenesis, the husbandry system, the density, spatial distribution and bio-ecology of the wildlife populations and transmission pathways.

The mammalian hosts for which the infection is notifiable include those species of bovids and cervids for which live animals or products are commonly traded. Regarding cervids, only those farmed were included. The Group also proposed to add roe deer, African buffalo, greater kudu and lechwe since they are high risk maintenance hosts and are regionally traded.

<sup>1</sup> EFSA (2009). Technical Report submitted to EFSA. Scientific review on Tuberculosis in wildlife in the EU. CFP/EFSA/AHAW/2008/3.

<sup>2</sup> Cousins, D.V. and Florisson, N. A review of tests available for use in the diagnosis of tuberculosis in non-bovine species. *Rev.sci.tech. Off.int.Epiz.*, 2005, **24** (3), 1039-1059.

The Group discussed the significance of small ruminants in tuberculosis dissemination. Sheep appear to be less susceptible to infection/disease than goats and the Group concluded that there is insufficient evidence to demonstrate that sheep can be significant maintenance hosts. However, for goats, compelling evidence has been published that indicate that the epidemiology of *M. caprae* infection in Spain was driven by caprine infection and that as a consequence *M. caprae* poses a health risk for goats, other domestic and wild animal species and humans<sup>3</sup>. Therefore, it appears that the disease can be maintained in this species which could lead to a potential animal and public health risk. However, to the knowledge of the Group, no tuberculosis problems related to goat trade have ever been reported. The association between goats and *M. caprae* is not absolute. Goats can be infected by any species of the *M. tuberculosis* complex and *M. caprae* is also predominant in some areas of central Europe where it has been isolated from cattle, pigs, red deer and wild boar. The Group discussed the addition of other species relevant to trade, such as camelids, and concluded that they did not have sufficient expertise to be able to recommend the inclusion of camelids. They suggested to the Scientific Commission that experts on camelid diseases should be asked whether camelids should be included as an epidemiologically significant species for tuberculosis in the *Terrestrial Code* chapter.

#### **Article 8.x.1. bis - Safe commodities**

A new article (Article 8.x.1.bis) was developed on safe commodities to harmonise the chapter with others that have recently been reviewed. Organs and lymph nodes constitute the main meat risk commodities for tuberculosis. The Group had a lengthy discussion on the inclusion or not of fresh meat and meat products as a safe commodity. The Group agreed that any meat should undergo post-mortem inspection but did not reach a definitive opinion on whether to include fresh meat and meat products as a safe commodity or keep it as a recommendation for trade, and therefore both options were retained in the draft chapter.

#### **Articles on disease freedom**

Country and zone freedom was proposed for cattle, water buffalo and wood bison, and for cervids in two distinct articles. Provisions for the maintenance of a free status were also drafted using the draft chapter on brucellosis as a model template.

The Group considered a Member Country's comment on adding the performance of a risk analysis of wildlife to establish, if appropriate, a monitoring programme for those animals found susceptible, to the provisions of country or zone disease freedom. The Group recommended that maintenance host species should be distinguished from incidental host species to develop appropriate risk mitigation measures. However, they considered that active wildlife surveillance is very expensive and scanning surveillance through road kills, catching or hunting could lead to a distorted, unrepresentative or misinformed risk assessment that would not be appropriate to distinguish the role of the wild animals in transmission to livestock. Nevertheless, passive surveillance was considered important for the detection of infection in wildlife.

For goats, provisions on freedom were not proposed since active surveillance was not considered a proportionate option. Similarly, for African buffalo, greater kudu and lechwe provisions were not proposed because meaningful active surveillance was not considered feasible.

Provisions differentiating the establishment from the maintenance of disease freedom were also drafted along the lines used for the draft chapter on brucellosis.

#### Article on compartmentalisation

The Group agreed to delete the article on compartments for tuberculosis since, as for brucellosis, the disease free status of herds should be sufficient to manage the risks posed by tuberculosis, both in terms of trade and disease control.

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<sup>3</sup> Rodriguez S et al. *Mycobacterium caprae* Infection in Livestock and Wildlife, Spain. *Emerg. Infect. Dis.*, 2011, **17**: 532-5.

Herd freedom (Article 8.x.3)

The Group merged the article on herd freedom for cattle, water buffalo, wood bison and cervids, as the two groups of species should comply with the same provisions.

In reply to a Member Country's comment on extending the period during which no clinical signs are observed for herd freedom in cattle, water buffalo and wood bison, from one year to three years, as was indicated in the current *Terrestrial Code* chapter on tuberculosis for farmed deer, the Group indicated that the progression of tuberculosis may be similar or more rapid in cervids than in cattle, water buffalo and wood bison. For this reason, the Group argued that the 3-year period without clinical signs to demonstrate herd freedom as currently stated in the *Terrestrial Code* for farmed deer was disproportionate to the risk, and aligned it with the existing provision for cattle, water buffalo and wood bison which considered 1 year as appropriate. The Group agreed that one year without clinical signs was sufficient to demonstrate freedom from infection in a herd, provided that the testing scheme is performed adequately and that pre-movement testing of animals was implemented. The period without infection, at the herd and country level, were not comparable since the higher sensitivity would be more difficult to attain at the country level.

In the establishment of herd freedom, the Group indicated that the first test, of the two needed at a minimal interval of six months, should take place after the *removal* of the last case, not the *slaughter* of the last case, as was indicated currently in the *Terrestrial Code* chapter. The wording was changed to allow management options for positive animals such as segregation.

The Group discussed the risk posed by mixed herds and, in order to grant the status of these herds, a provision was added (in line with the draft chapter on brucellosis) in which no evidence of infection should be present in other susceptible animals of the same epidemiological unit within the last 12 months.

In addition, new text was drafted to maintain the status in the herd.

Recovery of free status

With regard to the recovery of country/zone status, the Group agreed, after discussion, that, unlike brucellosis, the addition of a specific article on recovery of status was not needed for tuberculosis. This is because the proposed draft Chapter on tuberculosis allows country/zone free from infection with *M. tuberculosis* complex might have infection(s) in limited herds or animals (less than 0.2 or 0.1 %, respectively) while the draft Chapter on brucellosis requires that no case of *Brucella* infection has been recorded for at least the last three years in a country or zone free from *Brucella* infection without vaccination.

**Articles on importation**

The Group noted that no artificial insemination centers exist for cervids.

The Group proposed new articles for the importation of African buffalo, greater kudu, lechwe and goats, based on the absence of clinical signs or detection in the herd of origin for at least 3 years. A longer period of time was needed than that required for bovids and cervids due to the absence of provisions on herd free status for these species.

**3. Advantages and disadvantages on vaccination strategies for tuberculosis**

The Group was informed that the Scientific Commission had received a request from the Biological Standards Commission to discuss tuberculosis vaccination following an application to evaluate DIVA<sup>4</sup> tests for tuberculosis vaccination. Currently tuberculosis vaccination is not officially endorsed by the OIE, one of the reasons being the absence of a validated test to differentiate infected from vaccinated animals.

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<sup>4</sup> Test to differentiate infected from vaccinated animals

Prof Hewinson summarised the discussions of a workshop on tuberculosis vaccination organised by Welsh government that took place in Cardiff, United Kingdom, from 10 to 11 December 2012. The report was shared with the rest of the Group ("Cattle TB Vaccination Workshop Report", available at [www.cymru.gov.uk](http://www.cymru.gov.uk), accessed on 11 April 2013).

Tuberculosis vaccination using 'Bacillus Calmette-Guerin' (BCG) was practised in cattle in a number of European countries until the tuberculin test and slaughter control strategy was developed. This strategy was found to be more efficient and effective at removing tuberculosis infection from herds than BCG vaccination which had the added disadvantage that it sensitised cattle to the tuberculin skin test and so legislation was introduced in Europe and elsewhere to prohibit tuberculosis vaccination in cattle. However, in some countries, especially those that cannot afford to implement a test and slaughter control strategy or those countries with a wildlife reservoir of *M. bovis* that hampers attempts to eradicate bovine tuberculosis by conventional test and slaughter means, additional tools may be helpful to control bovine tuberculosis. Although vaccination of cattle with BCG is no panacea, when targeted effectively, it might be a useful additional component of a control programme.

Cattle vaccination may be expected to have a greater positive impact on cattle-to-cattle transmission than wildlife-to-cattle transmission as the former includes the effect of a reduction in the onward transmission from vaccinated individual cattle that become infected. The effect of vaccination of cattle in the face of a wildlife reservoir will depend on vaccine efficacy which, if below 100%, will not protect every cow against *M. bovis* infection from a wildlife source.

There have been numerous reports as to the efficacy of BCG vaccination in cattle over the years. However, as for human BCG trials, differences in BCG strains and doses used, the measured outcomes of vaccination, the lack of controls in many field reports, the variation in disease prevalence in target populations, age of vaccination, etc. make it impossible to precisely define vaccine efficacy for BCG in cattle from the existing literature. The only conclusion that can be drawn is that field results have been variable. Thus over the past ten years there has been a concerted effort to define the strain of BCG (BCG Danish – produced by Statens Serum Institut and licenced for use in humans in Europe) used in cattle, to use BCG manufactured to Good Laboratory Practices, to optimise the dose of BCG for use in cattle and to standardise experimental procedures and outcome measures so that results can be compared between studies. Experimental studies have demonstrated that BCG reduces the severity of infection with *M. bovis*, the majority of animals benefiting from vaccination with a proportion of animals fully protected from infection and a proportion of animals partially protected. However, a proportion of animals remain fully susceptible to infection after BCG vaccination. The duration of immunity has been demonstrated experimentally as between 1 and 2 years. In a small scale experiment carried out in Ethiopia using the optimised dose of BCG Danish, an efficacy of approximately 60% was observed over a 1-2 year period. This type of study still requires repeating in a number of different trials and locations to assess the robustness of these findings. Safety studies are also ongoing to determine the migration of BCG from the site of inoculation, the persistence of BCG in different tissues and the potential for vaccinated animals to shed BCG in milk.

Since the main reason for not allowing BCG vaccination of animals is that BCG sensitizes animals to the tuberculin skin test, there has been a concerted effort to develop tests that differentiate between vaccinated and infected animals (DIVA tests). Recent experimental studies have demonstrated that BCG vaccination induces strong skin-test responses in calves during the first six months but that there is a rapid decay in skin test sensitivity between 6 and 9 months representing a reduction from 80% to 8% without loss of protective immunity in this time. Modern genomic approaches have allowed the identification of antigens that are present in *M. bovis* but absent from BCG and these antigens have been used to develop candidate DIVA tests based on gamma interferon and skin test formats. The gamma interferon-based test is the most advanced and is ready for assessment in large scale field trials and such trials are being planned at present in Great Britain.

The Group discussed issues around vaccination and DIVA tests.

Vaccination: The Group suggested that performance of the vaccine might depend on age, breed or exposure to environmental mycobacteria, and that vaccination protection could be compromised by local health and nutrition conditions, which is why it would be important to detect infection before vaccination. The Group also envisaged potential problems related to revaccination which may desensitize the animals and even impair protection of subsequent vaccine doses inoculated. The Group also suggested that the effectiveness of BCG vaccination could decrease in the case of co-infection with paratuberculosis or other concomitant

environmental mycobacterial infections. Some members of the Group suggested that as it is a live vaccine, there might be a risk of selection pressure that creates a subpopulation of mycobacteria for which vaccination would be less efficient. However, the Group acknowledged that there had been no strong evidence for this happening in humans and did not come up with a proposal on how this possibility could be tested. The risk of spread of vaccine strain through different commodities is also not known but work is on-going to address this.

DIVA tests: The Group highlighted the fact that trade would be seriously compromised if infected animals cannot be differentiated from vaccinated ones. They also pointed out that the cost of a gamma-interferon based DIVA tests would be high and that there are challenging logistics associated with getting the blood to a laboratory in time and under controlled temperature conditions. Thus, for developing countries, it might not be a feasible option. The Group also pointed out that gamma-interferon tests cannot be carried out on animals less than six months of age. For the above reasons, the Group considered that it is unlikely that vaccines would be used in mass vaccination strategies in the near future. The Group recognised that the development of suitable DIVA tests might also be beneficial in developing a defined ‘tuberculin’ that facilitates the identification of tuberculosis infected animals from BCG vaccinated animals but also from those co-infected with paratuberculosis or other mycobacteria.

In conclusion, the Group identified that there is a need to develop field trials for the validation of DIVA tests and the safety and efficacy of vaccination. The Group agreed on the appropriateness to support large scale long lasting vaccination field trials.

#### 4. Other matters

##### Scientific update on gamma-interferon tests

In view of the recent scientific evidence in favour of the use of purified protein derivative-based gamma-interferon tests for control and trade purposes in cattle, following expected standardisation of the tests, the Group decided not to specify which test should be used in the *Terrestrial Code*, proposing to replace “tuberculin tests” by “tests” since a general reference to the *Terrestrial Manual* is made in the Article 11.6.1.

In addition, the Group noticed that the *Terrestrial Manual* considers gamma-interferon test as an alternative test for trade but not a prescriptive test. The Group recommended that the Biological Standards Commission be made aware of the latest evidence and the need to have updated international standards on the validation of the test as well as an agreed protocol. Some of the participants of the Group were also experts of OIE Reference Laboratories on tuberculosis. They agreed to propose a coordinated response as a Reference Laboratory network to the Biological Standards Commission.

The Group noted that the available gamma-interferon tests may not be suitable for all significant species, recommending that suitability of the different tests for target species be specified in the *Terrestrial Manual*.

Gamma-interferon tests are not suitable for calves less than 6 months old; below this age, only tuberculin test could be used. For this reason, the Group recommended that once gamma-interferon tests have been specified in the *Terrestrial Manual*, attention should be made when developing provisions on the use of gamma-interferon tests taking the age of the animals into account.

#### 5. Finalisation 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 TUBERCULOSIS  
Paris, 9-11 April 2013**

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**Agenda**

1. Opening, adoption of the agenda, appointment of chairperson and rapporteur
  2. Revision of the *Terrestrial Code* chapters on tuberculosis
  3. Advantages and disadvantages on vaccination strategies for tuberculosis
  4. Other matters: scientific update on gamma-interferon tests
  5. Finalisation and adoption of the draft report
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Appendix II

**MEETING OF THE OIE AD HOC GROUP ON TUBERCULOSIS**  
**Paris, 9-11 April 2013**

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

Paris, 11-13 March 2014

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A meeting of the *ad hoc* Group on tuberculosis (hereafter the Group) was held at the OIE Headquarters from 11 to 13 March 2014.

### 1. Welcome, adoption of the agenda, appointment of chairperson and rapporteur

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Elisabeth Erlacher-Vindel, Acting Head of the Scientific and Technical Department of the OIE, welcomed the Group and explained the objectives of the meeting. At its previous meeting in April 2013, the Group had discussed and proposed the draft chapter on tuberculosis following the same approach used for the draft chapter on brucellosis. At its meeting in September 2013 the Scientific Commission for Animal Diseases (Scientific Commission) reviewed the draft chapter and added comments. Dr Sergio J. Duffy, representative of the Scientific Commission, explained that the Scientific Commission requested the Group to address these comments and to re-discuss in particular the epidemiological significance of goats in tuberculosis and the feasibility of developing specific provisions if needed. The Group was also requested to further advise on the need for a test that differentiates infected from vaccinated animals (DIVA) in case of vaccination against tuberculosis would be applied.

The Group adopted the proposed agenda for the meeting. The Group was chaired by Dr Francisco Reviriego Gordejo, and Dr Sewellyn Watson and OIE Secretariat acted as rapporteurs.

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

### 2. Review and address comments from Scientific Commission on the amended draft chapter on tuberculosis taking into account the approach in the draft chapter on brucellosis

The Group was provided with the draft chapter on brucellosis that was endorsed by the Scientific Commission and the Terrestrial Animal Health Standard Commission (Code Commission) at their February 2014 meetings, for comparison of the overall approach, detail and harmonisation.

#### Article 8.X.1: General provisions

The Group agreed to use the sentence 'infection with *Mycobacterium tuberculosis* complex' to replace the previously used '*Mycobacterium tuberculosis* complex infection' throughout the chapter as relevant, to keep it in line with the chapter heading. The paragraph describing the meaning of *M. tuberculosis* complex was moved to create more fluency.

The Group agreed on the suggestion of the Scientific Commission to remove African buffalo, greater kudu and lechwe from the scope of the term 'animals'. These species may play a role at regional but not global level. However, the paragraph on susceptible animals in the preamble was expanded to note that wild animals may play a significant epidemiological role in maintaining infection with *M. tuberculosis* complex in some regions. The rationale behind this was to raise awareness among Veterinary Authorities of Member Countries to take into account wild animal populations in control programmes, when relevant.

The Group was informed that the request from the Scientific Commission on the role and importance of camelids would be considered during a meeting of the *ad hoc* Group on camelids that would be held from 1 to 3 April 2014 at the OIE Headquarters. The Group considered that the significance of camelids in the epidemiology of tuberculosis is not well known and that there are no prescribed tests for the diagnosis of tuberculosis in Camelids. The Group agreed to formulate what may be needed in the chapter on “Infection with *Mycobacterium tuberculosis* complex” only after having received the opinion of the *ad hoc* Group on camelids.

The Group had a lengthy discussion on epidemiological significance of goats in reply to the comments of the Scientific Commission. The Group agreed that goats are susceptible to tuberculosis and that they can act as maintenance hosts and transmission agents even if their significance at global level is not fully acknowledged. *M. tuberculosis* complex can be found in goat milk but its zoonotic significance is not known as the sources of tuberculosis in humans are not well known in areas where untreated goat milk is widely used i.e. the Mediterranean and the Middle East.

Both skin tests and gamma interferon tests are available but more data are required to validate these tests in goats before their use can be recommended for trade purposes. Furthermore, test results can be confounded if goats have been infected with or vaccinated against *M. avium* subspecies *paratuberculosis*. On that basis, the Group considered that with current scientific knowledge it was not possible to draft articles on country, zone or herd free from infection with *M. tuberculosis* complex in goats.

However, the Group recognised that goats should be kept in the chapter for notification and trade purposes, based on abattoir surveillance. Data provided from Member Countries to the OIE through the World Animal Health Information System (WAHIS), for example on post-mortem inspection on goats at abattoirs, could be collected and may contribute to determine the significance of goats in the epidemiology of infection with *M. tuberculosis* complex. If necessary, based on conclusions drawn from this data and new information, articles on the status of goats related to tuberculosis could be added at a later stage.

#### **Article 8.X.2: Safe commodities**

The Scientific Commission suggested removal of the sentence on ‘fresh meat and meat products’ from safe commodities. However the Group suggested to keep it as all slaughtered animals should undergo ante- and post-mortem inspection and any localised lesions could be excised, if lesions were generalised then the whole carcass would be condemned. The Group noted that this non-pathogen specific risk mitigating measure is covered in Chapter 6.2. of the *Terrestrial Animal Health Code (Terrestrial Code)* that refers to standards in the Codex Alimentarius. For fresh meat, ante- and post-mortem inspection is enough to ensure its safety and no specific trade related articles are needed – any articles would lead to unnecessary trade restrictions. This position was discussed with the representatives of the Scientific and the Code Commissions who explained that ante- and post-mortem inspection is a general risk mitigation approach that applies to a number of diseases in the *Terrestrial Code*.

#### **Article 8.X.3: Country or zone historically free from infection with *M. tuberculosis* complex in specified animal categories**

The Group suggested adding an article on historical freedom in line with the draft chapter on brucellosis, including the provision that ante- and post-mortem inspection should be in place for all slaughtered animals.

#### **Article 8.X.4 and Article 8.X.5: Country or zone free from infection with *M. tuberculosis* complex in bovids and in cervids**

The articles were reviewed in line with the approach used for brucellosis. The Group suggested using the term ‘bovids’ as defined in Article 8.X.1. instead of ‘cattle, water buffalo and bison’.

The Group proposed re-ordering the points on qualifying free status for clarity and consistency with the chapter on brucellosis and to apply this new order to other similar articles.

The term ‘animals’ in point 1 a) was kept instead of ‘bovids’ or ‘cervids’, as a country or zone cannot be free in one animal category without the disease being notifiable in all categories.

The Group suggested adding the term ‘entire’ to ‘country’ throughout the chapter when reference is made to notification. The rationale is that even if a country is free from infection in a zone, it is needed to notify the infection in the entire country and not only in a zone in a country.

The Group suggested removing the confusing term ‘periodic’ to harmonise with the brucellosis chapter.

#### **Article 8.X.6: Herd free from infection with *M. tuberculosis* complex in bovids and cervids**

In point 1 b) ii), the term ‘evidence of infection with *M. tuberculosis* complex’ was preferred to the term ‘case’ as it has a much broader meaning. The Group considered that in the case of tuberculosis, where confirmation of infection is difficult, a positive reaction to a skin test in an animal may be sufficient evidence not to grant free status to the herd.

The Group proposed a modification in the texts of point 2 on the frequency of testing to maintain the free status of the herds in countries or zones where herd prevalence is low. As the current wording could be misinterpreted, the Group proposed to modify it in order to clarify that all herds of the country or zone should be included in the surveillance.

#### **Article 8.X.7: Recommendations for the importation of bovids and cervids for breeding and rearing**

The Group considered the suggestion of the Scientific Commission on the possibility of splitting the provisions into separate articles. However the suggestion was not followed as the article, as it is, is already well balanced and harmonised with the chapter on brucellosis. The representative of the Scientific Commission agreed with the approach taken by the Group.

#### **Recommendations for the importation of African buffalo, greater kudu and lechwe for breeding or rearing**

The Group agreed with the Scientific Commission to remove the related article as these species have been deleted from the definition of ‘animals’ in Article 8.x.1.; trade of these species was only on a regional basis and anyway appropriate risk mitigation measures could be made on a bilateral agreement between two trading countries.

#### **Article 8.X.8: Recommendations for the importation of goats for breeding or rearing**

The article has been moved before the articles for slaughtering animals to conform to the structure of the *Terrestrial Code* chapters.

The Group suggested keeping the term ‘case’ in this article, in contrast to the similar article for bovids and cervids (Article 8.x.7), because there are no reliable diagnostic tests available for live goats.

The Group considered the Scientific Commission’s comment on testing goats and suggested that testing of goats should not be prescribed in the chapter. The rationale behind this recommendation is that there is insufficient data to validate the skin and the gamma interferon tests in goats, and test results could be confounded by infection with and vaccination against *M. avium* subspecies *paratuberculosis*.

The Group considered that ante- and post-mortem inspection of animals slaughtered at an abattoir gives information about the herd of origin to inform suitable risk mitigation.

**Article 8.X.9: Recommendations for the importation of bovids and cervids for slaughter**

The Group revised the wording to conform and align to that used in the chapter on brucellosis.

**Article 8.X.12: Recommendations for the importation of embryos and oocytes of bovids and cervids**

The Group proposed a minor change in the title (embryos and oocytes) and replaced in the text the term 'herd' by the term 'establishment' because different animals may be present in the same establishment but in different herds of the same animal category.

**Article 8.X.14: Recommendations on the importation of milk and milk products of goats**

The Group suggested expanding this article to include the fact that infection with *M. tuberculosis* complex should be a notifiable disease in goats for the reasons as described above in Article 8.X.8.

**3. Other matters**

The Group was requested to give an update on the situation on vaccination trials and DIVA tests. Prof. Glyn Hewinson gave an update of the situation:

In December 2013, following a request from the European Commission, the European Food Safety Authority (EFSA) published an opinion<sup>1</sup> relating to the design of field trials to test the performance of a vaccine for bovine tuberculosis, along with a test to detect infected among vaccinated animals (DIVA). In response to this advice, the Department for Environment Food & Rural Affairs (DEFRA) of the United Kingdom (UK) posted a call to a tender for the design of field trials which will inform future work in this area.

The goal of the vaccine field trials was to address the issues of test validation, vaccine efficacy and safety in a manner that provides robust data that may help decision makers. The Group recognised the importance of generating data that would inform and guide future developments in this area.

Because of the high cost of gamma interferon tests and a number of issues highlighted in the previous report of the Group (April 2013), the development of a DIVA skin test was underway. However both tests would have to be validated.

Prof. Hewinson informed the Group that from 16 to 19 June 2014 an international conference on *Mycobacterium bovis* would be held in Cardiff, UK. Vaccination would be one of the topics addressed at the conference.

**4. Finalisation 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

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<sup>1</sup> EFSA (2013). Scientific Opinion on field trials for bovine tuberculosis vaccination. <http://www.efsa.europa.eu/fr/efsajournal/pub/3475.htm>

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON TUBERCULOSIS**  
**Paris, 11-13 March 2014**

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**Agenda**

1. Welcome, adoption of the agenda, appointment of chairperson and rapporteur
2. Review and address comments from Scientific Commission on the amended draft *Terrestrial Code* chapter on tuberculosis taking into account the approach in the draft chapter on Brucellosis
3. Other matters
4. Finalisation and adoption of the draft report

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Appendix II

**MEETING OF THE OIE AD HOC GROUP ON TUBERCULOSIS**  
**Paris, 11-13 March 2014**

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**Rationale for the amendments to:**

**CHAPTER 15.1. INFECTION WITH AFRICAN SWINE FEVER (ASF) VIRUS  
provided by the Scientific Commission**

*To be considered together with the ad hoc Group report (Annex 10)*

Article 15.1.3. ASF free country, zone or compartment

The Commission discussed the need to have specific requirements for historical freedom. However, considering that the horizontal chapters prevail, this requirement was considered implicit and was removed.

Article 15.1.3.bis. ASF free compartment

The Commission decided to refer to the ‘establishment’ of a compartment instead to the ‘recognition’ to increase clarity of the provision.

Article 15.1.3.ter Establishment of a containment zone within a country or zone free from ASF

The Commission discussed the requirement for a containment zone and confirmed that since ASF was not a disease with official status, the containment zone could be established by the country without formal approval by the OIE.

Article 15.1.9. and 15.1.12.bis. Recommendation for importation of semen of domestic, captive wild pigs and fresh meat, from countries or zones considered as infected with ASF

The Commission acknowledged that importation of fresh meat from infected countries was not considered in the previous chapter. However, it was noted that movements from free compartments were already considered in Article 15.1.8. and 15.1.12. Importation from free country, zone and compartment. Thus, the Commission decided to delete the proposed provision of having been kept in a compartment free from ASF since birth. The Commission acknowledged the sampling effort that this provision will request if used.

Article 15.1.10. Recommendation for importation of *in vivo* embryos from countries or zones considered as free with ASF

Point 1a) was reintroduced to request that animals were kept since birth or for at least 3 months within the ASF free country, zone or compartment, to be in line with other articles and Chapters of the *Terrestrial Code*.

The Commission agreed that the revision of the ASF chapter was a good opportunity to also increase the information on surveillance, especially considering the spread of the disease in Eastern Europe.

The Commission also discussed the considerations of the *ad hoc* Group regarding a review of the CSF chapter and agreed that they would be taken into account when CSF chapter is revised. The revision of the CSF chapter has been maintained on the working programme of the Commission but not as a priority.

The Commission considered the definition of metapopulation provided by the *ad hoc* group and decided to seek the expert opinion of the upcoming Working Group on Wildlife.

