



**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, 10–14 September 2018**

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A meeting of the OIE Scientific Commission for Animal Diseases (the Commission) was held at OIE Headquarters in Paris, France, from 10 to 14 September 2018.

**1. Welcome and Induction Session**

Noting that this was the first meeting of the newly elected Specialist Commissions, it was agreed that the opening session of all Specialist Commission meetings would be dedicated to a half-day induction session.

The purpose of these sessions, for new and previously elected members, was to begin the process of getting to know one another, to better understand how the work of each of the Commissions fits into the mission of the OIE, and to clarify the roles of Commission members and OIE secretariat and other staff. There was general agreement that this new initiative was very valuable for all concerned and will assist in ensuring the success of the work of each Commission. The OIE will continue to explore other ways of supporting the Commissions in their work.

Dr Matthew Stone, OIE Deputy Director General for International Standards and Science, welcomed the members of the Commission and congratulated them on their election or re-election.

Dr Stone drew the Commission's attention to the expectations of OIE Members regarding the working procedures of the Specialist Commissions. He reminded the Commission of its responsibility to contribute to the scientific integrity of the *Terrestrial Animal Health Code (Terrestrial Code)* and indicated the importance of maintaining a clear separation between the roles of the Specialist Commissions. In particular, Dr Stone mentioned the responsibility of the Commission during the risk assessment process, while the Terrestrial Animal Health Standard Commission (Code Commission) was responsible for the risk management component of the standard-setting process. He committed to establish a good coordination and communication mechanism to ensure that the priorities of the Commission's work plan correspond with those of the OIE.

**2. Adoption of the agenda**

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

### 3. Terrestrial Animal Health Code

#### 3.1. Member Country comments received for SCAD consideration

##### a) Glossary

###### Animal product

The Commission agreed with the proposal of some Members to add the definition of “animal product” to the Glossary as it would improve clarity and support a more harmonised implementation of the OIE Standards. It discussed the possibility of including biological products in the new definition, to make it more complete, but convened that this might pose unjustified trade barriers for vaccines and other products of animal origin that are used for disease control purposes. Noting that this new definition would lead to some redundancies in the current definition of “commodity”, the Commission proposed to amend the latter definition accordingly.

The Commission considered the comments received from Members on the definitions of “Epidemiological unit” and “Early warning system”.

###### Epidemiological unit

The Commission took note of the opinion of the *ad hoc* Group on Surveillance (June 2017) and agreed with some Member comments that one ‘epidemiological unit’, depending on the epidemiology of the disease (*i.e.* glanders, rabies), could encompass one single animal.

###### Early warning system

The Commission disagreed with a Member who proposed not to amend the current definition and retain details about the components of an early warning system. It noted that the Glossary is meant to provide concise definitions to clarify the terminology used in the *Terrestrial Code*, and that detailed information should be included in the disease-specific chapters.

###### Captive wildlife

The Commission agreed with a Member proposal to clarify the meaning of direct “human supervision or control” and proposed expanding the definition of “captive wildlife” accordingly.

The proposed amendments to the definitions were forwarded to the Code Commission for consideration.

##### b) Chapter 1.4. Animal health surveillance

The Commission discussed the Member comments on the amended chapter that was circulated for the second time after the February 2018 Specialist Commission meetings, with the intention to be presented for adoption at the General Session in May 2019.

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

The amended chapter addressing Member comments was forwarded to the Code Commission for its consideration.

##### c) Chapter 1.6. Procedures for self-declaration and for official recognition by the OIE

The Commission discussed Member comments on the amended chapter that was circulated for the first time after the Specialist Commission meeting in February 2018.

The Commission clarified that the procedures for self-declaration were already in place (published in the OIE *Bulletin*) and the written procedures were mainly developed to clarify the procedure for “publication” by the OIE. It agreed that the information described in the self-declaration should be adaptable depending on the disease situation in the country concerned. For example, a country may self-declare itself as historically free from a certain disease in accordance with Article 1.4.6. 1a), unless otherwise specified in the relevant disease chapter.

The Commission noted that some areas of the standard operating procedure (SOPs) (*e.g.* point 2.1.1.b.) could be improved for clarity and would welcome Members’ consideration and comments to the OIE Status Department ([self-declaration@oie.int](mailto:self-declaration@oie.int)) prior to the adoption of draft Chapter 1.6.

#### Article 1.6.1bis. Official recognition by the OIE

In response to Member comments requesting the removal of official recognition of BSE risk status, the Commission reiterated that following the sharing of the scientific and technical document assessing the current risk associated with BSE (Annex 18 of February 2017 Commission’s report), the majority of Members did not support the discontinuation of the OIE official recognition of risk status for BSE, but requested the revision of the OIE standards on BSE as a priority and a first step towards the discussion. This work has commenced and is in progress (two *ad hoc* Groups, one dedicated to BSE risk assessment and one to BSE surveillance requirements).

The amended chapter addressing Member comments was forwarded to the Code Commission for its consideration.