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## OIE AD HOC GROUP ON AFRICAN SWINE FEVER

Paris, 23–25 April 2014

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A meeting of the OIE *ad hoc* Group on African swine fever (ASF) (hereafter the Group) was held at the OIE Headquarters, Paris, from 23 to 25 April 2014.

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

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Elisabeth Erlacher-Vindel, Deputy Head of the Scientific and Technical Department of the OIE, welcomed the Group and explained that the objective of the meeting was to update the OIE *Terrestrial Animal Health Code (Terrestrial Code)* Chapter 15.1. on ASF and, as far as possible, align with the recently amended Chapter 15.2. on classical swine fever (CSF), taking into account the differences between both diseases and the fact that for CSF a procedure for official recognition of Member Countries status exists. She communicated to the Group that another subject to be discussed was the possibility to develop new provisions for ASF specific surveillance taking into account Chapters 1.4., 1.5. and 15.2., if relevant. She informed the Group on the procedure and timing needed for the adoption by the OIE World Assembly of Delegates of the *Terrestrial Code* chapters and on the possibility that the Group could be convened a second time in the future.

The Group adopted the proposed agenda for the meeting. The Group was chaired by Professor José Manuel Sánchez-Vizcaíno, and Dr Trevor W. Drew and OIE Secretariat acted as rapporteurs.

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

### 2. Current ASF situation

Professor Mary-Louise Penrith and Professor Sánchez-Vizcaíno gave an overview on the current situation of ASF in Africa and in Europe respectively. The Group acknowledged the information provided and considered them a good basis for discussion.

### 3. Update of Chapter 15.1. on ASF and possible harmonisation with Chapter 15.2. on CSF

Dr Etienne Bonbon, representative of the Terrestrial Animal Health Standards Commission, explained that it is important that the structure of the *Terrestrial Code* chapters be harmonized. The general provisions of the *Terrestrial Code* chapters should include the epidemiologically important animal species and guidance on when and why an infection in selected animal species should be notified to the OIE by Member Countries. He continued explaining that articles on 'safe commodities', if any, 'free status' including the type of free status (country, zone and compartment), on 'trade' and also on 'surveillance' should be developed if relevant.

The Group agreed that the chapter on ASF should be amended in order to provide Member Countries with the ability to engage in safe trade and carrying out effective surveillance using the existing tools to manage, control and eradicate the disease.

The Group agreed to base its work on the current chapter on ASF of the *Terrestrial Code* as a template for revision and to follow the same approach used for the chapter on CSF.

The Group proposed the change of the title to align with the other chapters recently adopted, using pathogen name.

**Article 15.1.1. General provisions**

Dr Drew explained the approach taken to amend the chapter on CSF in order to facilitate the process of amendment of the chapter on ASF.

The Group proposed the definition of “infection with ASF virus” and harmonised the vocabulary with the definition for CSF infection.

The Group agreed to keep the requirement for an epidemiological link with a confirmed outbreak when using molecular detection, such as polymerase chain reaction and sequencing for confirmation, as prescribed in the chapter on CSF. The Group noted also that in the absence of clinical signs in ASF and the absence of antibodies the identification of cases could be hampered and concluded that it is important to have the presence of pathological lesions for this purpose.

The Group had a lengthy discussion on the risk of having the disease notifiable in wild animals if only serological positivity is found. The Group concluded that Member Countries should be encouraged to do surveillance and to notify if positive serology is found in single animals, but in the absence of clinical disease they should not be penalised.

The Group considered that it was also important to draw a distinction between domestic/captive wild and wild/feral pigs for the definition of infection for the purposes of international trade throughout the chapter and to include African wild suids as a separate category. African wild suids were added to the epidemiologically important animal species because, unlike the wild suids in other regions of the world, they play an important epidemiological role in ASF infection and spread. The Group agreed that cases in wild or feral pigs should be notified but would not affect the declared free status of a country or zone provided that biosecurity measures remained in place.

**Article 15.1.2. General criteria for the determination of the ASF status of a country, zone or compartment**

The Group discussed the use of the term ‘territory’ as used in the chapter on CSF and suggested that the use of the term ‘country’ was more appropriate for this article.

The Group added text to point 5), 6) and 7), in line with the chapter on CSF, including the provision that surveillance should also be required for African wild suids. The three points were modified to make them consistent, and also to guarantee that ‘appropriate surveillance programmes’ could be applied to both domestic/captive wild and wild/feral pigs. The Group considered that the term ‘appropriate’ refers to the resources that a country can use for surveillance activities, proportional to the likelihood of unrevealed infection.

**Article 15.1.3. ASF free country or zone**

Dr Bonbon explained that in the chapter on CSF, there is a separate article for the provisions related to the compartments because compartments don’t have an OIE official recognition of disease status. However, the Group noted that the provisions of this article are not completely applicable to compartments and suggested to delete the term ‘compartment’. The Group suggested including the provisions for compartment in a separate article, Article 15.1.3.bis.

The Group considered that a country could be declared free from infection in the domestic pig populations even if wild animals are infected, provided effective biosecurity measures are implemented and surveillance measures are in place.

The Group discussed the definition of a ‘case’ and of an ‘outbreak’ according to the glossary of the *Terrestrial Code* and considered that when talking about wild animals, the use of the term ‘outbreak’ is not applicable. The Group concluded that point 2) a) should be modified specifying that an outbreak should refer only to domestic and captive wild animals. The Group suggested deleting the points referring to wild animals because the occurrence of the infection in wild animals should not influence the free status of a country in the domestic and captive wild animal population.

The Group was confident that syndromic surveillance is sensitive enough in domestic pigs and captive wild boar, but considered that in wildlife, this approach would not be so effective.

The Group discussed the importance of ticks in ASF virus maintenance and spread. While it is evident that ticks play an important role in the epidemiology of the infection, the Group considered that for the time being there are not enough data on the time needed for a tick population to become free from ASF and it might not be the same for all tick species. For this reason the Group agreed on removing the point a) referring to a period of 'three years' for ASF free status if ticks are involved in an outbreak.

The Group discussed the need to add provisions related to arthropod surveillance and decided to address the topic in the specific surveillance articles.

**Article 15.1.3.bis ASF free compartment and Article 15.1.3.ter Establishment of a containment zone within a country or zone free from ASF**

Two new articles were developed on 'free compartment' and on 'containment zone' to harmonise the content with the chapter on CSF.

The Group observed that for the purposes of international trade a 'containment zone' should be considered as an 'infected zone' and so the same risk mitigation measures that are prescribed for an 'infected zone' should apply to a 'containment zone'.

The Group discussed the effect of the reoccurrence of an outbreak 'inside a containment zone' on the free status of a country. The Group noted that Article 15.2.5. in the chapter on CSF requires the loss of approval of the containment zone if an outbreak occurred therein. The Group noted that this was not specified within Chapter 4.3. on zoning and compartmentalisation and felt that it was unjustified and therefore decided not to include it in this chapter.

**Article 15.1.4. Recovery of free status**

The Group suggested removing the reference to ticks and acaricide treatment since this was considered ineffective. The surveillance requirements on wild animals have been removed for the same reasons described above for Article 15.1.3.

**Article 15.1.5. Recommendations for importation from countries, zones or compartments free from ASF (domestic and captive wild pigs)**

The Group suggested, for consistency and harmonisation purpose, replacing the temporal reference of 40 days with the period of three months prescribed in the chapter on CSF.

**Article 15.1.6. Recommendations for importation from countries, zones or compartments infected with ASF (domestic and captive wild pigs)**

The Group proposed to use the temporal frame of three months in an ASF free compartment to be in line with the chapter on CSF but acknowledged it could be less.

The Group suggested adding the reference to the quarantine station as a risk mitigation measure. The Group suggested using a period of 30 days instead of the 40 days prescribed in the chapter on CSF because this was sufficient to guarantee that an animal is not anymore at risk of incubating or spreading the disease being two times the ASF virus incubation period. The period of 40 days for CSF was justified being the results of a published experimental infection.

**Article 15.1.7. Recommendations for importation from countries, zones or compartments free from ASF (wild pigs)**

Article 15.1.7. was deleted because the ASF status of wild suids has no relevance to the status in domestic and captive wild pigs. Furthermore, the importation of wild suids is considered a very rare event, with highly variable degree of risk, dependent on the ASF status of the country of origin. The practicality of applying quarantine conditions to wild populations was also considered to be a real challenge. The Group therefore suggested that such importations would not be covered by the *Terrestrial Code*, but should be agreed between countries on a bilateral basis.

**Article 15.1.8. Recommendations for importation from countries, zones or compartments free from ASF (semen)**

The Group discussed the evidence for ASF being transmitted in semen. Whilst it was acknowledged that evidence of transmission was scant, there was evidence of the presence of the virus in semen and this was considered sufficient justification to apply recommendations concerning international trade in semen, as for those in the chapter on CSF.

**Article 15.1.9. Recommendations for importation from countries or zones considered infected with ASF (semen)**

The Group modified the timing from 40 days to three months for point 1) a and 30 days for point 1) b, to harmonise with conditions for live animals, described above.

**Article 15.1.10. Recommendations for importation from countries, zones or compartments free from ASF (embryos)**

The Article was aligned with the Article on semen, as for CSF. Point 1) a) was deleted because the provisions are for a country or zone free from the infection.

**Article 15.1.11. Recommendations for importation from countries or zones considered infected with ASF (embryos)**

The Group proposed to add test requirements.

**Article 15.1.12. Recommendations for importation from countries, zones or compartments free from ASF (fresh meat of domestic and captive wild pigs)**

The Group aligned the Article with its equivalent in the chapter on CSF and added captive wild pigs.

**Article 15.1.12.bis Recommendations for importation from a country or zone considered infected with ASF (fresh meat of domestic and captive wild pigs)**

The Group noted the absence of an article covering the importation of fresh meat of domestic and captive wild pigs from an infected country or zone. A new article was added to apply for fresh meat of domestic and captive wild pigs the same prescriptions that are recommended for wild pigs.

**Article 15.1.13. Recommendations for importation of fresh meat of wild and feral pigs**

The Group discussed the reliability of the existing diagnostic tests and concluded that virology and serology were sufficient to guarantee a negligible risk posed by meat if an animal was infected with ASF.

**Article 15.1.14. Recommendations for the importation of meat products of pigs**

The Group considered that specifying the intended use of meat products was irrelevant to the risk posed by the commodity - the purpose of the article was to mitigate the risk posed by the products regardless of their intended use. The Group proposed to simplify the two articles (15.1.14. and 15.1.15.) to refer the first in general to 'meat products' and the other to 'pig products not derived from fresh meat'. The Group suggested merging the two corresponding articles in the chapter on CSF.

**Article 15.1.15. Recommendations for the importation of pig products not derived from fresh meat**

The Group corrected the disparity between current title and the content.

**Article 15.1.16. Recommendations for the importation of bristles and Article 15.1.17. Recommendations for the importation of litter and manure (from pigs)**

The Group merged the two Articles 15.1.16 and 15.1.17 because the text was the same but for the title. The Group was reminded that the provisions of the *Terrestrial Code* should be a suggestion for Member Countries not only for trade purpose but also to control the disease within the country.

The Group suggested adding the five following articles, based on the chapter on CSF.

**Article 15.1.17. Recommendations for the importation of skins and trophies****Article 15.1.18. Procedures for the inactivation of the ASF virus in swill****Article 15.1.19. Procedures for the inactivation of the ASF virus in meat**

The Group considered that in point 2 of the equivalent CSF Article on 'natural fermentation' the lowest pH that could be achieved was not sufficient to inactivate the ASF virus, and therefore could not provide a protocol involving natural fermentation.

The Group considered if it was appropriate including an equivalent of point 3 a) and b) of the relevant CSF article, where procedures were defined only for two specific products, namely Italian style and Spanish style dried ham. The Group concluded that this was not appropriate and suggested to keep the procedures but delete the references to Italian and Spanish style hams. The Group proposed to reorganise the categories of dry cured pork meat products according to the European Food Safety Agency (EFSA) report. In particular the specific information coming from the EFSA journal <sup>1</sup> was used to draft Article 15.1.19. The Group considered that for the time being the data that are in the EFSA report are the only suitable figures and suggested that more scientific research is needed to have updated information on the inactivating procedures.

**Article 15.1.20. Procedures for the inactivation of the ASF virus in casing of pigs**

The Group acknowledged that casings are one of the most traded pig products worldwide and for this reason separate articles were developed in the *Terrestrial Code* chapters for diseases such as foot and mouth disease and CSF. The Group consulted the EFSA journal <sup>2</sup> and concluded that the treatment for FMD could also apply to ASF. The Group included a treatment of saturated salt alone, without phosphate, since for ASF this was appropriate (but not confirmed for CSF).

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<sup>1</sup> EFSA Journal 2010; 8(3):1556. Scientific Opinion on African Swine fever

<sup>2</sup> EFSA Journal 2012; 10(7):2820. Scientific Opinion on animal health risk mitigation treatments as regards imports of animal casings

**Article 15.1.21. Procedures for the inactivation of the ASF virus in skin and trophies**

The Group compared the processes used for CSF and ASF and decided to include for ASF the processes that are in common and to add the processes that are specific for ASF virus.

The Group agreed to apply the recommendations of the EFSA report<sup>3</sup> with respect to inactivation procedures directly relevant to ASF in skin and trophies.

The Group went through the recommendations of the EFSA opinion and incorporated the inactivation procedures specific for ASF virus while using the most stringent EFSA scientific opinion<sup>1</sup>.

The Group considered that there was no information on the effect of gamma irradiation of skins and trophies on ASF virus and decided to remove it.

**4. ASF specific surveillance**

Dr Drew informed the Group on the procedures followed for the chapter on CSF. He said that specific provisions were only added if not already addressed in other *Terrestrial Code* chapters. The Group followed this approach addressing specific aspects of surveillance, focusing on what is unique for ASF.

The Group used the articles of the chapter on CSF as a template to verify common points with ASF bearing in mind that the chapter on CSF was developed for official recognition of free status and that for ASF the provisions for surveillance could be less detailed.

**Article 15.1.22. Surveillance: introduction and Article 15.1.23. Surveillance: general conditions and methods**

The Group agreed to develop and address specific aspects of the surveillance for ASF without duplicating what was already prescribed in the general chapters. The Group considered the articles on surveillance of Chapter 8.3. on bluetongue for which the *Terrestrial Code* recognises the possibility of self-declaration of free status.

The Group had a lengthy discussion on the virulence of the ASF virus and recognised that in some areas the pathogenicity of the virus could follow different patterns. However it is not yet possible to demonstrate differences in virulence associated either with host or genotypic variability of the virus. The Group considered that the role of ticks as reservoir should be covered.

**Article 15.1.24. Surveillance strategies**

The Group ranked the tools for surveillance and agreed that clinical surveillance is the most important, and considered virological surveillance an effective tool followed by serology.

Serological surveillance is a good marker of infection and useful to detect potential carrier animals. A positive antibody test can indicate outbreak or a carrier – i.e. a current or past infection.

**Article 15.1.25. Surveillance procedures for recovery of free status**

The Group considered the need to add an article specific for surveillance for the recovery of free status. The provisions of this article were developed to be in line with the requirement of Articles 15.1.3. and 15.1.4. and would allow to recover quickly the free status. The Group considered that it is not possible to evaluate the prevalence of an infection in a wild animal population and that an estimate of the geographical distribution would be more appropriate.

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<sup>3</sup> EFSA Scientific Report CFP/EFSA/AHAW/2007/2. Scientific review on Classical Swine Fever

**Article 15.1.26. Surveillance for ASF virus in wild and feral pigs**

The Group considered it appropriate to use the term ‘metapopulation’ to refer to wild and feral pig populations. The Group suggested that it might be of general value to include the term in the OIE glossary. The definition that the Group suggested for the glossary of the *Terrestrial Code* is the following: A metapopulation is a group of spatially separated populations of the same species which interact at some level and may consist of several distinct sub-populations within an area of suitable habitat, parts of which may be currently unoccupied.

The Group suggested that, if inclusion is considered appropriate, the definition of metapopulation be reviewed by the OIE Scientific Commission for Animal Disease (Scientific Commission) and by the ‘Working Group on wildlife diseases’ for validation.

**Article 15.1.27. Surveillance for arthropod vectors**

The Group developed a new article on ‘surveillance for vectors’. The Group referred to Chapter 1.5. on ‘Surveillance for arthropod vectors of animal diseases’ to check if specific requirements and unique provisions were needed for ASF. The Group suggested that surveillance should be done not only for trade purposes but for the determination of a country status, on an ongoing basis.

The Group considered that it was important to address the surveillance for ticks of the *Ornithodoros* genus in selected places.

**5. Other matters**

The Group noted that the OIE technical disease card on ASF available on the OIE website needed to be revised in particular with reference to the role of “American wild pigs”<sup>4</sup>.

The Group recommended the Scientific Commission to review the chapter on CSF regarding:

- Incubation period of CSF (should be a single number, rather than a range) (Article 15.2.1.);
- General criteria for the determination of the CSF status should be in present tense (Article 15.2.2.);
- The effect of the reoccurrence of an outbreak ‘inside a containment zone’ on the free status of a country (Article 15.2.5.);
- The conditions of import from a CSF free compartment were less stringent than those applying to a quarantine station (Article 15.2.8. point 2);
- The practicality of the importation of wild suids should be considered (not included in the chapter on ASF) (Article 15.2.9.);
- The terms ‘wild’ should be in italic;
- Specifying the intended use of meat products was irrelevant since the purpose was to mitigate the risk posed by the products regardless of its intended use (Article 15.2.16.);
- Merging the two because the text was the same but for the title (Articles 15.2.19. and 15.2.20.);
- Treatment using 0.5 % formalin for trophies and skins (Article 15.2.21.);
- The need to insert a paragraph concerning the need to review surveillance strategies when the risk of incursion increases. It currently exists for serology but should not be limited to it (Article 15.2.28.);

<sup>4</sup> [http://www.oie.int/fileadmin/Home/eng/Animal\\_Health\\_in\\_the\\_World/docs/pdf/Disease\\_cards/AFRICAN\\_SWINE\\_FEVER.pdf](http://www.oie.int/fileadmin/Home/eng/Animal_Health_in_the_World/docs/pdf/Disease_cards/AFRICAN_SWINE_FEVER.pdf)

- The possible lack of coherence and disproportionate approach proposed for meat from wild pigs compared to pig meat from infected zones or countries. The formulation “regardless of the status” for wild boar meat implies that even historically free countries where CSF (and now ASF) was never seen are forced to test serologically and virologically - which could be disproportionate (Article 15.2.15.);
- The need of provisions for the importation of fresh meat of domestic and captive wild pigs from countries, zones infected with CSF.

## **6. 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 to the Group for comments and adoption. The report was finalised by correspondence.

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.../Appendices

Appendix I

**OIE AD HOC GROUP ON AFRICAN SWINE FEVER**  
**Paris, 23-25 April 2014**

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**Agenda**

1. Opening, Adoption of agenda, and appointment of chairperson and rapporteur
  2. Current ASF situation
  3. Update of Chapter 15.1 on ASF and possible harmonisation with Chapter 15.2 on CSF
  4. ASF specific surveillance
  5. Other matters
  6. Adoption of the draft report
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Appendix II**OIE AD HOC GROUP ON AFRICAN SWINE FEVER**

Paris, 23-25 April 2014

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**FOURTH MEETING OF THE OIE AD HOC GROUP ON INTERNATIONAL HORSE MOVEMENT  
FOR EQUESTRIAN SPORT**

**Paris, 2–4 June 2014**

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**1. Opening**

Dr Gardner Murray, Chair of the *ad hoc* Group (AHG), welcomed participants to the meeting. Dr Brian Evans, Deputy Director General and Head of the Scientific and Technical Department of the OIE, welcomed all participants to this fourth meeting. He noted that the adoption of the new chapter 4.16 *High Health Status Subpopulation* in the *Terrestrial Animal Health Code (Terrestrial Code)* during the OIE General Session was a great achievement. He encouraged the Group to work on the details of implementation of the concept. Furthermore, the Group should consider a critical review of the list of diseases of concern, make recommendations for updates of *Terrestrial Code* chapters and involve the Biological Standards Commission in matters regarding diagnostic tests and vaccines.

Dr Murray outlined the objectives of the meeting, namely to: (i) discuss the comments on the newly adopted *Terrestrial Code* chapter; (ii) continue working on the practical implementation of the concept; (iii) discuss the further development of the EDFZ<sup>1</sup> concept; (iv) discuss proposed research projects and the way forward to implement them; and (v) develop a communication strategy for this project.

At Dr Murray's request, all participants briefly introduced themselves.

Dr Murray thanked Dr Etienne Bonbon, vice President of the Terrestrial Animal Health Standards Commission, and Dr Kris De Clercq, vice President of the Scientific Commission on Animal Diseases, for making themselves available and for providing comments on behalf of the respective OIE Commissions.

**2. Adoption of the Agenda**

The adopted agenda for the meeting is given in [Appendix I](#) and the list of participants in [Appendix II](#).

**3. Record of the third meeting**

The minutes of the third meeting were approved.

**4. Review of actions arising and achievements**

Dr Susanne Münstermann presented an overview of the work completed since the last meeting. She highlighted that since the third meeting of the AHG, two expert sub-group meetings had been convened, namely on (i) HHP<sup>2</sup> health certificate in January 2014 and (ii) HHP operationalisation in April 2014. The reports of both meetings had been circulated to the members of the AHG. The report of the January meeting on HHP health certificate had been presented to the Scientific Commission for Animal Diseases (SCAD) and the Terrestrial Animal Health Standards Commission (Code Commission) in February in order to get their views.

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1 EDFZ: Equine disease free zone

2 HHP: High health high performance (horse sub-population)

Dr Münstermann indicated that key actions arising from the third AHG meeting will be followed up at this fourth AHG meeting and therefore she reported only on those activities that were not covered by this meeting's agenda:

- (i) Biosecurity Guidelines (BSG) for the FEI<sup>3</sup> 7<sup>th</sup> World Equestrian Games, to be held in Normandy, France in August 2014, had been developed and made available to the OIE. Dr Sarah Kahn reported on their similarities and differences with the OIE BSG.
- (ii) An *ad hoc* Group on Glanders met in November 2013; some members of this AHG participated in the meeting. The draft *Terrestrial Code* chapter was presented to SCAD in February 2014 and was not accepted because SCAD wished to have more evidence of interest by industry for official status recognition for glanders by the OIE.
- (iii) The HHP concept was presented to the World Customs Organisation's (WCO) General Assembly in November 2013. WCO proposed to convene a joint Working Group once the database for the HHP horse concept has been developed, in order to integrate it into the WCO database.
- (iv) Since the last AHG meeting, the HHP concept has been presented at several important meetings, namely to:
  - International Horse Movement Committee of IFHA<sup>4</sup> meeting in Hong Kong, December 2013
  - The New Zealand Veterinary Services, November 2013
  - FEI General Assembly, November 2013
  - OIE/FEI/IFHA Regional Conference on International Horse Movement for Asia, the Far East and Oceania, Hong Kong, February 2014
  - FEI Veterinary Committee, March 2014
  - Istituto Zooprofilattico Sperimentale Palermo, Italy, Equine Diseases Laboratory Diagnosis Training Course, April 2014
  - Asia Racing Conference, Hong Kong, May 2014
- (v) Dr Münstermann provided an update on the equestrian competitions that will take place during the Asian Games, to be held in late September in Korea (Rep. of). The Veterinary Authorities of Korea have embraced the HHP and EDFZ concept by developing *International health regulations* in line with HHP and by establishing an EDFZ around the venue.
- (vi) Dr Münstermann informed the Group that a separate webpage has been established on the OIE website and invited Group members to provide her with comments and suggestions to continually improve this page (<http://www.oie.int/en/our-scientific-expertise/specific-information-and-recommendations/international-competition-horse-movement/>)

## 5. Outcome of the OIE 82<sup>nd</sup> General Session

Dr Kahn summarised the introduction to the new *Terrestrial Code* chapter that Dr Alejandro Thiermann, President of the Code Commission, had given to the Assembly of OIE Delegates and the comments that OIE Member Countries had voiced. She explained that the chapter will be inserted into Section 4 of the *Terrestrial Code* where the chapters on zoning and compartmentalisation can also be found. The Group discussed several of the issues that had arisen:

- a) Europe had suggested changing the acronym for the subpopulation to HHS in line with the title of the chapter (high health status horse subpopulation).

After lengthy discussion, the Group opted to retain the acronym HHP mainly for the following reasons:

- (i) performance is an expression of fitness to compete, which is primarily determined by health

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3 FEI: Fédération Equestre Internationale

4 IFHA = International Federation of Horseracing Authorities

- (ii) “status” has a defined meaning in the *Terrestrial Code* for diseases with official recognition of health status (country or zone), e.g. for African horse sickness (AHS);
- (iii) the HHP acronym is now widely known and accepted, e.g. it comes up on internet search straight away linked to the OIE.

It was, however, agreed and highlighted that it is the industry that defines the level of performance for HHP horses and competitions/races. To integrate the HHP acronym into the HHS, Dr Etienne Bonbon proposed the following: *the status is given to the subpopulation of HHP horses.*

- b) The text of the draft chapter had been changed to include an *international biosecurity plan*. Clarification was given that it is the task of the public–private partnership to develop this plan in line with the OIE BSG and have it approved by the national Veterinary Authorities (VA). The term *biosecurity plan* is defined in the *Terrestrial Code* glossary.
- c) One country had commented that the use of microchips should be made compulsory rather than “preferably” as stated in the current *Terrestrial Code* chapter text. The Group was of the opinion not to limit the identification to microchips in view of problems reading them and new technologies, such as retina scanning, which could replace microchips in the future.
- d) The need for a designated official within the VA with responsibility for liaison with the equine performance sector was reiterated. There is an important need for a strategy to communicate the HHP concept to VAs, particularly during this period of development of the concept.

## 6. Operationalisation of the HHP concept

The Group was provided with a discussion paper that had been prepared on the basis of the report of the expert sub-group that met in January to develop Guidelines on operationalisation of the HHP concept..

Before going into the different elements of the management plan, Dr Anthony Kettle pointed out that not enough consideration has been given to diseases of concern to event organisers, such as strangles, and requested that highly contagious diseases and those with carrier status (equid herpesvirus: EHV) should be included in the list of diseases. The consensus was that those should be dealt with in the BSG. The industry should also assume responsibility for preventing those diseases, e.g. through their respective FEI and racing veterinary rules.

The VA could also request evidence of reporting history, e.g. for 3 years prior to an event and seek information through WAHIS<sup>5</sup> and PVS<sup>6</sup> reports.

The Guidelines on operationalisation of the HHP concept make a distinction between “countries of known health status” and those of “unknown health status”. Some members of the Group proposed to differentiate the former into “with diseases of concern” and “without diseases of concern”. In this regard, some experts wished to include contagious or ‘carrier state’ diseases additional to the six diseases for which the health status of an HHP horse is defined. In conclusion the Group agreed that there would be two distinct statuses – countries of known health status and countries of unknown health status. The HHP preparation period is 90 days (76 plus 14 days isolation) for the former and 104 days (90 plus 14 days isolation) for the latter group of countries.

It was also agreed that horses originating in a population that historically meets the defined health criteria for HHP can qualify for inclusion in the HHP by performing a 14 day period of isolation, providing that all health testing and certification requirements (other than the provision to be separated for a period of 90 days from horses that do not have HHP-equivalent status).

<sup>5</sup> WAHIS: World Animal Health Information System (of the OIE)

<sup>6</sup> PVS: Performance of Veterinary Services

With respect to the criteria for stables that will be used for holding HHP horses during the 76/90 day qualifying period ('preparation stables'), it was agreed that there were no particular construction and equipment requirements for these stables, as compared with the stables for the last 14 days isolation. However, during the preparation period, the health status of other horses in the stable needs to be verified by surveillance. For this surveillance to be reliable in countries of "unknown health status", no horses may be allowed to enter the preparation stable during the period of qualification and the horse under preparation cannot be moved to other stables or events. For countries of "unknown health status", the 14 day isolation period must be done using an "all in – all out" management system and in a stable that is registered with the industry body as an HHP approved premise. Conversely, for countries of "known health status", horses under preparation can move to participate in events, providing they are in contact only with horses of health status equivalent to HHP. Movement during the 14 days of isolation should not be permitted.

The need for vector protection in the registered HHP stable used for the 14-day isolation period was discussed and it was concluded that it was not necessary to specify a standard for vector protection.

In considering the completion of a 90-day cycle of international movement and the minimum period in the country of usual residence before the beginning of a new cycle of international movement, the Group decided that there was no need to specify an exact time period of residence, as horses would not have lost their HHP status during the 90 days of previous travel. However, the VAs in the countries of usual residence may require reconfirmation of the health status of a HHP horse (e.g. for dourine, equine viral arteritis (EVA), equine infectious anaemia (EIA), glanders, piroplasmiasis and, in Asia, for Japanese encephalitis (JE)) within 42 hours of re-entry to the country of usual residence. Dr Füssel reiterated that the entire system is based on the precondition that the country of usual residence must take the horse back.

For consistency with the draft HHP health certificate (see point 7 below), it was agreed to make reference to four diseases (Eastern and Western equine encephalomyelitis (EEE, WEE), JE and rabies) as diseases that should be notifiable in the country of usual residence (or country of export, meaning usual residence plus countries visited).

The Group discussed the respective responsibilities of the industry and the VA and confirmed that there the veterinary presence should comprise at least a treating veterinarian (private sector), an official veterinarian (as defined in the Terrestrial Code) and a veterinarian accredited by the VA to issue health certification of HHP horses and registration of HHP premises and venues.

## 7. HHP health certificate

The proposal to modify Section IV point 1b)<sup>7</sup> (on AHS) was discussed. The OIE has established a system of official recognition of countries and zones for freedom from infection with AHS. Given that this system has only recently been introduced and many OIE Member Countries have not had the time to assemble the dossiers for official recognition, it would be appropriate to introduce an alternative option as a transitional measure. The Group agreed that the existing provisions in the *Terrestrial Code* should be applied. This covers official health status and the possibility of importation from infected countries/zones, as stipulated in Article 12.1.9, more specifically in 3c) (14 days in vector protected stable and agent identification test).

It was proposed to amend Section IV point 2 c)<sup>8</sup> to read "Immediately prior to export" and add a point e) stating that horses have been held at HHP premises and venues throughout the period of continuous travel. In addition, point 2a) should be further clarified by adding "the disease certification requirements of 3 months free from VEE<sup>9</sup>, glanders and EIA" and deleting "HHP premises" from the same sentence.

<sup>7</sup> Now reading: "The country or zone is officially free from African horse sickness and no case has been reported in the country/zone in 12 months preceding the date of export of the horse" - which effectively eliminates most of Africa from the HHP concept

<sup>8</sup> Now reading: "Prior to export..."

<sup>9</sup> VEE : Venezuelan equine encephalomyelitis

Section IV point 3c)<sup>10</sup> on equine influenza (EI) was discussed with respect to the risk that horses travelling regularly will be subject to repeated vaccination for EI. Dr Ann Cullinane suggested that it would be appropriate to offer owners the alternative option of presenting evidence that the horse has antibody levels that are consistent with protection. Testing the horses after completion of a 90-day cycle of international travel therefore appears to be an option and the SRH<sup>11</sup> test as listed in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* should be recommended, as it is fully validated. This option should be included in the HHP health certificate.

## 8. Revised biosecurity guidelines

The BSG had been revised in view of the outcomes of the two expert sub-group meetings, which enabled the chapter on “home stables” to be written and the introduction to be revised as well as adjustments to be made to some other chapters.

The Group discussed whether these BSG were targeting a wide audience, combined of industry and VAs, or whether they should be specific for the HHP sub-population. The Group concluded that this comprehensive document has a lot of value and can be seen as a reference document for both stakeholders, but that its further development should be put on hold for the moment and an HHP-specific, short and concise document for use by VAs should be extracted, with the objective of assisting them in the different certification tasks of the HHP system.

Dr Barcos proposed a definition of the HHP sub-population for discussion with the Terrestrial Code Commission with a view to potential adoption in the *Terrestrial Code* in 2015.

### Draft Definition

*Includes registered horses (equidae) that are under permanent veterinary supervision to ensure the application and implementation of OIE standards specific to this subpopulation, that include the cooperation work between Veterinary Services and equestrian clubs, and also vaccination, laboratory analyzes, quarantine, individual identification, monitoring, performance, biosecurity and welfare, among others, for the sole purpose of participating in international equestrian competences and races through temporary movements.*

Prof. Peter Timoney pointed out that there is an urgent need to raise awareness about the importance of biosecurity amongst industry, owners and event organisers. Dr Murray added that for all these reasons, the BSG need to be reviewed and fully endorsed by FEI and IFHA before they can be published.

Some specific points in the document that needed clarification were discussed and resolved as follows:

- Page 4, definition, remove the word “status”
- Section 2.2.2, page 23, 8<sup>th</sup> bullet: change the word “exporting” to “host” and add surra (*Trypanosoma evansi*) to the diseases that need vector protection; change to “vector protected” rather than “insect proof”
- Section 2.2.4, page 24, 4<sup>th</sup> bullet: remove the word “internationally”
- Section 2.8.5, page 42. Dr Kettle disagreed with parts of this section and agreed to provide an alternative wording

## 9. The need for additional *Terrestrial Code* chapters

It was agreed that there was a need for a new chapter on surra (*Trypanosoma evansi*) as well as a chapter introducing the overall approach to the six priority diseases for the HHP horses’ movement certification. SCAD should be requested to set up an *ad hoc* Group for Surra (*Trypanosoma evansi*).

<sup>10</sup> Now reading: “The horse was immunized.... between 21 and 90 days before export...”

<sup>11</sup> SRH = single radial haemolysis

## 10. Equine disease free zones (EDFZ)

Dr Münstermann provided a brief summary on the developments regarding the temporary EDFZ established by the Republic of Korea for the Asian Games 2014 and the application by Azerbaijan to set up a permanent EDFZ in Absheron Peninsula. This led to the question of the need for more formalised EDFZ guidelines as compared with those published on the OIE website. More formalised guidelines could have a questionnaire with issues that the country needs to address when setting up an EDFZ, such as the structure of Veterinary Services, existence of legislation providing a legal basis for establishing zones and surveillance capacities (e.g. laboratories and other infrastructure). As the declaration of the EDFZ is a “self-declaration of freedom” in line with *Terrestrial Code* Article 1.6, the question was raised of whether more detailed guidance is required. The Group agreed to develop both types of guidelines, but after the more urgent documents, such as HHP health certificate and Operationalisation Plan and HHP BSG, have been finalised.

In this context the question of the feasibility of using an EDFZ approach in AHS-endemic countries was discussed. Given that it is a *self-declaration*, nothing can stop a country from doing this for AHS; however, the question remains of whether this declaration would be accepted by other countries. Dr Kris de Clercq highlighted the importance of following OIE policy on the matter of official recognition and noted that the OIE will not publish a self-declaration for freedom from foot and mouth disease or any other disease that is the subject of official recognition.

The Group concluded that the declaration to the OIE of official freedom of a Zone or an entire country is preferable under all circumstances; however, as a transitional measure, the option of certifying horses according to Article 12.1.9 (point 3c) (see Agenda item 7), was supported. The Group was aware of the problems the horse might face during onward travelling due to its AHS-vaccinated status.

This discussion led to an update on the state of play regarding the 2016 Olympic Games in Rio de Janeiro (Brazil). Dr Alberto Gomez da Silva informed the Group that Brazil is building a new arena for the equestrian events and that the country intends to use HHP and EDFZ concept approaches. The National Equestrian Federation has not yet advised on the dates of the test event to be held in 2015. Brazil has not yet started to develop the official import requirements for the Olympic Games.. Dr Barcos supported the view of Dr da Silva regarding the need to engage the Mercosur<sup>12</sup> countries in the preparatory work and proposed to contact the Secretary of Mercosur to accelerate the development of harmonised conditions for the temporary importation of horses from the region into Brazil.

## 11. Research projects

Equine Influenza (EI): EI had already been identified as the priority disease for research support during the previous AHG meeting.

Dr Cullinane summarised the outcomes of the OFFLU<sup>13</sup> STAR-IDAZ<sup>14</sup> meeting held at OIE Headquarters in April 2014 to develop a global animal influenza research agenda. The immediate research priorities identified for EI were the validation of a reverse-transcription polymerase chain reaction (RT-PCR) test to OIE standards and the development of evidence-based vaccination regimes. Dr Cullinane informed the Group that subject to funding, the four OIE Reference Laboratories for EI had agreed to work together to validate an RT-PCR assay under the auspices of the Expert Surveillance Panel. Countries from all continents would be engaged in the process so that the application for designation as the prescribed test would be based on broad international consensus. Prof. Alan Guthrie queried whether the test would be specific for EI or a pan-influenza test. It was explained that the consensus of the Expert Surveillance Panel was that it should be a pan-influenza test with the capacity to detect other Type A influenza viruses, for example avian influenza viruses that have the

12 Mercosur = Mercado Común del Sur ; member countries are Argentina, Brazil, Paraguay, Uruguay and Venezuela

13 OFFLU: OIE/FAO Network of expertise on animal influenza

14 STAR-IDAZ: Global Strategic Alliances for the Coordination of Research on the Major Infectious Diseases of Animals and Zoonoses

potential to cross the species barrier into equidae. This was demonstrated in China (People's Rep. of) in 1989 and, more recently, with the highly pathogenic avian H5N1 virus in Egypt.

Dr Cullinane also summarised the vaccination regimes study that had originally been submitted to the AHG at its meeting in October 2013. The aim of the study is to determine when in a horse's vaccination career it is of benefit to administer an influenza vaccine at 6-monthly intervals and at what stage annual boosters suffice. After discussion it was agreed that the study should be expanded to determine the effect of administering booster vaccines every 90 days as could occur with HHP health certificate. The Group recommended that both studies be funded.

Glanders: Dr Stéphan Zientara summarised progress on a project to develop an enzyme-linked immunosorbent assay (ELISA) for glanders, as already presented during the AHG October 2013 meeting. A prototype ELISA based on a crude antigenic fraction of *B. mallei* has been developed. Pakistani sera composed of sera from truly infected and potentially exposed equines (horses and mules), Brazilian sera collected in a farm with an ongoing outbreak of glanders as well as sera from glanders-free areas were tested. Preliminary results show a good specificity and sensitivity for this new ELISA test. The specificity, measured with 485 sera from glanders-free areas, was 98,8%. The 6 sera that gave a doubtful or positive result had a S/P value comprised between 43 and 70%. A slight adaptation of the cut-off would greatly improve the specificity to 99,6%. For the complete validation of the test, fresh sera from infected animals are needed and could allow a better definition of the interpretation criteria.

He indicated that although this EU funded project was progressing, additional funding could expedite developments. Dr Murray asked that he submit details for AHG consideration.

Dourine: Dr Zientara summarised a research proposal on treatment of *T. equiperdum* which was discussed during the OIE ad-hoc group meeting on non-tsetse transmitted Trypanosomiasis in May 2014, and which concluded that in the near future it is not to be expected that a test will be available that clearly differentiates between *T. evansi* and *T. equiperdum*. A successful outcome of such a study could lead to important changes in the regulations for this disease, as infected horses are either castrated (male) or euthanized. There was no great enthusiasm from the Group for progressing this proposal, at least at this point in time.

African horse sickness: Dr Münstermann informed the Group that a ring trial on different RT-PCR tests will be carried out by the four OIE Reference Laboratories to which the laboratory of Prof. Guthrie at the University of Pretoria and of Dr Zientara at Anses<sup>15</sup>, Paris, would also be invited.

She also encouraged the Group to support initiatives to develop improved AHS vaccines, including DIVA<sup>16</sup> vaccines.

## 12. Communication strategy for HHP concept

Ms Inka Sayed presented an outline for a planned Diploma study to develop a communication strategy for the HHP concept. The Group agreed that this offers a valuable opportunity to improve communication with Veterinary Services, especially the CVO<sup>17</sup>/OIE Delegate. Dr Barcos commented on the rapid turnover of OIE Delegates in the Americas (13 CVOs changed since 2012), which demonstrates the need to produce clear messages for different stakeholders and distribute them accordingly.

The need for an "equine liaison person" within Government was reiterated and Dr Barcos reminded the Group that this was one of the recommendations of the OIE-FEI Panama meeting on international horse movement in 2012. Prof. Timoney added that this position had existed in the United States of America, was then removed, and had recently been reinstated due to pressure by the industry. Dr Münstermann suggested to carry out a survey with the OIE Regional Representatives to find out how many Veterinary Services have such an "equine liaison officer", so that industry could focus its lobbying efforts on those countries that do not have one.

15 Anses: Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail

16 DIVA: differentiate infected from vaccinated animals

17 CVO: Chief Veterinary Officer

Dr Murray concluded that communications is a key element to take the HHP concept forward and that industry needs to play a key role in dissemination of these messages. He added that, following consideration by OIE and FEI of Ms Sayed's Report, AHG would be prepared to overview the implementation of the communications strategy.

### 13. Update on the HHP project workplan

Dr Münstermann presented the HHP project workplan and highlighted points that should be modified to reflect the decisions of the AHG. Dr Barcos identified three planned meetings in the Americas that could provide a forum for discussion of the HHP concept. These are the seminar for OIE Focal Points on Communication; the seminar of Laboratory Focal Points and a proposed follow-up to the Regional Conference on international horse movement held in Panama in 2012. The Group agreed that a meeting in Africa should also be envisaged and Dr Füssel suggested it be planned for end of 2015 in view of possible participation in the Brazil Olympics. Dr Murray added that there will be an inter-regional Conference on international horse movement held in Dubai at the end of September and that some African countries could already be invited to this meeting. Dr Graeme Cooke added that Eastern European countries had also expressed great interest in such a Conference.

### 14. General discussion and next meetings

In an attempt to evaluate the effectiveness of this AHG, Dr Murray opened the discussion on whether the approach needs to be changed. There was general agreement that a large group representing industry, governments and equine disease experts is needed to "pressure test" the progress, however, concrete results should be produced by smaller expert sub-groups. Dr Barcos proposed to include the OIE Regional Representatives into the distribution of the AHG reports so that they can also better disseminate the results. Dr McEwan encouraged the AHG to establish rapid turnaround of all correspondence and electronic discussions and Dr de Clercq added that discussions on topics such as the HHP health certificate and the Operationalisation guidelines should not be prolonged – they would receive sufficient country comments anyway!

Dr Murray again emphasised the critical importance of Members responding to draft papers or questions put to them in a timely manner. This was particularly important as it would enable the AHG to understand and take in to account the views of others at AHG or Sub Group Meetings.

The next full AHG meeting will be held in April 2015, dates will be advised closer to the time.

An expert sub-group meeting to finalise the HHP Certificate and the Operationalisation Guide will have to convene in July in order to meet the deadline for submission of the documents to SCAD and Code Commission in August.

### 15. Conclusions and resulting action

Dr Murray led the discussion summarising the key conclusions, as follows:

#### Sub Group Meeting

- Convene in July to finalise report on the HHP Health Certificate for international movement and Guidelines on the Operationalisation of the HHP Concept, to be considered by the SCAD and Terrestrial Code Commission at their meetings in September 2014.

#### Comments on new *Terrestrial Code* chapter:

- Retain acronym HHP rather than change to HHS

Revision or development of *Terrestrial Code* chapters:

- Review *Terrestrial Code* Chapter 8.8 (JE) and Chapter 12.4 (WEE and EEE) to include text similar to that in Chapter 8.17 (West Nile fever) “*Member Countries should not impose trade restrictions on dead-end hosts such as horses*”
- Develop a new Chapter on surra (*Trypanosoma evansi*)
- Revise Chapter 12.6 (EI) to include the option of post vaccination testing to detect poor responders
- Develop chapter on the HHP critical six diseases by starting with a scientific paper
- Develop chapter on the HHP health certificate with an accompanying “HHP horse management handbook”

Revision of *Terrestrial Manual* chapters:

- Prepare a request to the OIE Biological Standards Commission to consider restricting Chapter 2.5.13 to pathogenic strains of VEE only

Development/finalisation of other guidelines:

- Extract a short and concise HHP certification guideline for VAs from the more comprehensive full BSG
- Revise and expand the current EDFZ guidelines by adding a questionnaire-type check list, for inclusion on the OIE internet site, dealing with all requirements for an EDFZ
- Develop a guide to the self-declaration of an EDFZ

Research projects:

- Develop a call for proposals for the two prioritised EI projects
- Invited AHG Members to submit proposals or revised proposals for research projects

Communication strategy:

- A pilot communication strategy to be developed by end of August through interviews with representatives of VA and national equestrian federations.

Work Plan

- Update the Action Plan to take account of the outcomes of the AHG Meeting.

**16. Recommendations**

In drawing the meeting to a close, Dr Murray reiterated the need for industry to fully endorse the work of this AHG as most of the implementation of the Group’s recommendations will have to be done by FEI and IFHA. He once again stressed the need for an “equine liaison person” in the VAs, and also encouraged the industry to support this proposal.

He thanked the participants for the contributions that they have made, was particularly happy with progress in a difficult and new area, and acknowledged the significant support that the OIE has given to the Group.

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.../Appendices

Appendix I

**FOURTH MEETING OF THE OIE AD HOC GROUP ON INTERNATIONAL HORSE MOVEMENT  
FOR EQUESTRIAN SPORT**

**Paris, 2–4 June 2014**

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**Agenda**

1. Opening
  2. Adoption of the Agenda
  3. Record of the third meeting
  4. Review of actions arising and achievements
  5. Outcome of the OIE 82<sup>nd</sup> General Session
  6. Operationalisation of the HHP concept
  7. HHP health certificate
  8. Revised biosecurity guidelines
  9. The need for additional *Terrestrial Code* chapters
  10. Equine disease free zones (EDFZ)
  11. Research projects
  12. Communication strategy for HHP concept
  13. Update on the HHP project workplan
  14. General discussion and next meetings
  15. Conclusions and resulting action
  16. Recommendations
-

## Appendix II

**OIE AD HOC GROUP ON INTERNATIONAL HORSE MOVEMENT  
FOR EQUESTRIAN SPORT  
Paris, 2 – 4 June 2014**

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**REPORT OF THE MEETING OF A SUB GROUP TO THE OIE AD HOC GROUP ON  
INTERNATIONAL HORSE MOVEMENT FOR EQUESTRIAN SPORT**

**Paris, 10 – 11 April 2014**

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A meeting of an expert sub-group of the *ad hoc Group* on International Horse Movement for Equestrian Sport was held at the OIE Headquarters on 10 – 11 April 2014. The objective of this sub-group was to describe the **operationalization of the HHP concept at home stable, event venue and during transport.**

Note: in this report, ‘home stable’ and ‘premises (or place) of usual residence’ are equivalent terms.

**1. Opening**

Dr Brian Evans, Deputy Director General and Head of the Scientific and Technical Department, welcomed the members of the sub-group on behalf of the Director General. Apologies were received from Dr Gardner Murray, Chair of the *ad hoc Group*, who was unable to attend the meeting.

Dr Susanne Munstermann of the Scientific and Technical Department provided an update of activities since the last *ad hoc Group* (AHG) meeting in October 2013. The key points of this update were (i) a meeting organised by International Federation of Horse racing Authorities (IFHA) in Hong Kong, attended by several members of the AHG, in which the High Health, High Performance (HHP) concept was presented to the International Movement of Horses Committee (IMHC) of IFHA; (ii) OIE in collaboration with FEI and IFHA organised a regional meeting in Hong Kong in February 2014 to compare the current import regulations in the Region, based on a questionnaire to Member countries (iii) the Scientific Commission for Animal Diseases and the Terrestrial Animal Health Standards Commission discussed OIE Member countries’ comments on the draft code chapter on the *High Health status horse sub-population* during their meetings in February and (iv) OIE and FEI visited Azerbaijan to assess the feasibility of establishing an Equine Disease Free Zone (EDFZ) in the Absheron Peninsula.

Dr Münstermann explained that the outcome of the discussions of this meeting will be included in the Biosecurity Guidelines.

**2. Appointment of a chair and rapporteur**

The meeting was chaired by Dr Alf Fuessel and Dr Munstermann, with support from Dr Kahn, acted as rapporteur.

The Agenda is presented in [Appendix I](#), the Terms of Reference in [Appendix II](#) and the list of participants in [Appendix III](#).

### 3. Biosecurity measures and management at the home stable

The starting point for the discussion was the preparation period of 90 days, which is defined in the draft HHP health certificate as “the horse was kept continuously for at least 90 days on a premise or premises that meet (s) the disease certification requirements for an HHP premise”. For a horse to become an HHP horse, the health checks that need to be carried out during this preparation period comprise a glanders test (in the case where the country of origin is not free from the disease), a test for equine infectious anaemia (EIA) and a vaccination against equine influenza (EI). The requirements also include that the country or zone of residence of the horse is free from AHS<sup>1</sup> (either official country freedom or 2 years freedom from the disease and vaccination not practiced during the last 12 months) and freedom from VEE for at least 2 years.

The equine disease health status of the country of residence of the horse is the basis for determining the surveillance required for all other equidae in the home stable and the requirement to test for glanders and EIA. All equidae in the home stable should be vaccinated against equine influenza unless the country is free of the disease. In a situation where the country or zone health status is unknown, the individual horse seeking to qualify as an HHP horse must be moved at the end of the 90 day preparation period to a separate HHP facility, where it will undergo the 14 day isolation period. During this period, the horse is considered to have qualified for membership of the HHP subpopulation and therefore it must be held only with HHP horses or horses of equivalent or higher health status. In this case the period of preparation prior to international movement consists of 90 plus 14 days.

In a situation where the equine disease health status of the country of residence of the horse is well known, or the country holds prior approval from the Veterinary Authority of the country organising the event (into which the HHP horse will be temporarily imported), the horse seeking recognition as an HHP horse can qualify for export in a total period of 90 days. This is based on the horse being confirmed as free from infectious diseases, specifically glanders and EIA.

In addition, the health status is also determined by the performance or “fitness to compete” of a horse, which is a result of controlled health conditions.

In this case, the horse can be held in a premise or premises that fulfil the disease certification requirements for an HHP premise for 76 days and can remain in this stable or go to a registered HHP stable for the last 14 days. In this case the entire preparation period consists of 76 plus 14 days.

In the case where the horse seeking recognition is a long term resident of a population of at least equivalent health status to an HHP population, based on a documented negative EIA test and vaccination against equine influenza, the period of qualification for recognition as an HHP horse comprises only 14 days.<sup>2</sup>

It was agreed that horses could be moved during the period of preparation providing that the conditions for the first part (90 or 76 days) as given in 2a of the draft HHP health certificate (*..premises meet the disease requirements for an HHP premise*) and for the second part of 14 days as indicated in 2c (*.. premises that have a current HHP number*) are respected.

Dr Kettle mentioned that for race horses, the HHP stable number will be linked to a trainer and his entire stable will become an HHP stable, comprising all horses, whether they will travel internationally or not.

The entire 90 day period of preparation must be under continuous veterinary supervision, defined as being at least one visit by the accredited veterinarian per week, an inspection on Day 1 of the 14 day isolation period and a final visit 48 hours before exportation of the horse. The responsibility for the veterinary inspection should lie with the stable veterinarian, who ideally should be registered with the FEI or IFHA and, preferably, accredited by the national Veterinary Authority (VA).

<sup>1</sup> This part of the health certificate needs to be amended accordingly

<sup>2</sup> This statement was not as such concluded during the meeting, but it appears the logical consequence of all other statements and has been accepted by the group during email consultations

The Official Veterinarian should be informed prior to the start of the 14-day isolation period and alerted to the date for the pre-export visit for the purpose of health certification. It is important that the VA be well informed about the process of preparation of horses for export under the HHP conditions.

The VA will have the right to conduct audits of all parts of the HHP system (premises, venues, stop-over points). This may include unannounced visits.

In the case that different veterinarians are responsible for supervising the 90 day (or 76 day) and the 14 day isolation periods are taking place in different stables, a hand over report should be provided by the veterinary supervisor of the first period to the supervisor of the second period.

During the entire preparation period, records of the veterinary supervision should be kept. During the preparation period all new horses entering the stables should be vaccinated against equine influenza and of an equivalent or higher health status or cannot be allowed into the stable.

The stable unit in which the horse spends the last 14 days (or the entire period if it was carried out in a single stable) must be separated from all other units on the property that hold non-HHP horses. A supervisor that is dedicated to this unit must be designated as responsible for ensuring that it complies with the criteria listed below. Once qualified as an HHP premise, the stable should be registered with the FEI or IFHA as an **HHP stable**. The registered number of the HHP stable will be contained in the HHP database.

The criteria for a stable unit to qualify for registration as an HHP stable are as follows:

- Name and contact details of owner/trainer, location (GPS details) of the unit, contact details of the supervising veterinarian (including out of hours contact information)
- Construction and equipment
  - Unit is at a minimum distance of 50 meters and fenced off from any other unit containing horses on the property
  - Means of controlling entry of people and animals into the unit are provided
  - Facilities for training / exercising horses are available. If they have to be shared with other horses that are not in preparation for membership of the HHP subpopulation, operational measures to separate HHP and non HHP horses must be established (e.g. first to train)
  - There is equipment dedicated to the use of the horses in the HHP unit
  - There are means to allow for the isolation of horses with signs of infectious or contagious disease
  - The unit must have access to vehicles suitable to transport HHP horses and means to clean and disinfect these vehicles
- Management procedures
  - Access for horses and people to the unit is restricted; if personnel enter also other stables, they must clean and disinfect or change outer clothing and boots and wash and disinfect hands before coming into contact with horses being prepared to qualify for HHP membership
  - Daily health and temperature check of each horse shall be carried out by grooms dedicated to this stable unit; (SOP for this check to be developed and provided to grooms)
  - Records should be kept showing the results of daily inspections as well as veterinary visits and interventions; these records should be made available to the FEI/IFHA or VA for audit as may be requested

- Procedures for cleaning, disinfection, feeding and horse management should be documented
- Transportation of HHP horses is done according to documented procedures

Once a stable unit can fulfil these conditions, the owner/person responsible can apply to the FEI or IFHA for registration of the facility as an HHP premise. The FEI/IFHA may, if appropriate, request approval of the Veterinary Authority. Once the facility is approved, the stable unit will be allocated an HHP registration number.