#### **d) Chapter 4.4. Application of compartmentalisation**

The Commission discussed a Member comment on Article 4.4.2. made during the 85th General Session in May 2018.

The Commission concurred that a compartment should only be established so that the susceptible population within the compartment has a “higher” or “equal” health status than the susceptible population outside of the compartment and agreed with the wording suggested by the Member. However, the Commission considered it unnecessary to specifically mention that the claim of freedom from a disease should be based on the provisions of the disease-specific chapters of the *Terrestrial Code* as this is clearly described in Chapter 4.3. of the *Terrestrial Code*.

#### **e) Chapter 4.X. Vaccination**

The Commission reviewed the Member comments on the draft chapter that was circulated for the fourth time after its February 2018 meeting and adopted at the 85th General Session in May 2018. During the General Session, some Members made comments on the definition of “population immunity”. The President of the Code Commission agreed to review the definition during the Specialist Commission’s September meeting.

The Commission pointed out that for the purpose of this chapter, the definition of “population immunity” does not refer to an absolute concept, but to a relative measurement that quantifies the outcomes of the vaccination. It considered the adopted definitions of “population immunity” and “vaccination coverage” adequate for the purpose of this chapter, as they make a clear distinction between the concept of effectively immunised and vaccine administration, and therefore did not agree to amend the definition as proposed by the Member.

The amended chapter addressing Member comments was forwarded to the Code Commission for its consideration.

#### **f) Chapter 4.Y. Official control of listed and emerging diseases**

The Commission addressed the Member comments received on the amended chapter that was circulated for the third time after the Specialist Commissions’ meetings in February 2018.

The Commission made reference to its opinion of February 2018, noting that the modified title of the chapter did not reflect the content. The provisions of the chapter are mostly orientated to supporting outbreak management, as was stated in Article 4.Y.1. “The purpose of this chapter is to provide recommendations to prepare, develop and implement official control programmes in response to outbreaks”. Therefore, some of the recommendations may not be appropriate in certain circumstances, when the aim of the official control programme is not eradication but control. The Commission was of the opinion that the chapter, in its current form, did not provide guidance for Veterinary Authorities on designing and implementing official control programmes. If such guidance is needed, the Commission advised the OIE to develop it in addition to the proposed chapter that should focus on outbreak management. The Commission pointed out that some Member comments would be addressed by revising the structure of the draft chapter.

The Commission took note of a Member proposal to change the title, modifying the word “listed” with “notifiable”, as to account for situations where official control programmes cover diseases not included in the OIE List. The Commission proposed that the title of the chapter be “Management of outbreaks”, as it should support countries in managing all disease outbreaks.

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

The amended chapter addressing Member comments was forwarded to the Code Commission for its consideration.

**g) Chapter 8.14. Infection with rabies virus**

The Commission discussed the Member comments on the amended chapter that was first circulated after the February 2018 Specialist Commissions meetings.

The Commission decided to seek external expert opinion to address some of the Member comments. It acknowledged with thanks the support received from the two experts from the OIE Reference Laboratories for Rabies, who were also members of the *ad hoc* Group responsible for amending the chapter.

The Commission pointed out the importance of this chapter in supporting Members in their efforts to eliminate dog-mediated human rabies in line with the Global Strategic Plan to Prevent Human Deaths from Dog-mediated Rabies by 2030.

The Commission supported the proposal to develop a specific questionnaire to guide Members in the preparation of the dossier to be submitted to the OIE for endorsement of the official control programme for dog-mediated rabies, consistently with what is in place for other diseases for which the OIE endorses national control programmes (*i.e.* foot and mouth disease [FMD], peste des petits ruminants [PPR], contagious bovine pleuropneumonia [CBPP]).

The detailed rationale for the Commission’s proposed amendments is attached as [Annex 5](#).

The amended chapter addressing Member comments was forwarded to the Code Commission for its consideration.

**h) Chapter 15.1. Infection with African swine fever virus**

The Commission addressed the Member comments received on some revised articles that were circulated to Members following the Specialist Commissions meetings in February 2018.

The detailed rationale for the Commission’s responses to the comments is attached as [Annex 6](#).

The amended chapter addressing Member comments was forwarded to the Code Commission for its consideration.

### 3.2. Other considerations

#### a) Revision of Terrestrial Code chapters on OIE listed diseases of relevance to equids

- **Chapter 12.2. Contagious equine metritis**

Contagious equine metritis (CEM) is a venereal disease of horses. Following a request from the International Horse Sports Confederation (IHSC), OIE Reference Laboratories for CEM were consulted electronically to provide their expert's opinion regarding the risk of transmission of CEM that may be associated with the temporary importation of competition horses for competition purposes (*i.e.* not imported for breeding).

The OIE Reference Laboratories emphasised that indirect transmission of CEM can occur. Any activity associated with breeding (e.g. nose to tail contact with infected horses, handling or examination by exposed people or contact with infected fomites from breeding horses) may represent potential routes of infection. Therefore, supplementary to the absence of breeding, precautions should be taken to mitigate the risk of indirect transmission.