For FEI, the conditions that apply to HHP home stables will eventually be covered in the FEI Veterinary Regulations.

#### **Discussion points:**

The conditions under which new horses could enter a yard or property during the 90 day preparation period were discussed. New entrants could potentially compromise the health status of the group under preparation, particularly regarding EIA, in light of the extended (commonly 40 day ) period of seroconversion (e.g. a horse could have been tested negative during this period, but becomes infectious once introduced into the stable).

The requirements for training facilities at HHP stables was discussed. If they are constructed in such a way that HHP horses share airspace with non-HHP horses (e.g. in the case of indoor arenas), they could present a risk to the health status of horses in preparation for membership of the HHP subpopulation. In this situation, despite the availability of a separate stable unit, horses would need to be moved to other properties during the preparation period.

Concern was raised about the possibility of over-vaccination for EI. The draft health certificate stipulates “the horse was immunized between 21 and 90 days prior to export”. Horses making several 90-day HHP travel tours would be vaccinated every 3 months. A pilot study suggests that for horses that have been vaccinated for several years there is a negative correlation between antibody level and number of vaccine doses received. However, it was agreed that further studies are required and that at present the majority of importing countries currently require vaccination within 90 days prior to export.

Concern was raised that the draft certificate does not include a statement from the veterinarian “to the best of my knowledge, the horse has not been in contact with equidae suffering from an infectious or contagious disease in the 14 days prior to this declaration”. Such certification is essential to minimize the risk of conditions such as strangles and equine herpesvirus neurological disease.

#### **4. Biosecurity measures and management at the venue**

The Group agreed on the general principle that HHP horses at event venues must be held in separate stable units with similar characteristics to those of the home stable. The stable units must have dedicated personnel, feed, and isolation facilities and must be separate from stable units holding horses that do not have an equivalent health status. If physical separation of 50 m distance is not possible, other management or physical measures must be put in place to prevent the transmission of vector borne and respiratory diseases. Otherwise the same criteria as listed for the home stable apply.

While HHP horses must be stabled separately, they may be in the same area as other horses while training or competing / racing (“under tack”).

It was realized that the physical separation of HHP horse stables might be difficult in certain FEI events, particularly when they are indoors and space for stabling is limited. This situation should be addressed by the FEI by ensuring that these events are either limited to HHP horses or HHP horses are excluded from them.

#### **5. Biosecurity measures and management during transport**

The discussions touched on two aspects of transportation: (i) the actual transport means, e.g. airplanes, vehicles, trains, boats and (ii) lay-over points where HHP horses can be held temporarily during journey breaks.

It was agreed that HHP horses may only be transported with equids of equivalent or higher health status. The final decision on combining horses in consignments rests with the VA of the importing country.

Current import conditions normally stipulate “horses should not travel with other horses of different health status”. Therefore, the shipment of HHP horses with, for example, horses intended for permanent importation that have not achieved HHP or equivalent status, would present a problem for the latter horses!

Transporters of HHP horses shall follow a documented SOP for their transport. There is no need to register transporters as “HHP transporters”.

Examples were given for long-haul road transport e.g. from Belgium to Morocco with a minimum of 3 stops. For these situations a network of HHP approved lay-over points needs to be established. These points should meet biosecurity requirements sufficient to ensure that HHP horses will not be exposed to equids that are not of equivalent health status. The biosecurity measures should be guided by the conditions that apply for the HHP home stables (see point 2) and should be listed in the HHP database. These lay-over points can be stables en route, show grounds, veterinary clinics, animal hotels, Government quarantine stations or control points. All these premises should be HHP registered in order to be used by HHP horses.

### **Discussion points**

Concern was expressed over the apparent logistical difficulty of establishing a network of registered lay-over points for HHP horses. It was concluded that the setting up of this network would be step wise and event driven. In the preparation period for a big event with known participating countries, the routes used by those horses coming by road would be established and HHP lay-over points along these routes be created.

The scenario in which a HHP horse would need to transit through a country that either does not subscribe to the HHP principle or is not accepted by the importing country was discussed. The example of UAE was illustrated. This country has a list of approved countries and would not accept horses from or transiting through non-approved countries. The same holds true for the EU, which has a list of 56 approved countries.

This problem can only be addressed in the long term once the HHP concept is accepted by many countries, as it will require modification of national laws or regional agreements (e.g. EU, Mercosur) to allow for the importation of HHP horses from otherwise non-approved countries.

## **7. Finalisation and adoption of the draft report**

The Group finalised the report by correspondence.

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.../Appendices

Appendix I

**MEETING OF A SUB GROUP TO THE OIE AD HOC GROUP ON  
INTERNATIONAL HORSE MOVEMENT FOR EQUESTRIAN SPORT**

**Paris, 10 – 11 April 2014**

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**Agenda**

1. Opening
  2. Appointment of a chair and rapporteur
  3. Biosecurity measures and management at the home stable
  4. Biosecurity measures and management at the venue
  5. Biosecurity measures and management during transport
  7. Finalisation and adoption of the draft report
-

Appendix II

**MEETING OF A SUB GROUP TO THE OIE AD HOC GROUP ON  
INTERNATIONAL HORSE MOVEMENT FOR EQUESTRIAN SPORT**

**Paris, 10 – 11 April 2014**

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**Terms of Reference**

The **objective** of this meeting is to develop operationalisation guidelines for HHP horses which will form part of the Biosecurity Guidelines currently being finalised.

The members of this expert group shall consider the following tasks during this meeting:

1. Biosecurity measures to be put in place at the HOME STABLE
  - During the 90 days preparation period to qualify as an HHP horse
  - During the last 14 days isolation within these 90 days
  - During normal times, while the HHP horse is travelling, so that the horse can return to this stable
  - What are the criteria to be fulfilled for a stable to be registered as an HHP stable?
  - Consider possible differences between FEI horses and Racehorses for all of the above points
2. Biosecurity measures to be put in place at the VENUE
  - Requirements to be put in place to guarantee that HHP horses are at all times separated from non-HHP horses
    - For the stables at the venue
    - For the competition arena / race course
  - What are the criteria to be fulfilled for a venue to be registered as an HHP venue?
  - Consider possible difference between FEI events and races
3. Biosecurity measures to be put in place during TRANSPORT
  - How do we guarantee that HHP horses are separated from non-HHP horses during transport?
    - i. Air transport
    - ii. Road transport
  - Is there a need to register transporters as “HHP transporters”? if yes, what are the criteria they must fulfil?
  - Consider possible differences between FEI horses and race horses

If time allows, some open questions:

- Who else should be included in the registration for the HHP concept?
    - Veterinarians who assess compliance with biosecurity measures?
    - Handlers of HHP horses?
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Appendix III

**MEETING OF A SUB GROUP TO THE OIE AD HOC GROUP ON  
INTERNATIONAL HORSE MOVEMENT FOR EQUESTRIAN SPORT**

**Paris, 10 – 11 April 2014**

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**REPORT OF THE MEETING OF A SUB GROUP TO THE OIE AD HOC GROUP ON  
INTERNATIONAL HORSE MOVEMENT FOR EQUESTRIAN SPORT**

**Paris, 23 – 25 July 2014**

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A meeting of an expert sub-group of the *ad hoc Group* on International Horse Movement for Equestrian Sport was held at the OIE Headquarters on 23 – 25 July 2014. The objective of this sub-group was to finalise the operationalization of the HHP concept and in this context, to revise the HHP Certificate. Furthermore, a definition for the HHP horse was to be agreed upon.

**1. Opening**

Dr Brian Evans, Deputy Director General and Head of the Scientific and Technical Department, welcomed the members of the sub-group on behalf of the Director General. Apologies were received from Dr Alberto Gomez, who was unable to attend the meeting.

In his opening remarks, Dr Evans highlighted that the work of the *ad hoc Group* and its sub-groups has arrived at a critical stage as it is expected to deliver its outputs to the Code Commission meeting in September. Since the members of the Code Commission are elected by the General Assembly, it reflects the opinion of the OIE Member countries. This means that the quality of the products to be delivered to the Commissions need to be well thought through and of highest standard. He alluded to the situation that will present itself in 2015, the election year for all critical positions and Commissions in the OIE and advised to get the Group's output to the Commissions before this complete turn-over.

Dr Thiermann, President of the Code Commission, also welcomed the participants and recalled that the Group is developing a pilot concept which, if it works well, can be used as a show case for the compartmentalization concept. He alluded to the fact that the new Chapter 4.16 was accepted by the General Assembly with the expectation that answers to the questions of the Member countries will be provided in due course. Regional events such as the OIE Conferences, but also Regional Commission meetings with Delegates, are good opportunities to raise awareness for the concept and the details that are being developed by the Group.

Dr Murray, Chair of the *ad hoc Group*, concluded the introductions by promising to deliver a comprehensive package of management guidelines and a revised HHP Certificate in time for consideration by SCAD and Code Commission.

**2. Appointment of a chair and rapporteur**

The meeting was chaired by Dr Gardner Murray and Dr Munstermann acted as rapporteur.

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

**3. Definition of the sub-population and the members of the sub-population**

In the last meeting of the *ad hoc Group* in June 2014, the issue of agreeing on a definition and integrating such definition into the adopted Chapter 4.16 had been raised, but could not be finalised. The Group had resorted to moderated email discussion that lasted for 3 weeks. A draft definition as basis for the discussion was provided by Dr Barcos. This email discussion had produced 2 proposals for a definition, which were tabled to this expert group and discussed.

Based on the argument that a definition has to link the High Health Status Sub-population, as shown in the title of Chapter 4.16, to the individual animals populating this sub-population, which have since the beginning of the work on this concept, been termed *High health, high performance horse* = HHP horse, and that the definition should not reiterate what is already contained in the Chapter, the definition that was finally agreed upon is as follows:

*For the purpose of this chapter, High health, high performance (HHP) horse means a horse registered by the FEI or IFHA as member of a High health status subpopulation of horses, eligible to perform in international competitions and races and kept in establishments approved by the Veterinary Authority as applying biosecurity management systems that ensure, through surveillance, control and biosecurity measures, a distinct health status with respect to specific diseases.*

#### 4. Management of the HHP horse

##### 4.1. Background

A management proposal had been developed by an expert group that met in April 2014, in line with the output of the expert group that developed the draft HHP Certificate in January. These documents had been commented on by members of the AHG after they had been finalized and during the full AHG meeting in June 2014. The key argument on the side of industry was that the conditions proposed in both documents are more difficult to fulfil than current conditions prevailing in many countries, particularly those where racing circuits are already well established and bilateral protocols agreed, as well as in Europe and its approved third countries. Furthermore, during the 2014 OIE General Assembly, the Regional Commission meeting for Africa gave a clear recommendation to the OIE not to exclude Africa from the concept.

These comments had been taken into consideration by Dr Münstermann when preparing an alternative proposal in preparation for this July expert group meeting. The alternative proposal also considered that the HHP concept must have universal application and provide opportunities for international competition horse movements from all parts of the world subject to appropriate and rigorous risk management measures.

The alternative approach presented considers a qualifying period for the entire horse population of a given premises that wishes to register and takes into account the equine disease status of the country in which it is located. Once such premises have successfully undergone a 90-day approval period of **all resident horses**, they become an “approved premises” holding “high health status subpopulation horses” to be registered in the international FEI / IFHA database. From this high health status subpopulation the individual horses that wish to travel on the conditions of non-stop 90 days travel, can apply for their HHP registration.

##### 4.2. Specific points of discussion on the management concept

A key point raised in the discussions was the lack of confidence between countries when it comes to certification and the complexity of managing a compartment in such a way that it can be trusted. Dr Bonbon explained that confidence is a pre-assumption. The OIE assumes that Veterinary Services comply with what the Code states, hence the group should try and develop the standards in such a way that they can be complied with; however, it should also be in accordance with other *Code* Chapters on certification.

Another important discussion point was how to convince the clients to use the HHP concept, particularly those that are operating in facilitated conditions such as EU countries and racing circuits. Dr Cooke suggested that big events will create the need to apply the concept more than anything else. He mentioned that the Asian Games for which HHP-like conditions were put in place, have worked well and that such success must be highlighted through the next steps. He added that in his view big events will be the first to use the concept, followed by medium sized events. Racing did not contribute any such proposals.

To describe the phased approach explained below, the use of the acronym HHS for the “high health status subpopulation” was proposed. The usefulness of this, however, might require further discussion and acceptance by OIE Member Countries.

Dr Murray summarised this discussion by stating that the HHP concept is one of a number of options for international competition horse movements; for example using existing OIE standards, applying EDFZs or a combination of approaches. The choice is a business decision for industry, but the HHP horse concept provides real opportunities for developing areas with equestrian and racing interest to engage in international competitions using simplified but scientifically based certification arrangements. However, the system must be rigorous and consistent in its application recognizing differences in risk between countries and regions.

To be both attractive to industry and acceptable to veterinary authorities, the approach needs to be developed and progressed in an achievable and attractive manner. Importantly it provides opportunities for countries currently with poor prospects of engaging in international competitions, to do so subject to meeting specified conditions.

- **The proposed management system** (presented in the report of the Code Commission)

The document elaborates the system as agreed during this meeting. In summary, the proposed management system can be outlined as follows:

I. The premises

- All resident horses on premises that wish to register as holding a “high health status subpopulation” with the HHP system have to undergo a 90-day approval period in order to establish their high health status.
- It was agreed that such premises will be approved by the Veterinary Authorities and registered with the FEI and IFHA international database at the end of this 90-day approval period.
- If a premises hosts only HHP horses, it can be registered as HHP premises.
- The requirements during the 90-days differ according to the health status of the country in which the premises are located, in regards to the 5 diseases of relevance to the HHP system.
- Regardless to the country situation, the piroplasmosis serological status of an individual horse needs to be identified.
- Tests or vaccinations to be carried out during the approval period:
  - In countries of known health status for AHS, VEE, EIA, EI and glanders, the approval period includes a test for EIA and glanders and a vaccination for EI (note: these requirements apply to all other country situations also).
  - In countries of unknown health status for glanders, all animals will be tested for glanders twice.
  - In countries or zones not free from VEE, options are given to either vaccinate the animals or to keep them in vector protected quarantine and test twice.
  - In countries or zones not officially free from AHS, the preparation period includes a quarantine period. It envisages a first PCR test of the horse under vector protected conditions before the horse is moved to a vector protected quarantine station where it will stay for at least 14 days and will be re-tested (*Code* Chapter 12.1.7/3c. applies).

- Regardless of the equine health situation in a given country, the following general requirements apply:
  - Clear identification of all horses on the premises.
  - No breeding activities on the premises in the 90 days prior to registration.
  - Biosecurity plan and contingency plan in place.
  - No clinical signs of infectious diseases discovered during regular veterinary supervision
  - New entrants into the premises have to undergo the same tests before entering the premises and be kept in isolation from the other horses inside the premises for at least 2 weeks (Note: if they enter the premises before the resident animals are tested, they can be included in the testing; if they enter after the resident horses have already been tested, they need to be isolated).
  - A documented record of origin and movement of any new entrant has to be provided.

## II. The HHP horse

- When high health status subpopulation premises are approved by the Veterinary Authorities and have been registered with the international database, individual horses are eligible, with the appropriate testing and isolation, to be registered as HHP horses with the FEI and IFHA database.
- However, in countries not known to be free from glanders:
  - Horses must remain residents on the registered premises after the second serological test (a minimum of 10 days)
- Once a horse has been registered as HHP horse and received its entry into the database (= ticket to travel), it must travel, otherwise the entry in the database has to be cancelled after 10 days.
- Once a horse is a registered HHP horse, it can only stay together with other HHP horses or horses of at least equal health status.

## III. The Certificate

- The Certificate makes reference only to the fact that a horse is registered as a **HHP horse** and does not explain the careful assurance of its health status that has taken place during its preparation period. It was therefore decided that a brief explanatory note shall accompany the Certificate to explain the tests done at the subpopulation level from which the HHP horse originates.

## 5. The Model HHP Certificate

### 5.1. Background

The key revisions to the previous draft Certificate were (i) the clauses on AHS and VEE country freedom as compulsory requirements and (ii) the required 14-day residence period of an HHP horse before its start of travel. Furthermore the Certificate is now presented with options per diseases that allow for different choices in line with disease status of the country of origin.

Key points of discussion were the following:

- While it is well understood that HHP horse movement can happen due to the facilitation inbuilt into the system, between countries, there could be many situations in which intra-country movements could take place during the 90 day travel period. This problem was addressed by adding a “movement record” part in the owners declaration of the Certificate.

- The certificate contains a clause that in the country of dispatch a list of diseases must be notifiable. Equine Influenza was removed from this list, as it is not notifiable in many countries despite it being an OIE notifiable disease. It was included into the clause pertaining to “good records of OIE reporting”.
- The situation could arise that Japanese Encephalomyelitis and rabies are not notifiable diseases in a country, hence the clause on the notifiability of these diseases could not be met. It was concluded that Veterinary Authorities would need to make a case and give evidence that all animals in the subpopulation are vaccinated.
- The point of including options for travel from AHS infected countries was controversial and a member of the group considered this clause a “deal-breaker”, as it would be difficult to comply with for African countries on one hand and on the other hand possibly unacceptable for officially free countries. Dr Bonbon clarified that OIE standards have to be written in such a way that they include all Member countries. He further pointed out that conditions for compartments have to be negotiated on a bilateral basis and do not fall under WTO arbitration procedures.
- In order to give more assurance to the proposed health measures for AHS, the clause for agent identification testing was changed to qualify the tests as “validated”, a condition not yet achieved by any of the PCR tests currently in use. It is expected that with some of the ongoing activities of proficiency testing of existing PCR protocols, this condition might be in place once the HHP Certificate is approved by the General Assembly.

The Certificate is presented in the report of the Code Commission.

## 6. Points for discussion by the Terrestrial Animal Health Standards Commission

Dr Murray concluded the meeting by saying that with a positive attitude, the framework approach could be made to work. Certification proposals and management principles fit within the umbrella of the *Code* Chapter 4.16 and the proposed HHP definition. In short, subject to meeting specific requirements, high health status subpopulations in registered premises would be established from which HHP horses would be selected to engage in international competitions in accordance with detailed certification and management arrangements. The approach would permit industry flexibility in countries with a good and well understood health situation, while at the same time providing opportunity for those countries with known or unknown health status in respect of specified diseases to participate in international equestrian and racing events subject to meeting strict conditions. At first glance, the concept appears complex; however, proposals are consistent with approaches in other areas such as Artificial Insemination Centres and compartmentalisation. Critical to success will be communication and the need for Veterinary Authorities to work in tandem with industry, at the same time assuming their full responsibilities for legislative and compliance matters.

In light of the comments of Dr Bonbon, it was agreed that any recommendation of the sub-group that differs from the current conditions in the *Terrestrial Code* should be brought to the attention of the Code Commission in the report of this meeting. The following points are referred to the Code Commission for consideration:

**Testing for piroplasmosis:** Article 12.7.2 stipulates that the horse was subjected to diagnostic tests with negative results during the 30 days prior to shipment. The sub-group recommended to improve safety by testing with both of the tests prescribed in Chapter 1.3 (i.e. IFAT and ELISA) and to modify the timing of the test to require that it be conducted within 14 days prior to export.

**Timing of the issuance of the health certificate:** The sub-group agreed with Appendix H of Chapter 12.6, which provides that the inspection should be done and the health certificate signed within the 48 hours prior to the international movement of the horse. However, *Terrestrial Code* Article 5.4.4 stipulates that an Official Veterinarian should provide an international veterinary certificate within the 24 hours prior to shipment of live animals. The sub-group requested that the Code Commission clarify this apparent inconsistency.

**Vaccinations for EI:** The conditions of the certificate for EI vaccination differ from the *Terrestrial Code*. The *Terrestrial Code* recommends for temporary movement (where horses are kept in isolation) that the horse be vaccinated in accordance with the manufacturers' recommendations whereas the AHG recommends vaccination within 21 to 90 days of export. The AHG is of the opinion that the facilitated movement of the HHP horse with contact with horses from potentially multiple regions requires a higher level of protection.

**7. Finalisation and adoption of the draft report**

The Group agreed that the report would be subject to a period of circulation within the Group for comments. The report will be finalised through correspondence.

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.../Appendices

Appendix I

**MEETING OF A SUB GROUP TO THE OIE AD HOC GROUP ON  
INTERNATIONAL HORSE MOVEMENT FOR EQUESTRIAN SPORT**

**Paris, 23 – 25 July 2014**

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**Agenda**

1. Opening
  2. Appointment of a chair and rapporteur
  3. Definition of the sub-population and the members of the sub-population
  4. Management of the HHP horse
    - 4.1. Background
    - 4.2. Specific points of discussion on the management concept
  5. The Model HHP Certificate
  6. Points for discussion by the Terrestrial Animal Health Standards Commission
  7. Finalisation and adoption of the draft report
-

Appendix II

**MEETING OF A SUB GROUP TO THE OIE AD HOC GROUP ON  
INTERNATIONAL HORSE MOVEMENT FOR EQUESTRIAN SPORT**

**Paris, 23 – 25 July 2014**

**List of participants**

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**MEETING OF THE OIE AD HOC GROUP ON PORCINE EPIDEMIC DIARRHOEA**  
**Paris, 19–20 June 2014**

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A meeting of the OIE *ad hoc* Group on porcine epidemic diarrhoea (hereafter the Group) was held at the OIE Headquarters from 19 to 20 June 2014.

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

Dr Brian Evans, Deputy Director General and Head of the Scientific and Technical Department welcomed the participants of the Group on behalf of Dr Bernard Vallat, Director General of the OIE. He reminded that this meeting was an *ad hoc* Group meeting and as such, governed by the OIE Terms of References for *ad hoc* Groups. He emphasised that the members of an *ad hoc* Group have been nominated by the Director General of the OIE according to their internationally recognised expertise and the balanced geographical representation. Therefore, only the experts officially invited to participate to this Group could actively participate in the meeting. He reminded the members of the Group that they should fill in and sign a confidentiality undertaking and declaration of interest for this specific meeting.

Dr Evans summarized the concept of notifiable and emerging diseases according to the criteria established in the *Terrestrial Animal Health Code (Terrestrial Code)* and emphasised that listing a disease does not necessarily involve trade implications, but reporting obligations which enhance the transparency among Member Countries.

Dr Evans reiterated the expected outcome of the meeting being the OIE Technical Factsheet on porcine epidemic diarrhoea (PED) and the evaluation of the infection with PED virus against the criteria in Article 1.2.2 of the *Terrestrial Code* for possible inclusion in the OIE List of Diseases. When appropriate, specific or general guidelines to support Member Countries in their actions of controlling or preventing the disease would be also be expected.

Dr Evans highlighted that the Director General invited Dr Gideon Brückner, President of the Scientific Commission for Animal Diseases, to chair the Group and Dr Etienne Bonbon, Vice-President of the Terrestrial Animal Health Standards Commission, to attend the meeting on behalf of the Code Commission. Dr Pascale Aubry acted as a rapporteur.

Dr Brückner explained the rationale of convening this Group as discussed during the 82nd General Session. He outlined the working plan which is based on the experience of the OIE with previous recent emerging disease such as Schmallenberg virus infection. He also invited the experts to examine the information provided by the European Animal Protein Association and the North American Spray Dried Blood and Plasma Producers.

The Group endorsed the proposed agenda.

The Agenda and list of participants are presented as [Appendix I](#) and [II](#), respectively.

**2. Current situation of PED**

The experts from Canada, the United States of America, Japan and Spain provided updated information of the past and current situation of PED in their countries and regions describing the spatial-temporal pattern of the disease outbreaks and the impact of the infection in their pig population. Risk factors for introduction and spreading as well as the measures of control implemented in their regions were discussed.

### 3. Recent scientific findings on PED and review of the draft OIE Technical Factsheet on PED

The Chair reminded the Group that the purpose of the Technical Factsheet was to provide sound and comprehensive technical information to Member Countries to increase the understanding of the epidemiology of the infection with PED virus.

The Group was provided with a first version of the Technical Factsheet drafted by the Scientific and Technical Department and proceeded to thoroughly review and complete the technical information based on their expertise, available peer-reviewed publications and other relevant information.

The reviewed OIE Technical Factsheet on PED is presented as [Appendix III](#).

### 4. Assessment of infection with PED Virus against the criteria provided in Chapter 1.2. of the *Terrestrial Animal Health Code*

The Group was reminded that only the criteria for inclusion of a disease in the OIE List of Diseases described in Article 1.2.2. of the *Terrestrial Code* should be taken into consideration for listing/delisting any disease as adopted by the World Assembly of Delegates of the OIE in May 2014.

In accordance with Article 1.1.3.e) of the *Terrestrial Code* (2013 edition), Member Countries are obligated to notify the occurrence of any emerging disease with significant morbidity, mortality, or zoonotic potential in their territories even though they are not included in the OIE List of Diseases.

The rationale of the Chapter 1.2 was explained and the Group was provided with a brief description of Article 1.2.2. to ensure harmonisation in the interpretation of each of the provision of the article.

The Group evaluated infection with PED virus against the criteria as follows:

1. First criterion: “*International spread of the agent (via live animals or their products, vectors or fomites) has been proven.*”

The Group agreed on the fact that there was evidence that PED virus has spread internationally.

2. Second criterion: “*at least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the animal health surveillance provisions of the Terrestrial Code, in particular those contained in Chapter 1.4.*”

The Group recognised that to date, no country has claimed freedom from the disease based on the provisions described in Chapter 1.4. Some countries have not reported the disease, but to date no country has scientifically demonstrated that the virus is not present in its territory.

3. Third criterion

- 3a) “*Natural transmission to humans has been proven, and human infection is associated with severe consequences*”

The Group agreed that pigs are the only natural host of PED virus. No virus transmission to humans has been described and there is no scientific evidences suggesting humans could act as a host for PED virus.

- 3b) *the disease has been shown to cause significant morbidity or mortality in domestic animals at the level of a country or a zone*”

The Group agreed that the evaluation of the infection with PED virus against this criterion should be based on the current epidemiological knowledge and not exclusively on the clinical presentation in countries or zones where the disease recently emerged. The Group thoroughly discussed the

impact observed in regions where the disease is considered endemic (Europe, Asia) and in regions where the disease is emerging (Americas). The Group agreed that the disease can cause significant morbidity and mortality in naive populations at farm level but does not have a significant impact at national or regional level.

- 3c) *the disease has been shown to, or scientific evidence indicates that it would, cause significant morbidity or mortality in wild animal populations.”)*

The Group agreed that there was no sufficient scientific information supporting the occurrence of the infection with PED virus in wild animal populations.

4. ***Fourth criterion:*** “A reliable means of detection and diagnosis exists and a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections and infestations.”

The Group reviewed the laboratory techniques available for the diagnosis of PED and concluded that there are reliable diagnostic assays available.

The Group discussed the harmonisation of a case definition for the infection with PED virus and took into consideration the definition used in those countries where the infection is notifiable or reportable. The Group acknowledged that a case definition was possible and should be based on a confirmatory laboratory test.

***In conclusion:***

The Group unanimously concluded that according to scientific information currently available, infection with PED virus did not meet the criteria to be included in the OIE List of Diseases.

**5. Risk assessment and possible guidance on the potential spread of the infection through trade of live animals, blood, semen, embryos and meat**

The principal risk pathways for the transmission of the infection with PED virus were identified. The Group recognised that the major risk mitigation measures are strict biosecurity and management at farm level.

The Group was informed that it was foreseen to convene an *ad hoc* Group on biosecurity procedures in pig production with the purpose of drafting a new *Terrestrial Code* chapter on this topic and when available a reference will be included in an update of the Technical Factsheet.

**6. Identify knowledge gaps and establish research priorities**

The Group acknowledged that there are gaps in the existing knowledge of PED and that research groups are actively working to address some of those gaps. The Group recommended updating the information of the Technical Factsheet once more relevant information becomes available.

**7. Other issues**

The Group recommended that based on the epidemiological similarities between infection with PED virus and infection with transmissible gastroenteritis (TEG) virus, the current inclusion of TGE in the OIE List of Diseases may need to be re-evaluated against the listing criteria described in Chapter 1.2 on Criteria for the inclusion of diseases, infections and infestations on the OIE list.

**8. Finalisation and adoption of report**

The Group finalized and adopted the report at the meeting.

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.../Appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON PORCINE EPIDEMIC DIARRHOEA**

**Paris, 19-20 June 2014**

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**Terms of Reference**

1. Evaluation of the current epidemiological situation of PED,
  2. Review PED epidemiology, update with recent research finding and identify research priorities,
  3. Review the OIE draft Technical Factsheet on PED,
  4. Assess PED virus infection for possible inclusion in the OIE Listed Diseases against the criteria in the *Terrestrial Animal Health Code*, Chapter 1.2 for Listed Diseases,
  5. Provide advice on potential mitigation measures to reduce the risk of spreading through live animals and commodity trade.
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**Agenda**

1. Opening, adoption of the agenda and appointment of chairperson and rapporteur
  2. Current situation of PED
  3. Recent scientific findings on PED and review of the draft OIE Technical Factsheet on Porcine Epidemic Diarrhoea.
  4. Assessment of PED virus infection against the criteria provided in Chapter 1.2. of the *Terrestrial Animal Health Code*
  5. Risk assessment and possible guidance on the potential spread of the PED virus infection through trade of live animals, blood, semen, embryos and meat
  6. Identify knowledge gaps and establish research priorities
  7. Other issues
  8. Adoption of report
-

## Appendix II

## MEETING OF THE OIE AD HOC GROUP ON PORCINE EPIDEMIC DIARRHOEA

Paris, 19-20 June 2014

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## Infection with porcine epidemic diarrhoea virus

Porcine epidemic diarrhoea (PED), also occasionally referred to as porcine epidemic diarrhoea syndrome, is a non-zoonotic viral disease of pigs caused by a coronavirus and characterised by watery diarrhoea and weight loss. It was first identified and reported in 1971 but has now been diagnosed in naïve swine populations in countries previously not known to be affected by the disease. It affects pigs of all ages, but most severely neonatal piglets, reaching a morbidity and mortality of up to 100% with mortality decreasing as age increases. It is a contagious disease transmissible mainly by the faecal-oral route. The disease is clinically similar to other forms of porcine gastroenteritis including anorexia, vomiting, diarrhoea and dehydration. The prevention and management control are focussed on strict biosecurity and early detection. There is no specific treatment for the disease.

PED is not included in the OIE List of Diseases. However, consistent with the reporting obligations of Member Countries outlined in Article 1.1.3.e) of the OIE *Terrestrial Animal Health Code* (edition 2013) relating to emerging diseases, there has been an increase in the number of disease notifications received by and distributed through the OIE's World Animal Health Information System.

The information presented in this technical factsheet reflects the epidemiological observations and research done to date (June 2014) and will be updated when additional information is available.

### AETIOLOGY

#### **Classification of the causative agent**

PED virus is an enveloped RNA virus that belongs to the Alphacoronavirus genus of the Coronaviridae family. It does not demonstrate cross-immunity with other porcine enteric coronaviruses such as the virus responsible for transmissible gastroenteritis (TGE).

#### **Susceptibility to physical and chemical action**

##### **PED virus is susceptible to**

- Formalin (1%),
- Anhydrous sodium carbonate (4%), lipid solvents, iodophores in phosphoric acid (1%),
- Sodium hydroxide (2%).

##### **Survival:**

- The virus can survive for variable periods outside the host depending on the temperature and relative humidity, for example, it can survive at least 28 days in slurry at 4°C, 7 days in faeces-contaminated dry feed at 25°C, up to 14 days at 25°C in wet feed and at least 28 days in wet feed mixture at 25°C,
- The virus loses infectivity above 60 °C,
- It is stable at pH 6.5-7.5 at 37°C and pH 5-9 at 4°C.

### EPIDEMIOLOGY

#### **Host**

Pigs are the only known host of PED virus. The occurrence of PED in wild pigs is unknown.

PED is not a zoonosis and does not pose a risk to human health or to food safety.

## **Transmission**

Direct transmission occurs through ingestion of virus-contaminated faeces.

Indirect transmission occurs through vehicles which may be contaminated including feed trucks, service vehicles as well as personnel, equipment or other types of faeces-contaminated objects including feed.

Contaminated pig blood products, such as spray-dried plasma, that are incorporated into rations for feeding piglets have been suspected as a possible means to spread the virus. However, multiple experimental studies suggested that spray-dried porcine plasma is not a likely source of infectious virus provided that good manufacturing practices and biosecurity standards are followed.

Contaminated vehicles used for the movement of pigs have been identified as an important risk factor for spreading the disease.

## **Viraemia, incubation and infectious period**

The incubation period is estimated to be between 1 and 4 days. The infectious period can last between 6 and 35 days after the first onset of clinical signs. Viraemia has been detected on multiple days in pigs 2-4 weeks of age experimentally infected with PED virus.

## **Sources of virus**

The main source of this enteric virus is faeces.

## **Pathogenesis**

Oral ingestion results in viral replication in the epithelial cells of the small intestinal and colonic villi resulting in degeneration of enterocytes leading to shortening of the villi. This causes clinical manifestations of the disease including watery diarrhoea.

## **Occurrence and impact**

PED was first reported in the United Kingdom in 1971 and has since then been identified in several European countries, large parts of Asia and the Americas. PED virus has been associated with large-scale outbreaks of diarrhoea with severity depending on pig age. In endemic countries, the impact has been limited to scenarios with occasional clinical outbreaks. However PED can produce important losses in naïve populations. There have been increased reports since 2011 regarding high morbidity and mortality mostly in young pigs. In outbreaks described in 2013 and 2014, mortalities in suckling piglets ranging from 50 to 100% were detected at the farm level.

## **DIAGNOSIS**

### **Clinical diagnosis**

The clinical presentation of PED virus infection in pigs can be variable in its severity and is not distinguishable from other causes of diarrhoea. The clinical signs are dependent on age of the pigs, previous exposure and the immunological status of the pigs, presence of secondary infection, etc.

The following signs could be found in PED virus infection:

- Morbidity: up to 100%,
- Mortality varying according to age:
  - Suckling piglets: up to 100%
  - Piglets older than 10 days: less than 10%
  - Adult and fattening pigs: less than 5%
- Diarrhoea and vomiting
- Dehydration and metabolic acidosis.

## **Lesions**

Post-mortem findings in acutely affected pigs are similar to transmissible gastroenteritis (TGE) and can include:

- Thinning of the intestines, mostly limited to the small intestines,
- Presence of undigested milk in the stomach,
- Watery intestinal contents.

## **Differential diagnosis**

PED is clinically indistinguishable from other pig gastroenteric diseases such as those caused by TGE or rotavirus, by bacteria (*Clostridium spp.*, *E. coli*, *Salmonella spp.*, *Brachyspira spp.*, *Lawsonia intracellularis*, etc.) or by parasites (*Isospora suis*, *Cryptosporidium spp.*, *nematodes*, etc.).

Laboratory confirmatory tests are thus necessary to make a final and definitive diagnosis.

## **Laboratory diagnosis**

### **Samples**

- Fresh faeces,
- Oral fluids,
- Small intestine,
- Serum can be used to determinate the presence of antibodies.

### **Procedures**

#### *Identification of the agent*

- Reverse-transcriptase polymerase chain reaction (RT-PCR),
- Antigen enzyme-linked immunosorbent assays (ELISA),
- Immunohistochemistry (IHC),
- Virus isolation (difficult to isolate the virus).

#### *Serological tests*

- ELISA,
- Immunofluorescence,
- IHC,
- Serum neutralisation.

## **PREVENTION AND CONTROL**

There is no specific treatment other than symptomatic treatment of diarrhoea and control of secondary infections. Most growing pigs recover without treatment within 7-10 days unless secondary infections occur. Reinfection may occur when the immunity wanes.

Maternal antibodies via colostrum from immune sows can protect neonates against infection.

PED vaccines are available and applied in several countries.

Strict biosecurity is the most effective measure to prevent the introduction and spread of the virus, especially, introduction of pigs of known health status, on-farm movement control of pigs, material and people, disinfection of vehicles, equipment and appropriate disposal of dead pigs and slurry. The implementation and maintenance of high biosecurity programmes has been efficient to control PED in endemic countries. “All-in-all-out” practice has been demonstrated to be effective in breaking the transmission cycle within a farm.

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**REPORT OF THE MEETING OF THE OIE AD HOC GROUP TO SET UP A GLOBAL DATABASE  
ON THE USE OF ANTIMICROBIAL AGENTS IN ANIMALS  
Paris, 8 - 9 July 2014**

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**1. Opening**

The OIE *ad hoc* Group to set up a global database on the use of antimicrobial agents in animals met for the second time from 8 to 9 July 2014 at the OIE Headquarters in Paris, France. Dr Elisabeth Erlacher-Vindel, Deputy Head of the Scientific and Technical Department, welcomed the participants on behalf of the Director General of the OIE, Dr Bernard Vallat.

Dr Erlacher-Vindel provided an update of the OIE activities regarding antimicrobial resistance and the use of antimicrobial agents. She mentioned that an updated version of the Chapter 6.10. of the *Terrestrial Animal Health Code (Terrestrial Code)* was adopted at the last General Session (May 2014) by the World Assembly of Delegates. All the chapters of the *Terrestrial Code* related to antimicrobial resistance and the use of antimicrobial agents have been updated. She pointed out that, even if recently adopted, the Member Countries had the possibility to make comments on these updated versions. She informed that some comments have already been received and that they will be addressed by the *ad hoc* Group on Antimicrobial Resistance at their next meeting. Finally she informed the Group that in the framework of the regional seminar for the OIE National Focal Points for Veterinary Products, there will be a session dedicated to the OIE global database on antimicrobial agents used in animals.

Dr Bernard Vallat, Director General of the OIE, addressed the Group on the first day of the meeting regarding antimicrobial resistance and the use of antimicrobial agents. He thanked the Group for all the work done and he confirmed that antimicrobial resistance had become a priority topic for OIE and that there had been an evolution of the perception by politicians, media, and citizens, mainly in developed countries, on the importance of the topic. He mentioned that, with expectations growing to find solutions to this issue, there was a need for investment at both the political and the technical level in human and animal health. He pointed out that antimicrobial resistance was a global issue and should therefore be addressed by all the relevant international organisations and all countries as any measures taken should be implemented globally. He stated that the OIE had a key role to play and would participate in the global action to control antimicrobial resistance and to protect the efficacy of antimicrobial agents that are a global public good in collaboration with the World Health Organisation (WHO) and the Food and Agriculture Organization of the United Nations (FAO). He highlighted that relations with WHO and FAO on this topic were excellent and very efficient. He mentioned that the collection of data on the use of antimicrobial agents in humans and animals was a priority action as for the moment there was a lack of knowledge on this issue. He highlighted therefore the importance of this *ad hoc* Group to help the OIE to develop a database on the use of antimicrobial agents in animals and to harmonise the collection of data. The OIE has already established an on-line tool with all Member Countries via WAHIS that allows collection of different types of data related to animal health. He discussed the importance of being able to link information on production, cross-boundary movements, and national events (sales, use, and statistics on farm). The OIE should use different sources to be efficient and link the sources to produce the final estimation of the use of antimicrobial agents in animals. Finally he mentioned the existence of a global network of OIE National Focal Points for Veterinary Products. He stated that a focus would be made on their training to implement the OIE standards related to antimicrobial resistance and the use of antimicrobial agents and the collection of data on the use of antimicrobial agents in animals.

## **2. Adoption of the Agenda and appointment of chairperson and rapporteur**

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

The meeting was chaired by Dr Herbert Schneider and Dr Carolee Carson acted as rapporteur.

## **3. Presentation and finalisation of the template and instructions developed for the OIE Member Countries to report to the OIE data on the use of antimicrobial agents in animals**

A presentation was given by Dr Carson on the results of the test data from four participating countries. The presentation included an overview of modifications to the template for simplicity, an analysis of the administrative data provided, potential ways of reporting information, and identification of pending questions with the data provided in the template. The questions were discussed as follows:

### **1. Time frame for data collection**

The test data highlighted that there would be a time lag in the data provided, and that not all countries might have data available for the year requested. A lag of up to 3 years may be practically reasonable, though more up to date data are desired. It was discussed that some countries did not collect data every year and this may affect analysis of trends in sales data over time.

The Group decided that the pilot project countries would be requested to fill the template with the most recent data (starting with 2012) and to continue to provide more recent information in the years to come. If a country cannot easily provide data from 2012, yet has more recent data available, then the country could provide the more recent data. Retrospective data would also be welcome.

### **2. Coverage**

The test data highlighted that not all countries can provide 100% coverage of the data. The reasons for the lack of 100% coverage may be varied in nature, such as having information only on large urban areas and not in rural areas, or not having data from small pharmaceutical companies. Coverage may be an issue that can be revisited again in the future. The Group noted that issues might arise regarding extrapolation of data up to the national level.

The Group acknowledged that the data provided to the OIE via the template would have some limitations. The Group decided to maintain a question regarding coverage in the template. If one of the main aims of the database is to encourage countries to improve their data regarding antimicrobial agent usage in animals, then this would provide an indication of improvements over time.

### **3. Species included in food-producing animals**

It was noted that not all countries would have the same species designated as food-producing animals. It would be important that this is clearly identified at the beginning of the template in order to establish the right context for evaluation of the antimicrobial sales data.

### **4. Aggregated data and ionophores (polyether antimicrobial agents)**

Two of the four test countries provided some of their data as 'aggregated data'. In one of the aggregations, arsenicals (which are included in the proposed OIE template) were aggregated with the ionophores (which are not included in the proposed OIE template). There was subsequent discussion as to whether ionophores should be reconsidered to be included in the database. It was particularly relevant for the growth promoters, as the language in the instructions were not clear as to whether ionophores should or should not be included; as a result one country provided data on polyether antimicrobial agents under 'other' growth promoters.

The Group confirmed the decision taken at the last meeting not to include ionophores in the database as they are mostly used as antiparasitics.

## 5. Companion animals

In the test data, one country provided information for all antimicrobial agents and additionally provided specific information for terrestrial food-producing animals. This inherently identified the quantity of antimicrobial agents used for companion animals. In the subsequent revision of the template, this additional information on companion animals might be lost. The Group mentioned that the aim of the template was to collect the data that are available, but the focus of reporting should be on food-producing animals.

## 6. Antimicrobial growth promoters

The Group suggested that the definition of what was an antimicrobial growth promoter would need to be made clearer in the instructions to ensure appropriate and accurate capturing of information in the template.

## 7. Review of the revised template and instructions for completing the template

The Group reviewed changes made to the data collection template and instructions, and critically evaluated language and content.

### Administrative information

- Data provider

It was asked whether the OIE requires information on the data provider or whether just the country needs this. The contact point should be the OIE National Focal Point for Veterinary Products. The OIE would prefer the name of the individual for the data provider. The decision was made to keep this field in case someone other than the OIE National Focal Point for Veterinary Products provides the information.

- Data source

The response options were revised to a list of options for import, sales and purchase data sources and to allow multiple responses.

- Legal basis

The Group concluded that it would be confusing to request information on any legal basis for the collection of data on antimicrobial agent sales and recommended not to ask for such information as part of the pilot project.

- Animal species covered by the data

The Group concluded that the current listing would be useful to provide a quality check for the data reported, in particular the reporting level, and endorsed the current listing.

The Group agreed to add a multiple choice list field where countries would be asked to clarify which species they consider as food-producing species.

### Reporting levels 1 to 3

- Column 'Growth promoters'

The Group discussed whether certain classes could be disabled for data entry. It concluded that at this point in time insufficient information was available to allow such decision.

- Column 'Total amount'

The column would be moved to the beginning of the table and the heading of this column was harmonised for all three sheets to indicate that it would include growth promotion and therapeutic uses.

- Reporting level 3

It was noted that oral administration of antimicrobial agents for aquatic animals was the most significant route of administration and the template was amended for aquatic species to 'oral' and 'other' routes; the instructions will be amended accordingly.

- Antimicrobial production data

The Group considered whether to capture antimicrobial production information from manufacturers in the OIE template, noting the value such information would add. The Group concluded that it presently would be extremely difficult to get this type of data. The Group recommended that this would be addressed in the future and could be a topic of a tripartite meeting, as this not only affects veterinary antimicrobial agents, but also human antimicrobial agents.

The Group agreed that there should be reference to the OIE List of antimicrobial agents of veterinary importance in this document, and simplified the language making reference to growth promoters in the introduction. The explanations of 'Growth Promotion' and 'Therapeutic use, including prevention of clinical signs' were simplified in line with the purpose of this project, as was the explanation for 'list of growth promoters'.

#### Annex to the instructions for completing the OIE template

The Group decided to harmonise language referring to 'long acting salt' to a chemically correct term.

### **8. Next steps**

It was noted that the excel template will be converted into a database, with the user entering the data into a 'form'. This will also address the issue that countries can report qualitative information on antimicrobial agents sold for use in animals when quantitative information is lacking, as OIE data bases would allow for reporting of '...' where use is known to occur but quantification is not possible.

The Group reviewed the template and the instructions and made changes in accordance with the discussions.

The template and instructions as agreed by the Group are presented in Appendix III and IV respectively.

The Group proposed to test the revised template by completing it with the data provided by the different experts of the Group at this meeting to confirm the templates fitness for purpose.

The finalised template and instructions would be sent to all the OIE Member Countries as a pilot project. The Member Countries should be encouraged to provide their data within 6 months of the call for data.

### **4. Discussion and agreement on reporting of data to the OIE on the use of antimicrobial agents in animals including recommendations on a suitable denominator**

Dr Paula Caceres, Head of the OIE Animal Health Department, gave a presentation on the World Animal Health Information System (WAHIS) and Vaccine Production Facilities. The presentation provided information and the types of data already collected by the OIE and potential linkages to similar undertakings in another related fields.

Dr Jordi Torren Edo, Scientific Administrator Animal and Public Health in the European Medicines Agency, presented an analysis of information retrieved from the World Animal Health Information Database (WAHID), the Food and Agriculture Organization Corporate Statistical Database (FAOSTAT), and the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) as potential application as denominators for OIE antimicrobial agent sales reporting.

#### 4.1. Guiding Principles on the reporting of data on the use of antimicrobial agents in animals

After discussion and based on the report of the first meeting, the Group agreed on the following principles to ensure successful reporting of information from the global database:

1. Reports should include data from all animal species and focus on all food producing species including aquatic animals.
2. Data reporting at present is based on sales data, but in the future could expand to antimicrobial use data at the farm level and later if possible at antibiotic production level.
3. Member Countries are encouraged to publish their own national data.
4. The Group decided to not publish country level data in the initial reports, but may ask countries in the future whether data could be reported by the OIE at country-level.
5. Reports are envisioned to be published as part of the Annual World Animal Health Report of OIE Member Countries. Information reported would include quantities of antimicrobial agents sold along with information on the animal population.
6. Member countries submitting their report to the OIE are responsible to ensure the confidentiality of any commercial data.
7. Reports should facilitate the ability to discern trends over time and seek to be comparable year over year.
8. Report formats should be simple, harmonized and closely reflect the submitted data.
9. Reports should preferably use animal numbers reported to the OIE through the Annual World Animal Health Report. Additional refinement of the animal data may be necessary.
10. In order to take into account the difference in animal populations that may account for differences in antibiotic sales, reports should include guidance on a denominator, such as biomass of animals, e.g. "livestock units" (factors given to each food producing species). Agreement on a denominator will be valuable for interpretation of the data.
11. Data for inclusion in a report should meet a quality threshold.
12. Reports should contain links to national/regional reports when available.

#### 4.2. Suitable denominator

The Group identified the need to discuss specifically on the most appropriate denominator in the next months with the aim to agree on one at the next meeting. In order to develop a denominator or normalising factor, the following elements need to be considered: numbers of terrestrial and aquatic live animals; numbers of animals annually produced; age and gender distribution in the national herd; weight of the animals at potential treatment; correction factors between regions.

The Group agreed on the following:

The denominator or normalising factor should be a combination of the 3 items below:

- for terrestrial animals whose lifecycle is under a year (e.g. broilers or fattening pigs), either the tonnage slaughtered or the number of animals produced multiplied by a suitable average weight, which could be the estimated weight when antimicrobial exposure is most likely;

- for terrestrial animals whose lifecycle is over a year (e.g. dairy cows) the number of animals multiplied by a suitable average live weight;
- for farmed aquatic animals, the weight of animals harvested (aquaculture).

Only the weight of animals potentially exposed to treatment should be included. The weight might vary depending on the region.

Additional considerations that require further discussion by the Group include the following:

- future reporting could include channels of distribution
- inclusion/exclusion criteria for data included in reports needs to be developed
- review of the terminology 'denominator' and 'biomass' to more accurately describe the issue under discussion.

#### **4.3. Report formats**

The Group agreed to review a variety of potential report formats at the next meeting. The Group considered the examples provided in the presentation given by Dr Carson as a starting point for the discussion.

#### **4.4. Conclusion**

As a way forward, the Group concluded that for Phase I of piloting the database with Member Countries, denominators are not immediately needed. However, for a Phase II (medium to long term), denominators would be needed.

The Group stressed the importance to encourage OIE Member Countries to participate, even if data at the beginning were of lesser quality, and to encourage the development of systems to collect these data.

### **5. Other matters**

The Group proposed to meet from 10 to 12 December 2014 to address the OIE Member Country comments received on the chapters of the *Terrestrial Code* relative to antimicrobial resistance and the use of antimicrobial agents, the comments received on the OIE List of antimicrobial agents of veterinary importance, and the feedback from the OIE National Focal Points for Veterinary Products on the template and instructions developed for the OIE Member Countries to report to the OIE data on the use of antimicrobial agents in animals. This feedback would be collected at the coming regional training seminars of the OIE National Focal Points for Veterinary Products.

### **6. Adoption of report**

The Group adopted the report.

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.../Appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP TO SET UP A GLOBAL DATABASE  
ON THE USE OF ANTIMICROBIAL AGENTS IN ANIMALS  
Paris, 8 - 9 July 2014**

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**Agenda**

1. Opening
  2. Adoption of agenda and appointment of chairperson and rapporteur
  3. Presentation and finalisation of the template and instructions developed for the OIE Member Countries to report to the OIE data on the use of antimicrobial agents in animals
  4. Discussion and agreement on reporting of data to the OIE on the use of antimicrobial agents in animals including recommendations on a suitable denominator
  5. Other matters
  6. Adoption of report
-

Appendix II

**MEETING OF THE OIE AD HOC GROUP TO SET UP A GLOBAL DATABASE  
ON THE USE OF ANTIMICROBIAL AGENTS IN ANIMALS**

**Paris, 8 - 9 July 2014**

**List of Participants**

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Appendix III

OIE template for reporting quantities of antimicrobial agents sold for use in animals

Sheet 1 – Administrative information

| Microsoft Excel - Template_OIE_BDD for AHG-2014-07-30 (Compatibility Mode)                                  |   |  |  |
|---|---|--|--|
| A   | B   | C  | D  |
| <b>Administrative information</b>   |   | <b>This section of the OIE template should be completed by all OIE Member Countries</b>  |  |
|   |   | Questions/data requests in <i>italics</i> are not mandatory.   |  |
| <b>Contact Point (name and contact details):</b>  |   | Please provide details of the contact point only if different from the OIE Focal Point for Veterinary Products.  |  |
| 3   | Name (order: salutation, first name, surname)   |  |  |
| 4   | Organisation  |  |  |
| 5   | Address   |  |  |
| 6   | Phone number  |  |  |
| 7   | Email address   |  |  |
| <b>Data provider (name and contact details):</b>  |   | The contact person in the organisation providing the reporting OIE contact point with the data. This is important in case there are queries on the data.   |  |
| 9   | Name (order: salutation, first name, surname)   |  |  |
| 10  | Organisation  |  |  |
| 11  | Address   |  |  |
| 12  | Phone number  |  |  |
| 13  | Email address   |  |  |
| <b>Year of data collection</b>  |   | We aim for data from 2012, but will accept more recent data as well as the most recent older data  |  |
| 14  | Country   |  |  |
| <b>Are growth promoters authorised to be used in your country?</b>  |   | <input type="radio"/> Yes<br><input type="radio"/> No  |  |
| 16  | List of growth promoters authorised, if the response to the above question is 'yes'.  | 'Growth promotion' should be interpreted to include uses such as claims to stimulate weight gain and improve feed efficiency under either normal or stress/diseased conditions, for the purpose of the OIE template.   |  |
| <b>Data source</b>  |   | Please select the appropriate data sources of the sales information on antimicrobial agents for use in animals from the list of options. Multiple selections are possible.   |  |
| 18  | <input type="checkbox"/> Sales data - Wholesalers<br><input type="checkbox"/> Sales data - Retailers<br><input type="checkbox"/> Sales data - Marketing Authorisation Holders<br><input type="checkbox"/> Sales data - Registration Authorities<br><input type="checkbox"/> Sales data - Feed mills<br><input type="checkbox"/> Sales data - Pharmacies<br><input type="checkbox"/> Sales data - Farm shops/Agricultural suppliers<br><input type="checkbox"/> Purchase data - Wholesalers<br><input type="checkbox"/> Purchase data - Retailers<br><input type="checkbox"/> Purchase data - Feed mills<br><input type="checkbox"/> Purchase data - Pharmacies<br><input type="checkbox"/> Purchase data - Agricultural Cooperatives<br><input type="checkbox"/> Purchase data - Producer organisations<br><input type="checkbox"/> Import data - Customs declarations<br><input type="checkbox"/> Antimicrobial Prescription or delivery data<br><input type="checkbox"/> Antimicrobial use data - farm records<br><input type="checkbox"/> Other (further specified in 'Data source clarification') |  |  |
| <b>Data source clarification</b>  |   | When for 'Data source' the option 'Other' is selected, please describe here the origin of the data.  |  |
| 19  | Are quantitative data on sales available?   | <input type="radio"/> Yes<br><input type="radio"/> No  |  |
| <b>Estimated coverage (in %)</b>  |   | Please indicate the extent of coverage and describe the data not covered, if less than 100% coverage.  |  |
| 21  | Is the information extrapolated from representative samples?  | <input type="radio"/> Yes<br><input type="radio"/> No  |  |
| <b>Animals covered by the data</b>  |   | Please indicate here to which broad category of animals the data provided apply by selecting the appropriate category or categories from the list. Multiple selections are possible.   |  |
| 23  | <input type="checkbox"/> All animals<br><input type="checkbox"/> All food-producing animals (terrestrial and aquatic)<br><input type="checkbox"/> Terrestrial food-producing animals<br><input type="checkbox"/> Aquatic food-producing animals   |  |  |
| <b>Animals raised in your country and considered 'food producing species'</b><br>Reptiles (e.g. crocodiles) |   | Animal species that are considered as food-producing animals vary between countries. OIE needs to gain an understanding how this difference impacts the reporting of summary data by OIE. Please indicate here which animals are considered as food-producing animals in your country. Multiple selections are possible. |  |
| 24  | <input type="checkbox"/> Cattle<br><input type="checkbox"/> Swine<br><input type="checkbox"/> Sheep<br><input type="checkbox"/> Goats<br><input type="checkbox"/> Sheep and goats (mixed flocks)<br><input type="checkbox"/> Poultry<br><input type="checkbox"/> Buffaloes (not Syncerus caffer)<br><input type="checkbox"/> Cervidae<br><input type="checkbox"/> Camelidae<br><input type="checkbox"/> Equidae<br><input type="checkbox"/> Rabbits/Hares<br><input type="checkbox"/> Bees<br><input type="checkbox"/> Fish - fish farmed in salt and brackish water<br><input type="checkbox"/> Fish - fish farmed in fresh water<br><input type="checkbox"/> Molluscs<br><input type="checkbox"/> Crustaceans<br><input type="checkbox"/> Amphibians<br><input type="checkbox"/> All  |  |  |
| <b>National report available on the web?</b>  |   | Please insert the link to the site where the report is available.  |  |
| 25  | If 'Aggregated class data' are reported on the forms for Reporting level 1, Reporting level 2 or Reporting level 3, please list here the classes combined   | Please use the terminology of the OIE list of antimicrobial agents of veterinary importance; alternatively you may use the terms used for  |  |
| <b>Choosing your reporting level</b>  |   |  |  |
|   |   | Please choose your reporting level in accordance with the table and complete the corresponding form.   |  |
| 29  | National sales data available   | Information available for food producing terrestrial or aquatic animals or both  | Data available per route of administration |
| 30  |   |  |  |
| 31  | Reporting Level 1   | Y  | N  |
| 32  | Reporting Level 2   | Y  | N  |
| 33  | Reporting Level 3   | Y  | Y or N                                     |

## Sheet 2 – Reporting level 1

| Microsoft Excel - Template_OIE_BDD for AHG-2014-07-30 [Compatibility Mode]               |   |  |   |
|--|---|--|---|
| A  | B   | C  | D   |
| <b>OIE template for the collection of data on antimicrobial sales for use in animals</b> |   |  |   |
| <b>Reporting level 1 - All animal species without further differentiation</b>            |   |  |   |
| 1  | Does the 'Total amount' include growth promotion use? | <input type="radio"/> Yes<br><input type="radio"/> No              |   |
| 2  |   |  |   |
| 3  |   |  |   |
| 4  |   | <b>Total amount (Growth promotion and Therapeutic indications)</b> | <b>Therapeutic indications (including prevention of clinical signs)</b> |
| 5  | <b>Antimicrobial class</b>                            | <b>All animal species<br/>Total sales (kg)</b>                     | <b>All animal species<br/>Sales (kg)</b>                                |
| 6  | Aminoglycosides                                       |  |   |
| 7  | Arsenicals  |  |   |
| 8  | Cephalosporins ( all generations)                     |  |   |
| 9  | 1-2 gen. cephalosporins                               |  |   |
| 10   | 3-4 gen cephalosporins                                |  |   |
| 11   | Fluoroquinolones                                      |  |   |
| 12   | Glycopeptides   |  |   |
| 13   | Glycophospholipids                                    |  |   |
| 14   | Lincosamides  |  |   |
| 15   | Macrolides  |  |   |
| 16   | Nitrofurans   |  |   |
| 17   | Orthosomycins   |  |   |
| 18   | Other quinolones                                      |  |   |
| 19   | Penicillins   |  |   |
| 20   | Phenicols   |  |   |
| 21   | Pleuromutilins  |  |   |
| 22   | Polypeptides  |  |   |
| 23   | Quinoxalines  |  |   |
| 24   | Streptogramins  |  |   |
| 25   | Sulfonamides (including trimethoprim)                 |  |   |
| 26   | Tetracyclines   |  |   |
| 27   | Others  |  |   |
| 28   | <b>Aggregated class data</b>                          |  |   |
| 29   | <b>Total kg</b>                                       |  |   |

Sheet 3 – Reporting level 2

| OIE template for the collection of data on antimicrobial sales for use in animals                                     |   |   |  |   |   |
|---|---|---|--|---|---|
| Reporting level 2 - All animal species with differentiation by food-production and terrestrial versus aquatic animals |   |   |  |   |   |
| 1   | Does the 'Total amount' include growth promotion use? | <input type="radio"/> Yes<br><input type="radio"/> No       |  |   |   |
| 2   |   |   |  |   |   |
| 3   |   |   |  |   |   |
| 4   |   | Total amount (Growth promotion and Therapeutic indications) | Therapeutic indications (including prevention of clinical signs) |   |   |
| 5   | Antimicrobial class                                   | All species Sales (kg)                                      | All animal species Sales (kg)                                    | All food producing animals (terrestrial and aquatic) Sales (kg) | Terrestrial food producing animals Sales (kg) |
| 6   | Aminoglycosides                                       |   |  |   |   |
| 7   | Arsenicals  |   |  |   |   |
| 8   | Cephalosporins ( all generations)                     |   |  |   |   |
| 9   | 1-2 gen. cephalosporins                               |   |  |   |   |
| 10  | 3-4 gen cephalosporins                                |   |  |   |   |
| 11  | Fluoroquinolones                                      |   |  |   |   |
| 12  | Glycopeptides   |   |  |   |   |
| 13  | Glycophospholipids                                    |   |  |   |   |
| 14  | Lincosamides  |   |  |   |   |
| 15  | Macrolides  |   |  |   |   |
| 16  | Nitrofurans   |   |  |   |   |
| 17  | Orthosomycins   |   |  |   |   |
| 18  | Other quinolones                                      |   |  |   |   |
| 19  | Penicillins   |   |  |   |   |
| 20  | Phenicols   |   |  |   |   |
| 21  | Pleuromutilins  |   |  |   |   |
| 22  | Polypeptides  |   |  |   |   |
| 23  | Quinoxalines  |   |  |   |   |
| 24  | Streptogramins  |   |  |   |   |
| 25  | Sulfonamides (including trimethoprim)                 |   |  |   |   |
| 26  | Tetracyclines   |   |  |   |   |
| 27  | Others  |   |  |   |   |
| 28  | Aggregated class data                                 |   |  |   |   |
| 29  | Total kg  |   |  |   |   |

| OIE template for the collection of data on antimicrobial sales for use in animals |   |   |   |
|---|---|---|---|
| 1   | Does the 'Total amount' include growth promotion use? |   |   |
| 2   |   |   |   |
| 3   |   |   |   |
| 4   |   | Growth promotion                          |   |
| 5   | Antimicrobial class                                   | Aquatic food producing animals Sales (kg) | All food producing animals (terrestrial and aquatic) Sales (kg) |
| 6   | Aminoglycosides                                       |   |   |
| 7   | Arsenicals  |   |   |
| 8   | Cephalosporins ( all generations)                     |   |   |
| 9   | 1-2 gen. cephalosporins                               |   |   |
| 10  | 3-4 gen cephalosporins                                |   |   |
| 11  | Fluoroquinolones                                      |   |   |
| 12  | Glycopeptides   |   |   |
| 13  | Glycophospholipids                                    |   |   |
| 14  | Lincosamides  |   |   |
| 15  | Macrolides  |   |   |
| 16  | Nitrofurans   |   |   |
| 17  | Orthosomycins   |   |   |
| 18  | Other quinolones                                      |   |   |
| 19  | Penicillins   |   |   |
| 20  | Phenicols   |   |   |
| 21  | Pleuromutilins  |   |   |
| 22  | Polypeptides  |   |   |
| 23  | Quinoxalines  |   |   |
| 24  | Streptogramins  |   |   |
| 25  | Sulfonamides (including trimethoprim)                 |   |   |
| 26  | Tetracyclines   |   |   |
| 27  | Others  |   |   |
| 28  | Aggregated class data                                 |   |   |
| 29  | Total kg  |   |   |



Sheet 4 – Reporting level 3 (contd)

| Microsoft Excel - Template_OIE_BDD for AHG-2014-07-30 [Compatibility Mode] |                                       |                                   |                                |   |
|--|---------------------------------------|-----------------------------------|--------------------------------|---|
|  | L                                     | M                                 | N                              | O   |
| 1  |                                       |                                   |                                |   |
| 2  |                                       |                                   |                                |   |
| 3  |                                       |                                   |                                |   |
| 4  |                                       |                                   |                                | <b>Growth promotion</b>                                     |
| 5  | <b>Aquatic food-producing animals</b> |                                   |                                | <b>All food-producing animals (terrestrial and aquatic)</b> |
| 6  | <b>Oral route Sales (kg)</b>          | <b>Injection route Sales (kg)</b> | <b>Other routes Sales (kg)</b> | <b>Sales (kg)</b>   |
| 7  |                                       |                                   |                                |   |
| 8  |                                       |                                   |                                |   |
| 9  |                                       |                                   |                                |   |
| 10   |                                       |                                   |                                |   |
| 11   |                                       |                                   |                                |   |
| 12   |                                       |                                   |                                |   |
| 13   |                                       |                                   |                                |   |
| 14   |                                       |                                   |                                |   |
| 15   |                                       |                                   |                                |   |
| 16   |                                       |                                   |                                |   |
| 17   |                                       |                                   |                                |   |
| 18   |                                       |                                   |                                |   |
| 19   |                                       |                                   |                                |   |
| 20   |                                       |                                   |                                |   |
| 21   |                                       |                                   |                                |   |
| 22   |                                       |                                   |                                |   |
| 23   |                                       |                                   |                                |   |
| 24   |                                       |                                   |                                |   |
| 25   |                                       |                                   |                                |   |
| 26   |                                       |                                   |                                |   |
| 27   |                                       |                                   |                                |   |
| 28   |                                       |                                   |                                |   |
| 29   |                                       |                                   |                                |   |
| 30   |                                       |                                   |                                |   |

Appendix IV**DRAFT****World Organisation for Animal Health 2014****Guidance for the Completion of the OIE template for the collection of data on Antimicrobial Use in Animals****Introduction**

The OIE proposes to collect data on antimicrobial use in animals from OIE Member Countries implementing Chapters 6.7 of the OIE *Terrestrial Animal Health Code* and 6.4 of the OIE *Aquatic Animal Health Code*, and to contribute to the global effort against antimicrobial resistance development.

Member Countries differ in the degree to which they collect, collate and publish data on antimicrobial sales or use in animals and also in the degree to which they can separate the quantities of antimicrobial agents sold for or used in different species.

Through this initiative, the OIE seeks to collect data on antimicrobial use in animals from all OIE Member Countries in a harmonised way by means of a specific template for data collection developed by the OIE (OIE template). This will occur in a phased approach where initially the OIE will focus on **sales** of antimicrobial agents destined for use in animals as an indicator of actual use. All antimicrobial agents destined for use in animals and listed in the OIE List of antimicrobial agents of veterinary importance<sup>1</sup> plus certain antibiotics only used for growth promotion should be reported in this survey, whether they are categorised as veterinary medicines, feed additives, growth promoting agents, stock remedies or any other classification, with the exception of ionophors which are mostly used for parasite control. The OIE places highest priority on food-producing animals, however data on all animals may be reported. Reporting will occur at class and, on one occasion, at sub-class level.

For the purpose of reporting data on antimicrobial quantities, animals are grouped into all animal species, all food-producing animals, terrestrial food-producing animals, and aquatic food-producing animals.

Further refinement of the OIE approach for the collection of data on antimicrobial sales or use in animals is anticipated in the light of the experience gained with the utilisation of the OIE template and additional changes will be necessary as Member Countries capabilities of reporting differentiated data develop.

For questions on the OIE template please contact Barbara Freischem at [b.freischem@oie.int](mailto:b.freischem@oie.int), copy to Francois Diaz at [f.diaz@oie.int](mailto:f.diaz@oie.int).

**The individual sheets of the OIE data collection template**

There are four worksheets in the OIE template (four tabs in the Microsoft excel file) labelled 'Administrative Information', 'Reporting level 1', 'Reporting level 2', and 'Reporting level 3'.

**All OIE Member Countries** should complete the sheet **Administrative Information**. In addition, according to the level of detail available in the reporting country, either the sheet labelled **Reporting level 1** or **Reporting level 2** or **Reporting level 3** should subsequently be completed.

**Sheet 1 – Administrative information**

This sheet collects administrative information relevant to the data collected with this template. It should be completed by **all OIE Member Countries**.

At the bottom of this sheet a matrix is provided to help OIE Member Countries decide which Reporting level form to complete next. Ideally, for the completion of one of the following sheets quantitative national surveys on sales of antimicrobial agents for use in animals should be in place in the reporting country. However, **Reporting level 1** may also be used to report qualitative information on the classes of antibiotics used in the reporting country (more details below). Only if you do not know which substances or classes of substances are used in animals in your country is the completion of the OIE template terminated after filling in **Sheet 1 – Administrative information**.

<sup>1</sup> [http://www.oie.int/fileadmin/Home/eng/Our\\_scientific\\_expertise/docs/pdf/OIE\\_list\\_antimicrobials.pdf](http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/OIE_list_antimicrobials.pdf)

**Sheet 2 – Reporting level 1** (amount of antimicrobials sold for use in animals without differentiation).

The form **Reporting level 1** is designed for the reporting of data for use in all animals and accommodates reporting without much differentiation. Data may be reported overall for all animal species; but it allows for differentiation by antimicrobial class, therapeutic use, including prevention of clinical signs, or growth promotion use (see definitions below). If you know which classes of antimicrobials agents are sold for use in animals in your country, but not how much is sold, you can still use this sheet. Instead of a number, please enter three dots, <...>, in the table.

**Sheet 3 – Reporting level 2** (amount of antimicrobials sold for use in animals with differentiation between all animals and food-producing animals).

If data can be differentiated by use in all animals, in all food-producing animals, and / or by use in terrestrial and aquatic food-producing animals, **Reporting level 2** is the appropriate form. Differentiation by antimicrobial class, therapeutic use, including prevention of clinical signs, or growth promotion use is also possible.

**Sheet 4 – Reporting level 3** (amounts of antimicrobials sold for use in all animals with differentiation by route of administration).

If the data can be differentiated by route of administration, **Reporting level 3** is the appropriate form; this form additionally allows for differentiation by antimicrobial class, use in food-producing species and, where possible, by use in terrestrial and aquatic food-producing species as well as therapeutic use, including prevention of clinical signs, or growth promotion use.

### Guidance notes on the data to be provided in the OIE template

A number of terms require definition in the context of the OIE template, in order to ensure a harmonised approach to data collection.

**Antimicrobial classes for use in animals:** Any agent listed on the OIE List of antimicrobial agents of veterinary importance and sold for use in animals, without ionophors since these are mostly used for parasite control, but including specific antimicrobials used exclusively for growth promotion. All uses of these substances should be reported, whether the antimicrobials are categorised as veterinary medicines or not. Examples for possible alternative categories include classification such as growth promoter, feed additive, or stock remedy.

**Growth promotion:** For the purpose of data collection through the OIE template 'Growth promotion' should be interpreted to include uses such as growth promotion, but also claims to stimulate weight gain and improve feed efficiency or similar under either normal or stress/diseased conditions.

**Therapeutic use, including prevention of clinical signs:** For the purpose of data collection through the OIE template all uses not falling under the above explanation for 'Growth promotion' should be reported as 'Therapeutic use including prevention of clinical signs'.

The following text sets out the fields on the individual sheets of the OIE template and explains what information should be provided. Some fields may be filled by choosing one or several options from the lists provided; others are free text or number fields. Fields formatted in *Italics* are not mandatory, but you are encouraged to provide data to the greatest extent possible.

### Administrative information

| Field name                                      | Information to be provided  |
|---|---|
| <b>Year of data collection</b>                  | Calendar year for which you have collected the data. The aim of the pilot is to collect data from 2012. However, if you have data for other years, please provide those data and indicate the year for which data have been provided. For each year a separate form needs to be filled in. If possible, please submit your data within 6 months of the call for data.   |
| <b>Contact point (name and contact details)</b> | Normally, the contact point for OIE would be the OIE Focal Point for Veterinary Products. If this is the case for your country, please write 'OIE Focal Point for Veterinary Products' in the 'name' field. If someone else is responsible, please complete the fields as follows:<br><b>Name:</b> Salutation (e.g. Dr, Ms, Mr), first or given name, surname or family name<br><b>Organisation:</b> Name of the organisation you work for, administrative subunit – if necessary, and position – if necessary<br><b>Address:</b> Full mailing address of your organisation<br><b>Phone number:</b> Please provide your full telephone number including the international dialling code.<br><b>Email address:</b> Please provide the email address where you can best be reached. |

| Field name  | Information to be provided   |
|---|--|
| <b>Data provider (name and contact details)</b>                     | Please provide the contact details of the contact person in the organisation responsible for providing you with the reported data, in case there are queries on the data. Please complete the fields as follows:<br><b>Name:</b> Salutation (e.g. Dr, Ms, Mr), first or given name, surname or family name<br><b>Organisation:</b> Name of the organisation the data provider works for, administrative subunit – if necessary, and position – if necessary<br><b>Address:</b> Full mailing address of the data provider's organisation<br><b>Phone number:</b> Enter the data provider's telephone number including the international dialling code.<br><b>Email address:</b> The email address where the data provider can best be reached.  |
| <b>Country</b>  | Please enter your country's name in full text in English.  |
| <b>Are growth pro-moters authorised to be used in your country?</b> | Please respond by ticking either 'Yes' or 'No'. Choose 'Yes' if your country's legislation / regulations has no provisions for growth promotion, but use of growth promoters is known to occur. Please consider 'growth promoter' in the light of the definition provided above.<br>Related information is collected for <b>Reporting level 1, 2 and 3</b> , where you will be asked to indicate whether the data reported actually include data on growth promoters or not.   |
| <b>List of growth promoters authorised</b>                          | If growth promoters are used (that is the response to the question above is 'Yes'), please list the substances used for growth promotion. Please report using either the simplified terminology of the tables on <b>Reporting levels 1, 2 or 3</b> , or by using the terminology of the OIE List of antimicrobials of veterinary importance.   |
| <b>Data source</b>  | Please describe the origin of the data on antimicrobial sales for use in animals. To facilitate the data collection and identify the best providers of information you are encouraged to map out how antimicrobials for use in animals are distributed in your country to identify best providers of information and to enable elimination of duplicate reporting of quantities sold. Experience has shown that whenever possible sales data at the package level should be collected.<br>The following options can be selected from a multiple choice list:<br>Sales data - Wholesalers<br>Sales data - Retailers<br>Sales data - Marketing Authorisation Holders<br>Sales data - Registration Authorities<br>Sales data - Feed mills<br>Sales data - Pharmacies<br>Sales data - Farm shops/Agricultural suppliers<br>Purchase data - Wholesalers<br>Purchase data - Retailers<br>Purchase data - Feed mills<br>Purchase data - Pharmacies<br>Purchase data - Agricultural Cooperatives<br>Purchase data - Producer organisations<br>Import data - Customs declarations<br>Antimicrobial Prescription or delivery data<br>Antimicrobial use data - farm records<br>Other (further specified in 'Data source clarification')<br>Please choose all data sources that apply. |
| <b>Data source clarification</b>                                    | If under <b>Data source</b> the option 'Other (further specified in 'Data source clarification')' is selected, please specify here which source of information was used.   |
| <b>Are quantitative data on sales available?</b>                    | Please indicate whether quantitative data on the sales of antimicrobial agents for use in animals are available, by choosing 'Yes' or 'No' from the drop-down list.<br>If quantitative data is available for part of your country, choose 'Yes' and indicate the extent of the coverage in per cent (in relation to the overall use) when responding to the question 'Estimated coverage (in %, please also provide a description of the information not covered, if there is less than 100% coverage)'<br>If the data available in your country is qualitative (e.g. types of antimicrobials used in animals), choose 'No'. If you know which substances or classes of antimicrobials are used in your country you may report this in the form for <b>Reporting level 1</b> by entering three dots, '...', in the table cells that would normally hold the numbers for quantities sold.<br>If you do not know which substances or classes of substances are used in animals in your country, the completion of the OIE template terminated after completing the <b>Administrative information</b> form.   |

| Field name   | Information to be provided   |
|--|--|
| <i>Estimated coverage</i>  | Please provide an estimate of the extent to which the quantitative data you report is representative of the overall antimicrobial sales for use in animals in per cent of the total sales in your country. If less than 100% are reported, please describe the data not covered. Examples include but are not limited to situations that use may be well known for urban but not rural environments; or, that there may be legally allowed importation for limited uses that cannot be quantified.   |
| <i>Is the information extrapolated from representative samples?</i>  | Please indicate here, whether the data provided in your report have been extrapolated from representative samples or less than 100% coverage.  |
| <i>Animals covered by the data</i>   | Please indicate here to which broad category of animals the data provided apply by selecting the appropriate category or categories from the list. The choices are: 'All animal species', 'All food-producing species (terrestrial and aquatic) only', 'Terrestrial food-producing species only', 'Aquatic food-producing species only'. Multiple selections are possible.   |
| <i>Animals raised in your country and considered 'food producing species'</i>  | Animal species that are considered as food-producing animals vary between countries. The OIE needs to gain an understanding how this difference impacts the reporting of summary data by the OIE. Please indicate here which animals are considered as food-producing animals in your country. Multiple selections are possible.   |
| <b>National report available on the web?</b>   | If a national report on antimicrobial sales and/or use in animals is available in your country please insert the link to the site where the report is available on the internet.   |
| <b>If 'Aggregated class data' are reported on the forms for Reporting level 1, Reporting level 2 or Reporting level 3, please list here the classes combined</b> | To protect confidential (proprietary) information and/or as required by legislation it may not be possible to individually report sales of certain classes of antimicrobial agents for animal use. In such cases, please report the sum of the amounts sold for those classes that cannot be individually reported in the row <b>Aggregated class data</b> of the table on the forms for <b>Reporting level 1, Reporting level 2 or Reporting level 3</b> . At the same time please enter three dots, <...> in the table for those substances for which sales quantities have been aggregated. Specify in this field on the <b>Administrative data</b> sheet all additional classes of antimicrobials for which data have been aggregated that are not captured in the table (for example: ionophors). Please use the terminology from the tables for the three reporting levels, or of the OIE List of antimicrobial agents of veterinary importance, <a href="http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/OIE_list_anti_microbials.pdf">http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/OIE_list_anti_microbials.pdf</a> . |

### Classes of Antimicrobials

All antimicrobial classes intended for use in animals (for therapeutic purposes including prevention of onset of clinical signs as well as growth promotion and irrespective of whether they are classified as veterinary medicines or not) should be included in the table by the reporting OIE Member Country. Dermatological, eye, and ear preparations may be excluded as experience in countries with regular surveys has shown that the sales of these products are typically very low and do not contribute significantly to overall sales quantities.

| Antimicrobial class       | Guidance   |
|---------------------------|--|
| <b>Aminoglycosides</b>    | Includes aminocyclitols (e.g. streptomycin, dihydrostreptomycin and spectinomycin) and all other aminoglycosides (e.g. gentamicin, kanamycin, neomycin, apramycin).  |
| <b>Arsenicals</b>         | Includes nitarsons, roxarsone and others.  |
| <b>Cephalosporins</b>     | May be reported combined as <b>Cephalosporins (all generations)</b> or in relevant category groupings ( <b>1-2 generation cephalosporins</b> as one category and <b>3-4 generation cephalosporins</b> as a second category). |
| <b>Fluoroquinolones</b>   | Includes danofloxacin, difloxacin, enrofloxacin, marbofloxacin and other fluoroquinolones, but not other quinolones (flumequine, oxolinic acid, nalidixic acid) that are reported separately.                                |
| <b>Glycopeptides</b>      | Includes avoparcin and others.   |
| <b>Glycophospholipids</b> | Includes bambarmycin (synonym flavomycin).   |
| <b>Lincosamides</b>       | Includes lincomycin, pirlimycin and others.  |
| <b>Macrolides</b>         | Includes substances with all macrolide structures, such as erythromycin, spiramycin, tylosin, tylvalosin, gamithromycin, tildipirosin, tulathromycin and others.   |
| <b>Nitrofurans</b>        | Includes furazolidone, nitrofurantoin, nitrofurazone and others.   |
| <b>Orthosomycins</b>      | Includes avilamycin and others.  |
| <b>Other quinolones</b>   | Includes flumequine, nalidixic acid, oxolinic acid and others.   |
| <b>Penicillins</b>        | Includes all penicillins (e.g. natural penicillins, aminopenicillins and others), but excludes other beta lactam antibiotics like cephalosporins.  |
| <b>Phenicol</b>           | Includes florfenicol and others.   |
| <b>Pleuromutilins</b>     | Includes tiamulin, valnemulin and others.  |
| <b>Polypeptides</b>       | Includes bacitracin, colistin, polymyxin B and others.   |

| Antimicrobial class                          | Guidance   |
|--|--|
| <b>Quinoxalines</b>                          | Includes carbadox, olaquinox and others.   |
| <b>Streptogramins</b>                        | Includes virginiamycin, pristinamycin, and others.   |
| <b>Sulfonamides (including trimethoprim)</b> | Includes all sulfonamides, as well as trimethoprim and similar compounds.  |
| <b>Tetracyclines</b>                         | Includes for example chlortetracycline, doxycycline, tetracycline, and oxytetracycline.  |
| <b>Others</b>                                | All others not covered, including for example coumarin antibiotics like novobiocin, fusidic acid, kirromycins, phosphonic acids like fosfo- or tobramycin, rifamycins, thiostrepton.   |
| <b>Aggregated class data</b>                 | Report the cumulative amount sold for classes of antimicrobial agents that cannot be reported independently by the country for confidentiality/proprietary reasons. If more than one data aggregation is reported in your country, please sum them up for the OIE template. Also refer to the guidance for the form <b>Administrative information</b> , field 'If 'Aggregated class data' are reported on the forms for Reporting level 1, Reporting level 2 or Reporting level 3, please list here the classes combined'. |

### Reporting levels 1, 2 and 3 – reporting quantities

The amount of the antimicrobial agent sold for use in animals in kilograms (kg) should be reported. In certain cases, when the antimicrobial agent is a pro-drug, long-acting compound or stated in international units or % weight per volume (% w/v) some mathematical conversion will be necessary, which is explained in the annex. In cases where the amount sold for the listed class is part of a data aggregation reported under **Aggregated class data**, please enter three dots <...> in the table for all classes, for which quantities sold have been summarised.

Ideally, the OIE is interested in the amount of active moiety (for example: benzylpenicillin), not the total weight of the chemical form (salt, ester or other; for example: sodium or potassium benzylpenicillin). However, reporting on active moieties only requires significant mathematical conversion which is not justified by the gain in precision, as experience has shown in countries with existing monitoring systems. Therefore, the OIE template will focus on the amount of the complete chemical form with the exception of the cases listed in the annex.

Data sourced from customs, import or other bulk trading, information will likely come as tons of chemical substance. Please convert into kg for reporting in the OIE template; the annex provides conversion factors to kg from different weight units. Also check the annex whether any specific conversions are necessary, for example in case of a pro-drug.

For ready-to-use veterinary products the content of the antimicrobial active agent(s) may be stated in one of several ways, including (i) strength in milligram (mg) or gram (g) of the active ingredient per volume or weight or other unit, for example millilitre (ml), or kilogram (kg) or tablet, (ii) strength in mg or g of a long-acting salt or pro-drug of the active ingredient per volume or weight or other unit, (iii) strength in International Units (IU) per weight, volume or other unit, or (iv) strength in per cent (%) weight per weight (w/w) or weight per volume (w/v). In some cases the active substance is a pro-drug or long-acting compound. The annex provides details on the necessary conversions.

For veterinary products containing more than one active ingredient, the amounts of each active ingredient should be added to the respective class columns.

If there are no quantities to report for a class or route of administration, please enter a zero, 0, in the corresponding field of the table.

### Reporting level 1, 2 and 3: Differentiation by use purpose

At the top of the form for each Reporting level, please indicate whether **Data on growth promoters are not available separately and are included in the column 'Total amount'** or whether **Data on growth promoters are not available and not reported, only data for therapeutic use including prevention is reported**. Please tick either 'Yes' or 'No'. If sales for use in animals can be differentiated into sales for therapeutic purposes and growth promotion purposes, please report the data separately.

For **Reporting level 1**, complete the columns **Therapeutic indications (including prevention of clinical signs)**, and **Growth promotion**. The sum of sales for **Therapeutic indications** and **Growth promotion** should equal **Total sales** for each class.

For **Reporting level 2 and 3**, **Growth promotion** can be reported jointly for terrestrial and aquatic food-producing animals.

### Reporting level 2 and/or 3: Differentiation by animal species category

If sales for use in animals can be differentiated into sales for therapeutic purposes and growth promotion purposes and in addition by animal species category, please complete under the heading **Therapeutic indications (including prevention of clinical signs)** the columns for **All animal species**, **All food-producing animals (terrestrial and aquatic)**, **Terrestrial food-producing animals**, **Aquatic food-producing animals**. These animal categories include all age groups and life stages of the relevant species. The last column on both sheets allows reporting of the total amount for all use and animal categories per antimicrobial class.

### Reporting level 3: Differentiation by Routes of administration

In the category of **Therapeutic indications (including prevention of clinical signs)**, the OIE is interested in the proportions of sales for routes of administration that are suitable for mass treatment (e.g. oral route) versus those more suited for treatment of individual animals (injection route, other routes). If sales for therapeutic indications can be sub-divided by route of administration, please report the quantities sold for the listed route of administration categories for the different animal categories.

| Column label           | Guidance   |
|------------------------|--|
| <b>Oral route</b>      | Includes all orally administered pharmaceutical forms, including “in water” or “in feed” administration, but also oral bolus administration.   |
| <b>Injection route</b> | Includes all forms of parenteral administration that readily lead to elevated blood levels of the active ingredient, such as subcutaneous, intramuscular, intravenous, including intravenous infusion (intravenous drips).         |
| <b>Other routes</b>    | Summarises all other routes of administration, including intramammary preparations, and, mostly for aquatic animals, the bath route where an animal or a group of animals immersed in a solution containing the active ingredient. |

## Annex to the Instructions for completing the OIE template for the collection of data on antimicrobial use in animals:

### Considerations on converting content of antimicrobial active ingredients in veterinary medicines into kilograms

#### Calculating the quantities to report in kilogram (kg)

Sales data on antimicrobial agents sold for use in animal comes in various forms. The OIE template for the collection of data on Antimicrobial Use in Animals (OIE template) currently collects data on the amounts of antimicrobial agents for use in animals in reference to the active ingredients as they are stated on ready-made pharmaceutical products, whereas the sales information may come as anything from bulk quantities to numbers of pack of a ready-made veterinary medicine sold, with the content of antimicrobial agents stated in a number of possible ways. In most cases it will be necessary to calculate the data collected through the OIE template. The following text explains the necessary calculations.

The following abbreviations and symbols will be used:

| Symbol/abbreviation | Explanation   |
|---------------------|---|
| Strength            | amount of antimicrobial agent per unit of ready-made veterinary product |
| % w/v               | per cent weight per volume  |
| mg                  | milligram   |
| g                   | gram  |
| kg                  | kilogram  |
| t                   | ton (metric)  |
| ml                  | millilitre  |
| l                   | litre   |

#### For data on bulk quantities

Such information is usually sourced from customs, import or other bulk trading. It will likely come as a weight in a number of possible units (e.g. metric tons) of substance and needs to be converted to kg.

**Step 1:** Multiply the amount of antimicrobial agent with the appropriate conversion factor from the table 2 below.

$$\text{Antimicrobial agent (kg)} = \text{antimicrobial agent (unit Z)} \times \text{conversion factor}$$

Table 1: Converting weight units into kg

| Unit reported (unit Z) | Conversion factor to kg |
|------------------------|-------------------------|
| Metric ton             | 1000                    |
| Imperial ton (long)    | 1016                    |
| Imperial ton (short)   | 907.18                  |
| Stone (Imperial)       | 6.35                    |
| Imperial Pound         | 0.4536                  |
| Ounce                  | 0.0283                  |

**Step 2:** If the antimicrobial agent is a long-acting compound or prodrug listed in table 2 below, additionally multiply with the corresponding conversion factor.

$$\text{Antimicrobial agent (kg)} = \text{Step 1 antimicrobial agent (prodrug)kg} \times \text{prodrug conversion factor}$$

#### For data on ready-to-use veterinary products

For ready-to-use veterinary products data on quantities sold is likely to be available as numbers of packages of product sold, with each package containing a specified quantity of product with a specified amount of antimicrobial agent. In such cases first the amount of antimicrobial active ingredient per package needs to be calculated and subsequently the result needs to be multiplied with the number of packages of the presentation sold to obtain the overall amount of antimicrobial active ingredient, which should be reported in kg.

The most common ways to indicate the content of the antimicrobial active agent(s) of a ready-to-use veterinary product are:

- (i) Strength in mg or g of the active ingredient per volume or weight or other unit, (for example: ml, l, kg, tablet),
- (ii) Strength in mg or g of a long-acting compound or pro-drug of the active ingredient per volume or weight or other unit,

- (iii) Strength in International Units (IU) per weight, volume or other unit,  
 (iv) Strength in per cent (%) weight per weight (w/w) or weight per volume (w/v).

Each situation requires a different kind of mathematical conversion.

*Re (i) – content of antimicrobial active ingredient (antimicrobial agent) stated in milligram per volume or weight or other unit (for example millilitre, litre, kilogram, tablet) of content*

Step 1: Calculation of the content of active ingredient (antimicrobial agent) per package

Multiply the amount of antimicrobial agent per unit of content with the total number of units contained in the package

$$\begin{aligned} \text{Content of antimicrobial agent per package} \\ = \text{Strength (amount antimicrobial agent per unit)} \times \text{number of units per package} \end{aligned}$$

*Example A:*

Tiamulin 100 g/kg premix for medicated feeding stuff; package sizes: (a) 1 kg, (b) 5 kg and (c) 20 kg

Calculation of content of antimicrobial agent, tiamulin, per package:

$$(a) \text{ Pack content} = 100 \text{ g/kg} \times 1 \text{ kg} = 100 \text{ g}$$

$$(b) \text{ Pack content} = 100 \text{ g/kg} \times 5 \text{ kg} = 500 \text{ g}$$

$$(c) \text{ Pack content} = 100 \text{ g/kg} \times 20 \text{ kg} = 2000 \text{ g}$$

*Example B:*

Tetracycline intrauterine tablet containing 2000 mg tetracycline hydrochloride per tablet; package sizes: (a) carton with 1 blister of 5 intrauterine tablets, (b) carton with 4 blisters of 5 intrauterine tablets each (20 tablets), (c) carton with 20 blisters of 5 intrauterine tablets each (100 tablets).

Calculation of content of antimicrobial agent, tetracycline, per package:

$$(a) \text{ Pack content} = 2000 \text{ mg} \quad \times \quad 5 \quad = 2 \text{ g} \times 5 = 10 \text{ g}$$

$$(b) \text{ Pack content} = 2000 \text{ mg} \quad \times \quad 20 \quad = 2 \text{ g} \times 20 = 40 \text{ g}$$

$$(c) \text{ Pack content} = 2000 \text{ mg} \quad \times \quad 100 \quad = 2 \text{ g} \times 100 = 200 \text{ g}$$

*Example C:*

Tilmicosin 300 mg/ml solution for injection for cattle; package sizes: containers of 100 ml and 250 ml; packs of (a) 6, (b) 10 and (c) 12 units of 100 ml and 250 ml.

Calculation of content of antimicrobial agent, tilmicosin, per package:

$$(a) \text{ Container content} = 300 \text{ mg/ml} \quad \times \quad 100 \text{ ml} = 30000 \text{ mg} = 30 \text{ g}$$

$$\text{Pack content: } (a) \quad 6 \times 30 \text{ g} = 180 \text{ g}$$

$$(b) \quad 10 \times 30 \text{ g} = 300 \text{ g}$$

$$(c) \quad 12 \times 30 \text{ g} = 360 \text{ g}$$

$$(b) \text{ Container content} = 300 \text{ mg/ml} \quad \times \quad 250 \text{ ml} = 75000 \text{ mg} = 75 \text{ g}$$

$$\text{Pack content: } (a) \quad 6 \times 75 \text{ g} = 450 \text{ g}$$

$$(b) \quad 10 \times 75 \text{ g} = 750 \text{ g}$$

$$(c) \quad 12 \times 75 \text{ g} = 900 \text{ g}$$

Step 2: Sum up the antimicrobial agent contained in all presentations and packages sold

Convert all contents of antimicrobial agent calculated under step 1 to the same weight unit and add up the total

Step 3: If necessary: convert the total sum of antimicrobial agent contained in all packages of all presentations sold to kg

Multiply the result from step 2 with an appropriate conversion factor to achieve the result in kg

*Re (ii) – content of antimicrobial agent stated in mg or g of a long-acting compound or pro-drug of the active ingredient per volume or weight or other unit of content*

Where the antimicrobial agent contained in the veterinary product is a long-acting compound (mostly a salt or ester, potentially also another chemical form; example: benzathine or procaine salt) or a pro-drug (example: penethamate hydroiodide) and the content is stated in weight in reference to the specific chemical form (example: product x contains 500 mg/ml benzylpenicillin benzathine), an additional conversion step is needed to calculate the amount of antimicrobial active ingredient relevant for the OIE data collection. However, if the active ingredient is described in reference to the antimicrobially active ingredient (example: product y contains cloxacillin benzathine equivalent to 500 mg cloxacillin activity) no additional conversion step is necessary.

Relevant conversion factors are listed in Table 2; the amount of the specific chemical form (example: benzylpenicillin benzathine) needs to be multiplied with the conversion factor to obtain the corresponding amount of the antimicrobial active ingredient (example: benzylpenicillin).

Table 2: Conversion of mg, g or kg of long-acting chemical forms and prodrugs into corresponding mg, g or kg antimicrobial active ingredient

| Substance                          | Antimicrobial active ingredient | Conversion factor |
|------------------------------------|---------------------------------|-------------------|
| Benethamine benzylpenicillin       | Benzylpenicillin (as Na salt)   | 0.65              |
| Benzathine benzylpenicillin        | Benzylpenicillin (as Na salt)   | 0.39              |
| Benzathine phenoxymethylpenicillin | Phenoxymethylpenicillin         | 0.37              |
| Penethamate hydroiodide            | Benzylpenicillin (as Na salt)   | 0.63              |
| Procaine benzylpenicillin          | Benzylpenicillin (as Na salt)   | 0.61              |

Reference for all values: Martindale: The Complete Drug Reference © 2014 The Pharmaceutical Press  
Calculation of the Conversion factors: Molecular weight (MW) Antimicrobial active ingredient / MW Substance = Conversion factor

Step 1–3: As described for (i)

Step 4: Multiply the final result in kg obtained by following steps 1 to 3 with the appropriate conversion factor listed in table 2

$$\begin{aligned} \text{Content of antimicrobially active moiety (kg)} \\ = \text{Content of antimicrobial agent (kg)} \times \text{table 2 conversion factor} \end{aligned}$$

*Re (iii) – content of antimicrobial active ingredient (antimicrobial agent) in International Units (IU) per weight, volume or other unit (for example millilitre, litre, kilogram, tablet) of content*

Where the strength of the antimicrobial agent in the veterinary product is stated International Units (IU) per unit of finished product, an additional conversion step is necessary to obtain results in mg, g, or kg. Table 3 is used to convert content of specific antimicrobial agents into mg: either divide the total number of IUs of an antimicrobial agent by the value in the column 'International Units (IU) per mg' for this agent in table 3, or, if multiplication is preferred, multiply the total number of IUs with the conversion factor listed for the agent. To convert mg values into kg, please multiply the result of the conversion with  $1 \times 10^{-6}$  equalling 0.000001.

Step 1: Calculating the content of antimicrobial agent per package in IU

Multiply the amount of IU antimicrobial agent per unit of content with the total number of units contained in the package

$$\begin{aligned} \text{Content of antimicrobial agent per package in IU} \\ = \text{Strength (amount IU antimicrobial agent per unit)} \times \text{number of units per package} \end{aligned}$$

Step 2: Converting the content of antimicrobial agent per package in IU into mg

$$\text{Content of antimicrobial agent per package in mg} = \text{Content of antimicrobial agent in IU} \times \text{conversion factor}$$

Steps 3-4: Follow steps 2-3 described for (i)

Please note that the IU content or the strength stated on a veterinary product may refer to the antimicrobial active moiety to be reported rather than to the salt or chemical form actually included; for example: a product may contain penethamate hydroiodide, or procaine benzylpenicillin, but the strength in IU may be stated in reference to benzylpenicillin (product X containing penethamate hydroiodide, xx IU in reference to benzylpenicillin, or, product Y containing procaine benzylpenicillin, equivalent to yy IU benzylpenicillin). In such cases please use the conversion factor for the relevant antimicrobial active ingredient (in the examples used: benzylpenicillin (penicillin G) (potassium or sodium salt)).

Table 3: Conversion of International Units (IUs) of certain antimicrobial agents into mg and relevant antimicrobial active moieties

| Antimicrobial agent in the veterinary product   | Antimicrobial active moiety for reporting to OIE | International Units per mg | Conversion factor to mg for multiplication |
|---|--|----------------------------|--|
| Bacitracin <sup>2</sup>   | Bacitracin                                       | 74                         | 0.013514                                   |
| Bacitracin zinc <sup>2</sup>  | Bacitracin                                       | 62.9                       | 0.015898                                   |
| Benethamine benzylpenicillin <sup>2</sup>   | Benzylpenicillin                                 | 1053                       | 0.000949                                   |
| Benzylpenicillin (penicillin G)(potassium or sodium salt) <sup>2</sup>  | Benzylpenicillin                                 | 1666.67                    | 0.000599                                   |
| Benzathine benzylpenicillin <sup>2</sup>  | Benzylpenicillin                                 | 1333.34                    | 0.000749                                   |
| Procaine benzylpenicillin <sup>2</sup>  | Benzylpenicillin                                 | 1000                       | 0.001000                                   |
| Phenoxymethylpenicillin (penicillin V) (potassium salt) <sup>2</sup>  | Benzylpenicillin                                 | 1600                       | 0.000625                                   |
| Chlortetracycline <sup>2</sup>  | Chlortetracycline                                | 900                        | 0.001111                                   |
| Colistin methane sulfonate sodium (colistimethate sodium INN) <sup>2</sup>  | Colistin   | 12700                      | 0.000079                                   |
| Colistin (as the sulfate) <sup>2</sup>  | Colistin   | 20500                      | 0.000049                                   |
| Dihydrostreptomycin (as the sulfate) <sup>2</sup>   | Dihydrostreptomycin                              | 777                        | 0.001287                                   |
| Erythromycin <sup>2</sup>   | Erythromycin                                     | 920                        | 0.001087                                   |
| Gentamicin (as the sulfate) <sup>2</sup>  | Gentamicin                                       | 620                        | 0.001613                                   |
| Kanamycin (as the sulfate) <sup>2</sup>   | Kanamycin  | 796                        | 0.001256                                   |
| Neomycin (as the sulfate) <sup>2</sup>  | Neomycin   | 762                        | 0.001312                                   |
| Neomycin B (Framycetin) (as the sulfate) <sup>2</sup>   | Neomycin B (Framycetin)                          | 706                        | 0.001416                                   |
| Oxytetracycline (as the dihydrate) <sup>2</sup>   | Oxytetracycline                                  | 920                        | 0.001087                                   |
| Oxytetracycline (as the hydrochloride) <sup>2</sup>   | Oxytetracycline                                  | 870                        | 0.001149                                   |
| Paromomycin (as the sulfate) <sup>2</sup>   | Paromomycin                                      | 675                        | 0.001481                                   |
| Penethamate hydroiodide (when strength is stated as IU of benzylpenicillin; to be reported under benzylpenicillin) <sup>2</sup> | Benzylpenicillin                                 | 1058                       | 0.000945                                   |
| Polymyxin B (as the sulfate) <sup>2</sup>   | Polymyxin B                                      | 8403                       | 0.000119                                   |
| Procaine (benzyl)penicillin <sup>2</sup>  | Benzylpenicillin                                 | 1667                       | 0.000600                                   |
| Rifamycin (as the sodium salt) <sup>2</sup>   | Rifamycin  | 887                        | 0.001127                                   |
| Spiramycin <sup>2</sup>   | Spiramycin                                       | 3200                       | 0.000313                                   |
| Streptomycin (as the sulfate) <sup>2</sup>  | Streptomycin                                     | 785                        | 0.001274                                   |
| Tobramycin <sup>2</sup>   | Tobramycin                                       | 875                        | 0.001143                                   |
| Tylosin <sup>2</sup>  | Tylosin  | 1000                       | 0.001000                                   |

*Re (iv) – content of antimicrobial active ingredient (antimicrobial agent) in per cent (%) weight per weight (w/w) or weight per volume (w/v) of content*

The amount of antimicrobial agent contained in a veterinary product concerned may be stated in per cent weight per weight (% w/w) (example 1: product X contains tylosin 100% w/w or, example 2, product Y contains amoxicillin 22.2 % w/w) or in per cent weight per volume (% w/v) (example: product Z contains procaine benzylpenicillin 30% w/v). Such figures first need to be converted into mg/g, g/g, or mg/ml, followed by the calculations described under (i).

**Converting % w/w:** Conversion calculations are performed by relating the content of antimicrobial agent to 1 g of the finished product. Divide the percentage value by 100 to obtain the amount of antimicrobial agent in g per g finished product.

$$\text{value antimicrobial agent in g per gram finished product} = \frac{\text{value (\%)}}{100} \times g$$

$$= \frac{\text{value (\%)}}{100} \times g \text{ (finished product)}$$

Example 1: Product X containing 100% w/w tylosin will contain 100/100 x g = 1g tylosin per g finished product.

Example 2: Product Y containing 22.2% w/w amoxicillin will contain 22.2/100 = 0.222 g amoxicillin per g finished product.

<sup>2</sup> WHO International Standards for Antibiotics, held at the European Directorate for the Quality of Medicines (EDQM), (<http://crs.pheur.org/db/4DCGI/search?vSelectName=4&vContains=1&vtUserName=ISA&OK=Search>), accessed on 18 March 2014

<sup>3</sup> European Pharmacopoeia Standard (based on the WHO standard) (<http://www.edqm.eu/en/eur-ph-reference-standards-products-649.html>), accessed on 19 March 2014

<sup>4</sup> Martindale: The Complete Drug Reference © 2014 The Pharmaceutical Press

<sup>5</sup> WHO, The International Pharmacopoeia, (<http://apps.who.int/phint/en/p/doc/>); accessed on 18 March 2014

<sup>6</sup> Information retrieved from the veterinary chemical, pharmacological and clinical databases of the Institute for Pharmacology and Toxicology of the University of Zurich (<http://vptserver1.uzh.ch/indexcpt.htm>), accessed on 18 March 2014

Continue with Steps 1-3 of (i)

Converting % w/v: Conversion is based on the assumption that 1 ml of the products weighs 1000 mg. Multiply the percentage value with 10 to obtain the content in mg/ml.

$$\text{value antimicrobial agent in g per ml finished product} = \frac{\text{value (\%)} \times 10 \times \text{mg}}{1 \text{ ml (finished product)}}$$

Example: Product Z containing 30% w/v benzylpenicillin will contain (30 x 10 x mg)/1ml, equal to 300 mg/ml benzylpenicillin.

Continue with Steps 1-3 of (i)

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## OIE AD HOC GROUP ON MERS-CoV INFECTION IN ANIMALS

Paris, 15-17 July 2014

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A meeting of the OIE *ad hoc* Group on MERS-CoV Infection in Animals (hereinafter the Group) was held at the OIE Headquarters, Paris, from 15 to 17 July 2014.

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

Dr Bernard Vallat, Director General of the OIE welcomed the Group. He reminded the Group of their Terms of Reference and highlighted that MERS-CoV was an important topic owing to its public health impact. Dr Vallat highlighted that OIE was in permanent consultation with the WHO on MERS-CoV and that it was important to develop an expert opinion on certain aspects relating to MERS-CoV infections in animals.

Dr Vallat explained that the Group had been convened following recommendations made during the reports of the Biological Standards Commission and the Scientific Commission for Animal Diseases, at the 82<sup>nd</sup> OIE General Session in May 2014.

Dr Vallat introduced Dr Gideon Brückner, President of the OIE Scientific Commission for Animal Diseases, to chair the Group and Dr Alex Thiermann, President of the OIE Terrestrial Animal Health Standards Commission (Code Commission). Dr Vincenzo Caporale, President of the OIE Biological Standards Commission, sent his apologies for not being able to attend. In place of Dr Caporale the Biological Standards Commission was represented by the Chairman of the OIE *ad hoc* Group on camelid diseases, Dr Mehdi Elharrak.

The Group endorsed the proposed agenda.

The Terms of Reference and Agenda, and list of participants are presented as Appendix I and II, respectively.

Unless otherwise specified, in this report 'camel(s)' refers to 'dromedary camel(s)'.

### 2. Current state of knowledge about MERS-CoV in humans and animals

The experts from the World Health Organization (WHO), University of Hong Kong, and Erasmus Medical Centre, the Netherlands, presented the latest information on the disease situation in humans, findings from epidemiological studies in camels, scientific data on the performance of diagnostic tests, and outputs from research studies done in collaboration with Member Countries. Representatives from the Kingdom of Saudi Arabia presented plans for epidemiological studies in animals.

The Group noted that data from serological studies indicated that MERS-CoV infection of camels had been widespread across North Africa; that camels with high titres of antibodies to MERS-CoV had been reported to shed virus; that virus had been detected in nasal and oral secretions, in faeces, and in milk of camels (and that for milk samples testing positive, the possibility of cross contamination could not be ruled out). It was also noted that accurate serology and PCR tests were available for MERS-CoV and that several MERS-CoV lineages existed.

### 3. Review of current public health guidance

The WHO representative presented the current General Recommendations on MERS-CoV transmission from animals to humans and interim recommendations for at risk groups ([Annex III](#)), explaining that in the absence of having a full understanding on the exact route of transmission from camels to humans the recommendations were based on basic hygiene principles; where possible, available evidence from ongoing studies had been considered in developing this guidance.

The Group were supportive of the recommendations and agreed that they should be regularly reviewed to account for new evidence. The Group also suggested that the recommendations specific to MERS-CoV should apply to countries where there was a risk of transmission of MERS-CoV from camels to humans.

### 4. Guidance on:

#### a) A case definition for MERS-CoV infection in animals

In accordance with Article 1.1.3.e) of the *Terrestrial Code (Version 2013)*, Member Countries are obliged to notify the occurrence of any emerging disease with significant morbidity, mortality, or zoonotic potential in their territories even though the pathogen is not included in the OIE List of Diseases. Detections of MERS-CoV in animals were considered to be reportable to the OIE owing to their zoonotic potential, even though there had been no evidence of any significant disease in animals.

The Group agreed that serological positive results from animals indicated previous infection with MERS-CoV and that positive serology findings should be further investigated with virological sampling. Virological positive results (by PCR or virus identification) in samples taken from camels or other animals should be reported to the OIE as an emerging disease with zoonotic potential.

#### b) Surveillance for MERS-CoV in camels

The Group agreed that for the topic under discussion, the term 'epidemiologic studies' may be more appropriate than 'surveillance', because there was not a defined systematic approach to sampling neither were there any animal health control measures to be implemented on positive findings.

The Group agreed that the epidemiologic studies should take into account the principles for Animal Health Surveillance described in Chapter 1.4 of the OIE *Terrestrial Code*.

The objectives of MERS-CoV epidemiologic studies in camels were driven by concern over the public health implications and should focus on:

- determining whether MERS-CoV infections were present in camels in a country, holding, or camel population;
- assessing the risk profile of a country;
- assessing public health risk and management measures;
- monitoring strains and lineages of MERS-CoV circulating in camel populations.

The Group recommended that there was benefit in sampling camels from different industry sectors within a country e.g. racing, dairy, meat, show camels. Sampling could also be targeted to account for age groups and points of camel gathering (races, markets, slaughterhouses). Evidence suggested that serological surveillance should focus on older camels (older than two years) and virological studies should focus on younger camels (less than two years old). Epidemiological studies should also aim to gather and generate data on basic epidemiologic characteristics (incubation period, shedding period etc.) and risk factors for infection.

The Group also highlighted the critical importance of investigating significant morbidity and mortality events in camels (and other species of animals) where the cause was unknown.

The Group strongly endorsed the recommendation of the OIE *ad hoc* Group on camelid diseases ‘to include veterinary counterparts in the investigation of human and animal MERS cases in the field’.

**c) Surveillance for MERS-CoV in other animal species if relevant**

The Group suggested that in countries where MERS-CoV is present in camels, studies to assess the presence of MERS-CoV in wild and other domestic species can be conducted to detect possible infection in other hosts and to contribute to understanding the origins of the virus.

**d) Appropriate guidance on action, if any, to be taken on positive surveillance findings in animals**

The Group recommended that the general public health recommendations ([Annex III](#)) of the World Health Organisation (WHO) should be implemented when animals were confirmed as being virological positive for MERS-CoV.

**e) Appropriate science-based animal health management measures to limit potential for further human infections**

The Group highlighted that there was currently not enough evidence to make specific recommendations about possible animal health management measures. However in the future when more evidence became available it may be possible to propose disease management procedures and interventions to reduce transmission within the camel population and to propose science-based recommendations to mitigate the risk at the human-animal interface.

**f) Communications strategy including updating of Questions and Answers (Q and A) on the OIE website and fact sheet for multiple audiences**

The Group reviewed and amended the current OIE Q and A on MERS-CoV reflecting the latest scientific knowledge. It was also recommended that the Scientific Commission for Animal Diseases, with the help of the OIE Scientific and Technical Department, compose an OIE Fact Sheet on MERS similar to other fact sheets currently on the OIE Website. An updated version of the Q and A can be found in [Appendix IV](#).

**5. Recommendations on further research studies in animals**

The Group discussed the importance of conducting further epidemiologic and research studies aimed at better understanding the behaviour of MERS-CoV infections in animals, and identifying measures to reduce risks to public and animal health. The Group endorsed the previous recommendations of the OIE *ad hoc* Group on camelid diseases relating to research activities and identified an updated list of research priorities as follows:

- To further develop and validate user-friendly diagnostic tests for MERS-CoV as fit for purpose for surveillance of infections in animal populations (live animals and at slaughter).
- Comparative epidemiological studies, in all countries with significant camel populations, to determine the prevalence, distribution, and demographics of MERS-CoV infections in camels in different settings
- Studies to characterise the clinical and pathological effects, kinetics of virus shedding, and immune response to MERS-CoV in experimentally and naturally infected camels
- Studies to assess risk factors and potential exposure sources for camel infection and the relationship between camel infections and human cases of MERS

- Studies to investigate and assess the potential effectiveness of intervention measures aimed at reducing public health risk
- Conduct genetic analyses of both MERS-CoV and infected hosts from different geographical areas to gain a better understanding of the properties of MERS-CoV and to monitor evolution of the virus
- Presence, viability and survival of MERS-CoV in different animal products and the environment
- Research on immunology and vaccine development
- Identification and evaluation of socioeconomic factors that are associated with risk of MERS-CoV infection in camel populations
- Assess potential socioeconomic impact of the MERS-CoV infections, and interventions and control strategies in camels, including on trade
- Studies to obtain an insight into culturally acceptable risk reduction measures
- Studies to determine the original animal source of the virus, including wildlife

## 6. Recommendations concerning solicitation of interest for possible establishment of an OIE Reference Centre

The Group was informed that the OIE had already received requests from OIE Member Countries to establish an OIE Reference Centre of expertise for MERS-CoV. The Group noted the mandate of OIE Reference Laboratories and OIE Collaborating Centres and agreed that the establishment of an OIE Reference Centre with expertise in MERS-CoV would be helpful in supporting further disease surveillance and research, as well as providing technical advice to the OIE Member Countries. Experts from institutes, including WHO Reference Centres, recognised to have relevant expertise were encouraged to apply for OIE Reference Centre status.

It was noted that whilst current available diagnostic tests were accurate and fit for purpose for animal surveillance they had not yet been validated according to OIE Standards for validation of diagnostic assays for infectious diseases. The Group agreed that an OIE Reference Centre could also undertake such validation work, in close collaboration with the OIE *ad hoc* Group on camelid diseases and the Biological Standards Commission.

## 7. Evaluation on whether MERS-CoV infection in camels should be an OIE listed disease

The President of the OIE Terrestrial Animal Health Standards Commission explained the criteria for inclusion of diseases, infections and infestations on the OIE list and the rationale for doing so. The Group reviewed each criterion (described in Chapter 1.2 of the *Terrestrial Code*) against current data on MERS-CoV.

### 1) *International spread of the agent (via live animals or their products, vectors or fomites) has been proven*

The Group decided that although it was plausible that camels may have spread MERS-CoV infections internationally (and there was some genetic and field evidence to suggest that international spread had occurred), it had not yet been sufficiently proven that MERS-CoV had been spread internationally by camels or their products. Potential routes of spread other than camels could not be ruled out.

AND

### 2) *At least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the animal health surveillance provisions of the Terrestrial Code, in particular those contained in Chapter 1.4*

The Group agreed that no country had yet carried out systematic surveillance in accordance with the requirements of Chapter 1.4 of the *Terrestrial Code* to demonstrate freedom of MERS-CoV from animal populations. However it was recognised that some countries, with small camel populations, may be able to demonstrate freedom from their camel populations relatively easily if they implement the prescribed surveillance guidelines to do so.

AND

- 3a) *Natural transmission to human has been proven, and human infection is associated with severe consequences*

The Group agreed that evidence from epidemiologic studies (including case control studies) and outbreak investigations suggested that natural transmission of MERS-CoV from camels to humans had occurred, and that MERS-CoV had been demonstrated to cause severe disease in humans.

- 3b) *The disease has been shown to cause significant morbidity or mortality in domestic animals at the level of a country or zone*

The Group agreed that significant morbidity or mortality in domestic animals had not been attributed to MERS-CoV infection. However the Group recommended that further studies were needed to assess the pathogenicity and prevalence of MERS-CoV infections in camels.

- 3c) *The disease has been shown to, or scientific evidence indicates that it would, cause significant morbidity or mortality in wild animal populations*

The Group agreed that significant morbidity and mortality in wild animals had not been attributed to MERS-CoV infection.

- 4) *A reliable means of detection and diagnosis exists and a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections and infestations*

The Group agreed that although there is no clear clinical syndrome in camels, accurate molecular and serological diagnostic techniques were available to detect past and current infections of MERS-CoV in camels.

In conclusion, the Group decided that based on available scientific evidence, infections with MERS-CoV in camels did not meet the criteria for an OIE listed disease. However, the Group emphasised that MERS-CoV was a serious public health problem with zoonotic potential and that infection in animals should remain reportable to OIE as an emerging disease. The Group also recommended that the status of MERS-CoV should be kept under review. More data should be collected by Member Countries, and generated by research, to provide evidence for science based recommendations, particularly in relation to whether MERS-CoV should be listed. These data should include data from Member Countries on baseline surveillance in camel populations and the geographic distribution of MERS-CoV infections.

## **8. Any other business**

The Group were thanked for their efforts and their contribution to the meeting.

## **9. Finalisation and adoption of the report**

The report was finalised and adopted by the Group.

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.../Appendices

Appendix I

**OIE AD HOC GROUP ON MERS-COV INFECTION IN ANIMALS**  
**Paris, 15-17 July 2014**

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**Terms of Reference**

1. To summarise the latest scientific evidence relating to the potential role of animals in the epidemiology of MERS, and available diagnostic methods
  2. To review current public health guidance on:
    - a. Surveillance in humans with a high degree of contact with camels
    - b. Personal protection and hygiene practices for those handling potentially infected camels
    - c. Consumption of camel products (raw milk, raw meat, urine) from potentially infected animals
  3. To develop guidance on
    - a. A case definition for MERS-CoV infection in animals
    - b. Surveillance for MERS-CoV in camels (location and sampling strategy)
    - c. Surveillance for MERS-CoV in other animal species if relevant (target species, sampling strategy)
    - d. Appropriate guidance on action, if any, to be taken on positive surveillance findings in animals
    - e. Appropriate science-based animal health management measures to limit potential for further human infections
    - f. Communications strategy including updating of Q's and A's on website and fact sheet for multiple audiences
  4. To provide recommendations on further research studies in animals
  5. To provide recommendations concerning solicitation of interest for possible establishment of an OIE Reference Laboratory
  6. To provide an opinion on whether MERS-CoV infection in camels should be an OIE Listed Disease
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**OIE AD HOC GROUP ON MERS-COV INFECTION IN ANIMALS**  
**Paris, 15-17 July 2014**

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**Agenda**

1. Welcome and introductions
  2. Current state of knowledge about MERS-CoV in humans and animals
    - a. Update from WHO
    - b. Country updates (Qatar, Kingdom of Saudi Arabia)
    - c. Updates from researchers
  3. Review of current public health guidance on:
    - a. Surveillance in humans with a high degree of contact with camels
    - b. Personal protection and hygiene practices for those handling potentially infected camels
    - c. Consumption of camel products (raw milk, raw meat, urine) from potentially infected camels
  4. Guidance on
    - a. A case definition for MERS-CoV infection in animals
    - b. Surveillance for MERS-CoV in camels (location and sampling strategy)
    - c. Surveillance for MERS-CoV in other animal species if relevant (target species, sampling strategy)
    - d. Appropriate guidance on action, if any, to be taken on positive surveillance findings in animals
    - e. Appropriate science-based animal health management measures to limit potential for further human infections
    - f. Communications strategy including updating of Q's and A's on website and fact sheet for multiple audiences
  5. Recommendations on further research studies in animals
  6. Recommendations concerning solicitation of interest for possible establishment of an OIE Reference Centre
  7. Opinion on whether MERS-CoV infection in camels should be considered as an OIE Listed Disease
  8. Any other business
-

Appendix II

**OIE AD HOC GROUP ON MERS-COV INFECTION IN ANIMALS**  
**Paris, 15-17 July 2014**

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Appendix III**Middle East respiratory syndrome coronavirus (MERS-CoV)  
13 June 2014****Update on MERS-CoV transmission from animals to humans, and interim recommendations for at-risk groups**

Over the past year, several investigations into the animal source of MERS-CoV have been conducted. MERS-CoV genetic sequences from humans and camels in Egypt, Oman, Qatar and Saudi Arabia demonstrate a close link between the virus found in camels and that found in people in the same geographic area. These and other studies have found MERS-CoV antibodies in camels in Africa and the Middle East.

Preliminary results from an ongoing investigation in Qatar show that people working closely with camels (e.g. farm workers, slaughterhouse workers and veterinarians) may be at higher risk of MERS-CoV infection than people who do not have regular close contacts with camels. In Qatar and several other countries, animals, including goats, cows, sheep, water buffalo, swine and wild birds, have been tested for antibodies to MERS-CoV, with no positive results. The absence of antibodies in these animals indicates that the likelihood of other animals having a substantial role in transmission of MERS-CoV is very low. These studies provide evidence that camels are a likely primary source of the MERS-CoV that is infecting humans.

The current pattern of disease appears to be the result of repeated introductions of the virus from camels to people, resulting in limited human-to-human transmission, but not in sustained transmission. Therefore, discovery of the routes of transmission, whether direct or indirect, between camels and people, is critical to stopping transmission of the virus.

WHO is working with partner agencies with expertise in animal health and food safety, including FAO, OIE and national authorities, to facilitate ongoing investigations.

Investigation protocols and guidelines for dealing with new cases are available on the WHO website ([http://www.who.int/csr/disease/coronavirus\\_infections/en/](http://www.who.int/csr/disease/coronavirus_infections/en/)).

**General recommendations**

As a general precaution, anyone visiting farms, markets, barns or other places where camels are present should practice general hygiene measures, including regular hand washing after touching animals, avoiding touching eyes, nose or mouth with hands, and avoiding contact with sick animals. People may also consider wearing protective gowns and gloves while handling animals.

The consumption of raw or undercooked animal products, including milk and meat, carries a high risk of infection from a variety of organisms that might cause disease in humans. Animal products processed appropriately through proper cooking or pasteurization are safe for consumption but should also be handled with care, to avoid cross-contamination with uncooked foods. Recent studies in Qatar show that MERS-CoV can be detected in raw milk from infected camels. Whether camels excrete MERS-CoV in milk or the virus gets into the milk through cross-contamination during milking is unclear. However, if MERS-CoV is present, it will be destroyed by pasteurization or cooking. Camel meat and camel milk are nutritious products that can continue to be consumed after cooking, pasteurization, or other heat treatments. Safe alternatives should be developed to the tradition of sales of raw camel milk for direct consumption, along roadsides and farm gates.

### **Recommendations for at-risk groups**

Until more is understood about MERS, people with diabetes, renal failure, chronic lung disease, and immunocompromised persons are considered at high risk of severe disease from MERS-CoV infection. Therefore, these people should avoid contact with camels, should not drink raw camel milk or camel urine, and should not eat meat that has not been properly cooked. Such recommendations should also be disseminated to travellers, tourists and pilgrims with above mentioned underlying conditions coming to the region from around the world.

Preliminary results from recent studies in Qatar indicate that people handling or working with camels are at increased risk of infection with MERS-CoV compared with people who do not have contact with camels. Until more evidence is gathered, it is prudent for camel farm workers, slaughterhouse workers, market workers, veterinarians and those handling camels at racing facilities to practice good personal hygiene, including frequent hand washing after touching animals. They should wear facial protection where feasible and protective clothing, which should be removed after work and washed daily.

Workers should also avoid exposing family members to soiled work clothing, shoes, or other items that may have come into contact with camel excretions. It is therefore recommended that these clothes and items remain at the workplace for daily washing and that workers have access to and use shower facilities at their workplaces before leaving the premises.

Camels infected with MERS-CoV may not show any signs of infection. It is therefore not possible to know whether an animal in a farm, market, race track or slaughterhouse is excreting MERS-CoV that can potentially infect humans. However, infected animals may shed MERS-CoV through nasal and eye discharge, faeces, and potentially in their milk and urine. The virus may also be found in the organs and meat of an infected animal. Therefore, until more is known about infection in animals, the best protection is to practice good hygiene and avoid direct contact with all of these. Obviously sick animals should never be slaughtered for consumption; dead animals should be safely buried or destroyed.

People who are not wearing protective gear should avoid contact with any animal that has been confirmed positive for MERS-CoV until subsequent tests have confirmed that the animal is free of the virus.

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Appendix IV**Update August 2014 – OIE Questions & Answers on Middle East Respiratory Syndrome Coronavirus (MERS-CoV)****What is MERS-CoV?**

MERS-CoV is a coronavirus (CoV) which causes Middle East Respiratory Syndrome (MERS), a severe respiratory disease, in humans. It was identified in humans in April 2012.

Sporadic human cases of MERS have occurred and continue to occur over a wide geographical distribution with the majority of cases reported from the Arabian Peninsula. Infections in dromedary camels also have been detected in a wide geographic distribution and appear to be widespread in some countries. Some human MERS cases are thought to be related to zoonotic transmission (transmission from animals to humans). In other cases human infections are either linked to health care settings or are unexplained. There is no evidence of sustained human to human transmission in the community but the clusters that have occurred in health care settings and households demonstrate that human to human transmission is possible.

So far, three patterns of infection have been reported by the World Health Organization (WHO):

1. community acquired cases (the exposure sources remain unknown and are believed to include direct or indirect contact with animals, especially camels, or environmental source)
2. hospital acquired infections
3. infections acquired through close human to human contact (household).

MERS-CoV and antibodies to MERS-CoV have been detected in samples taken from camels. To date, MERS-CoV has only been isolated from dromedary camels<sup>1</sup> and humans, but the exact relationship between MERS-CoV infections in humans and animals remains unclear.

**What are coronaviruses?**

Coronaviruses are a family of RNA (ribonucleic acid) viruses. They are called coronaviruses because under an electron microscope the virus particle exhibits a characteristic '*corona*' (crown) of spike proteins around its lipid envelope. Coronavirus infections are common in animals and humans, and there is a history of coronaviruses crossing species and adapting to new hosts. There are many species and strains of coronavirus which have different characteristics, causing a range of clinical signs– from mild to severe disease – in humans and in different animal species.

MERS-CoV is genetically and biologically distinct from other known coronaviruses, e.g. the coronavirus causing Severe Acute Respiratory Syndrome (SARS) in humans.

**Why the concern?**

MERS-CoV is considered by the WHO to be a serious public health threat to humans, because:

1. the infection can cause severe disease in humans
2. infection appears to be widespread in dromedary camels
3. coronaviruses may adapt to new hosts, and then become more easily transmittable between humans

For these reasons, it is important to prevent introduction of these viruses into the human population.

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<sup>1</sup> In this text 'camel(s)' refers to 'dromedary camel(s)'.

### **What is the source of MERS-CoV?**

MERS-CoV is thought to have an origin in animals. Evidence suggests that MERS-CoV has adapted to camels and that camels are a host for the virus. However, not all community acquired cases of MERS-CoV had reported prior animal contact and it is unclear how these persons were infected. Therefore, investigations of human cases of MERS-CoV infection should continue to include gathering of information about potential sources of exposure, including other humans, camels (including certain raw products, such as raw milk and meat and secretions/excretions), other domestic and wild animals, as well as the environment, food and water.

The OIE together with its partner organisations, the WHO, the Food and Agriculture Organization of the United Nations (FAO) and national animal health authorities of affected countries is closely following investigations which aim to better understand the epidemiological aspects of the disease, including its transmission and the potential relationship between human and animal infections with MERS-CoV.

### **Are animals responsible for MERS-CoV infections in people?**

MERS-CoV has been isolated from humans and camels and recent studies suggest that camels are a source of human infections. Nevertheless, the exact relationship between MERS-CoV infections in camels and humans remains unclear. Joint human health and animal health investigations are needed to establish the source for human infections with MERS-CoV when not acquired from another human.

There remains the possibility that other animal species may be involved in the maintenance and transmission of MERS-CoV.

### **What is known about MERS-CoV in camels?**

Between November 2013 and July 2014, Qatar, Oman and Kuwait have met their obligations to OIE by reporting that MERS-CoV has been identified in camels.

Other published studies have indicated that MERS-CoV and genetic material from MERS-CoV have been identified in camels in countries in the Middle East and North Africa; antibodies to MERS-CoV or a very similar virus have been identified in samples taken from camels in the Middle East and Africa. Similar strains of MERS-CoV have been identified in samples taken from camels and humans in the same locality and in some cases there has been an association between infections in humans and camels.

Serological studies suggest that antibodies to MERS-CoV have been detected with a prevalence range of 0-100% (varying within countries and between countries) in populations of camels in Middle East and African countries. This range of prevalence indicates the need to assess risk factors for infection between and within herds.

Infections with MERS-CoV have sometimes been associated with mild respiratory signs in camels, but this needs further investigation. Significant morbidity or mortality of unknown aetiology should be investigated.

Evidence from MERS-CoV infections in camels suggests that infection has resulted in virus shedding for a limited period. The possibility for reinfection of camels cannot at this stage be excluded since immunity to infection is poorly understood. MERS-CoV has been identified in camels which have antibodies against the virus. The implications of these findings for management and control recommendations need further investigation. .

To develop a more complete understanding of the potential role of camels (and other animals) in the epidemiology of MERS several types of investigation are needed:

- Comparative epidemiological studies, in all countries with significant camel populations, to determine the prevalence, distribution, and demographics of MERS-CoV infections in camels
- Studies to characterise the clinical and pathological effects and kinetics of virus shedding and immune response to MERS-CoV in experimentally and naturally infected camels
- Studies to assess risk factors and potential sources for camel infection and the relationship between camel infections and human cases of MERS
- Studies to assess the potential effectiveness of intervention measures aimed at reducing public health risk
- To conduct genetic analyses of both MERS-CoV and infected hosts from different geographical areas to gain better understanding of the properties of MERS-CoV and to monitor evolution of the virus

- To further assess diagnostic tests used for MERS-CoV surveillance in camels (and other animals) for the reliability of their results in these species.

OIE together with WHO and FAO reiterate the importance of the public health sector and the animal health sector working together to share data and design studies to develop a better understanding of the overall epidemiology of MERS.

### **Are other animal species involved?**

Although genetically related viruses have already been detected in bat species around the world, and a fragment of viral genetic material matching the MERS-CoV was found in one bat from Saudi Arabia, current evidence does not indicate a direct link between bats and MERS-CoV in humans. More evidence is needed to directly link the MERS-CoV to bats or other animal species.

According to published literature other species of animals (including sheep, goats, cattle, water buffalo and wild birds) have tested negative for the presence of antibodies to MERS-CoV. However owing to the relatively small sample sizes the results of these studies cannot exclude infection in other animal species. Based on receptor studies other animal species have been identified as potential hosts.

In countries where MERS-CoV is present, studies to assess the presence of MERS-CoV in wild and other domestic species should be conducted to detect possible infection in other hosts.

It is important to remain open minded about all potential sources of exposure for humans and camels until more information is available.

### **How can camels and other animals be tested for MERS-CoV infection or previous exposure?**

Serological tests detect antibodies produced by the host against the virus but do not detect the virus itself. Depending on the test that is used, the presence of antibodies may indicate previous exposure to MERS-CoV or a similar virus. Virus neutralisation is the most specific assay.

PCR (molecular) tests detect genetic material of the virus. Genome sequencing of the virus (parts of, or full genome) is the best way to confirm that the genetic material belongs to a MERS-CoV. Genetic data also provide important information about the evolution of the virus and how closely related MERS-CoV isolates are.

It is important that diagnostic tests used to detect MERS-CoV in animals are assessed for reliability of results when used in different animal species and when reported to the OIE.

Specific confirmatory molecular and serology diagnostic tests are now available for MERS-CoV. Positive results from screening tests should be confirmed using a confirmatory test. Processing of samples and laboratory testing should be conducted under appropriate biorisk management conditions.

### **What action should be taken when an animal is confirmed to be positive for MERS-CoV?**

Infection by MERS-CoV in animals is confirmed by a positive detection of the virus or genetic material belonging to the virus in a sample taken from an animal.

OIE Member Countries are obliged to report a confirmed case of MERS-CoV in animals to the OIE, as an “*emerging disease*” with zoonotic potential in accordance with [article 1.1.3](#) of the OIE *Terrestrial Animal Health Code*. If MERS-CoV is identified in an animal this would not necessarily mean that the animal is a source of human infection. Detailed investigations are needed to understand the relationship between any animal cases and human cases, and whether a finding in animals would be significant for human infection.

Given the current situation there is no evidence to support the implementation of specific animal health measures following the detection of MERS-CoV in animals or herds. When MERS-CoV is identified in an animal or herd, precautionary public health measures should be implemented to reduce the risk of human infection in accordance with WHO’s guidance on the WHO website. OIE will regularly review its guidance based on the latest scientific information.

**Is a vaccine or treatment currently available for MERS-CoV in animals?**

There are no vaccines or treatments available for MERS-CoV in animals. Further research is needed to assess the likely effectiveness of intervention measures.

**What is OIE doing?**

OIE is working closely with its partner organisations FAO and WHO to collate and share data to gain a better understanding about the disease situation in animals and to assess implications for animal and human health.

OIE has consulted its *Ad Hoc* Group on MERS-CoV Infections in Animals and the *Ad hoc* Group on Camelid diseases to provide advice on the latest scientific information and to provide recommendations and guidance, including on priority research activities for the animal health sector.

The OIE is also working closely with its Member Countries to provide technical support and to encourage reporting of MERS-CoV detections in animals.

OIE develops and publishes international standards and guidelines on the prevention, control and surveillance of animal diseases including zoonoses (animal diseases transmissible to humans). These science-based standards provide guidance on the best control measures which should be applied, where appropriate, to allow control of infection in the identified animal source.

The OIE is the reference organisation for international standards relating to animal health and zoonoses under the World Trade Organization Sanitary and Phytosanitary Agreement (SPS Agreement). Decisions related to safe trade in terrestrial animals and animal products must respect the standards, recommendations and guidelines found in the [OIE Terrestrial Animal Health Code](#).

For further information about public health implications visit the [WHO website](#).

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## **JOINT MEETING BETWEEN THE SCIENTIFIC COMMISSION AND THE CODE COMMISSION**

**Paris, 16 September 2014**

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The Scientific Commission and the Code Commission held a joint meeting on Tuesday 16 September 2014 to discuss issues of mutual interest. All members of both Commissions as well as the Director General, Deputy Director General, and his staff participated in the meeting.

The main discussion points were as follows:

### **1. Procedure for reviewing chapters in the *Terrestrial Code***

Considering the increasing complexity, horizontality, integration and multi-layered inputs and decision-making process to address the issues presented to both Commissions, *ad hoc* Group and the OIE Headquarters (HQ) required to support the development of new or amended chapters, it was agreed that the OIE HQ would establish revised procedures for improving the internal coordination for management of working documents and the provision of comments received from Members to both of the Commissions as appropriate.

### **2. FMD**

The revised FMD chapter was extensively discussed and both Commissions agreed that the chapter should be circulated for Member Country review in both clean text format and usual “double underline and strikethrough” format. It was reiterated that Member Countries are advised to consult not only the Code Commission report but also the Scientific Commission report and the associated *ad hoc* Group reports when reviewing the revised chapter.

### **3. International horse movement for equestrian events**

Both Commissions noted the work of the *ad hoc* Group on the draft veterinary certificate for horses in the high health status subpopulation. The Scientific Commission explained its view on Chapter 4.16. and the draft certificate to assist the Code Commission in their review of the *ad hoc* Group work.

### **4. PRRS**

Both Commissions noted the significant volume of comments received from Member Countries on this draft chapter. It will be included in the agendas of the February Commission meetings.

### **5. BSE**

Considering the evolution of this disease, in particular in respect of recent cases of atypical BSE, both Commissions recognised the need of in-depth analysis and further discussion on how to deal with atypical BSE.

## 6. Other disease chapters for revision

The Scientific Commission informed the Code Commission on the draft revised chapters on African swine fever and tuberculosis, which would be forwarded to the Code Commission as soon as the Scientific Commission concluded its deliberations and endorsed the *ad hoc* Group reports during the course of week. Similar procedures would be followed with the HQ proposal with the harmonisation of chapters on African horse sickness, bluetongue and epizootic haemorrhagic disease.

## 7. Criteria for Listing diseases

The Director General explained that during the 82<sup>nd</sup> General Session a commitment was agreed to convene an *ad hoc* Group to review the OIE disease listing criteria. Both Commissions recommended that the *ad hoc* Group should meet before the February meetings of both Commissions. It was also recommended that, if possible, the Member Countries that had expressed concerns on the current listing criteria should be involved in this *ad hoc* Group. Both Commissions also agreed that should the listing criteria be modified by the *ad hoc* Group, they would then be reviewed by the Commissions and eventually submitted for adoption by the World Assembly of Delegates. Once adopted, the current OIE listed diseases would be individually reviewed against the new criteria by selected disease specific experts, rather than all listed diseases being reviewed together by a single group.

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Summary of Commission Decisions on *Terrestrial Code* Chapters. Sep 2014

| Chapter   | Status before SCAD meeting   | Commission Decision   |
|---|--|---|
| <b>Chapter 8.X</b> Infection with Mycobacterium Tuberculosis Complex  | Draft chapter amended by AHG in response to SCAD recommendation during its September 2013 meeting  | Amendments proposed and the scientific rationale forwarded to TAHSC |
| <b>Chapter 15.1.</b> Infection with African swine fever virus   | Chapter amended by AHG   | Amendments proposed and the scientific rationale forwarded to TAHSC |
| Harmonisation of the Terrestrial Code chapters on African horse sickness, bluetongue and epizootic haemorrhagic disease | Based on the ad hoc Group revision and on the comments from the Code Commission, the OIE Headquarters proposed a further detailed comparison of the three chapters to both Commissions | Amendments proposed and the scientific rationale forwarded to TAHSC |
| <b>Chapter 12.10.</b> Infection with <i>Burkholderia mallei</i> (Glanders)  | Reviewed the chapter forwarded by the TAHSC  | Amendments proposed and the scientific rationale forwarded to TAHSC |
| <b>Chapter 8.7.</b> Infection with foot and mouth disease virus   | Review and clarify certain uncertainties raised by Member Countries during the 82 <sup>nd</sup> General Session in preparation of the joint meeting with the TAHSC                     | Amendments proposed and the scientific rationale forwarded to TAHSC |

AHG = *Ad hoc* Group

SCAD = Scientific Commission for Animal Diseases

TAHSC = Terrestrial Animal Health Standards Commission

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