The Commission reviewed and edited the provisions to mitigate the risk of direct and indirect transmission of CEM that may be associated with the temporary importation of competition horses, which were drafted based on the electronic consultation of OIE Reference Laboratories for CEM (draft Article 12.2.4.).

The Commission considered that under the provisions proposed in draft Article 12.2.4., the risk of CEM transmission associated with the temporary importation of competition horses would be negligible.

These draft provisions were forwarded to the Code Commission for its consideration.

- **Chapter 12.6. Infection with equine influenza virus**

Article 12.6.6. on recommendations for the importation of domestic equids for unrestricted movement, recommends (point 3) that domestic equids be "immunised in accordance with the recommendations of the vaccine manufacturer with a vaccine complying with the standards described in the *Terrestrial Manual* between 21 and 90 days before shipment either with a primary course or a booster".

The Commission considered the outcome of an "Evaluation of current equine influenza vaccination protocols prior to shipment" coordinated by an OIE Reference Laboratory for equine influenza,<sup>1</sup> and supported in the context of the public-private partnership between the OIE and the IHSC.

This study included a clinical trial aimed at determining the optimum interval between vaccination and shipment of horses. The results of this trial suggest that 14 days is the optimal minimal period to allow for the response to vaccination prior to shipment. The study also included a clinical trial aimed at determining antibody persistence after booster vaccination. The results of this trial suggest that for horses that have previously received four or more doses of vaccines and are older than four years, there is little benefit in requiring a booster vaccination within 90 days prior to shipment rather than within 180 days, as their antibody levels are relatively stable. In contrast, a recommendation of vaccination, either with a primary course or a booster, within 90 days prior to shipment for horses younger than four years of age would result in higher antibody levels than within 180 days.

The Commission acknowledged that these results support an update of the 21 to 90 days before shipment window for vaccinating against equine influenza. However, the Commission noted that these clinical trials were performed on competition horses, the health status and monitoring, physical and physiological conditions, and vaccination histories of which may not be comparable to other domestic equids. The Commission could not confirm whether the outcomes of these trials would also apply to other domestic equids. It was therefore suggested that the trial

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<sup>1</sup> A scientific publication on this study is in preparation by the Irish Equine Centre, OIE Reference Laboratory for equine influenza

outcomes be captured in specific recommendations for the vaccination of competition horses prior to shipment.

The Commission reviewed and amended provisions which were drafted based on the outcome of these trials in consultation with an OIE Reference Laboratory for equine influenza (draft Article 12.6.X.).

These draft provisions were forwarded to the Code Commission for its consideration.

- **Chapter 12.7. Equine piroplasmosis**

Equine piroplasmosis is one of the six diseases for which disease-specific requirements apply to High Health, High Performance (HHP) horses.<sup>2</sup> The expert Group which developed the HHP Model Veterinary Certificates noted that the mitigating measures defined in Article 12.7.3. of the *Terrestrial Code* which provides “Recommendations for the importation of competition horses on a temporary basis” were equivalent to those defined in the HHP Model Veterinary Certificates for equine piroplasmosis. Therefore, noting that Article 12.7.3. recommends horses be “accompanied by a passport in accordance with the model contained in Chapter 5.12.”, this Group advised that for HHP horses identified as belonging to a high health status subpopulation as defined in Chapter 4.16., the HHP identification could be an alternative to the use of a passport based on Chapter 5.12 for the purpose of Article 12.7.3.

The Commission agreed with this rationale and endorsed the proposed amendment to Article 12.7.3. and forwarded it to the Code Commission for its consideration.

- b) **Draft Chapter 8.X. Infection with *Trypanosoma evansi* (non equine surra) and Chapter 12.3. Infection with Trypanozoon in equids**

In February 2018, the Commission took note of the disagreement of some Members with the scope and approach of draft Chapter 8.X. Infection with *Trypanosoma evansi* (non equine surra) and amended Chapter 12.3. Infection with *Trypanozoon* in equids (*i.e.* *Trypanosoma evansi*, *Trypanosoma equiperdum*, *Trypanosoma brucei*). The Commission, in agreement with the Code Commission, recommended seeking the expert opinion of the *ad hoc* Group on animal African trypanosomoses on how to best address infection with animal African trypanosomes, infection with *Trypanosoma evansi* and infection with *Trypanosoma equiperdum* in the *Terrestrial Code*.

The Commission took note of the recommendation of this *ad hoc* Group that infection with *Trypanosoma evansi* (in all susceptible species) and infection of *Trypanosoma equiperdum* (in equids) be addressed in distinct chapters of the *Terrestrial Code*. In light of the different routes of transmission of these agents, and of their different areas of distribution, the Commission agreed with this recommendation.

The Commission considered the finalisation of the draft chapter on animal African trypanosomoses a priority and recommended that prior to further developing any provisions for infection with *Trypanosoma evansi* and infection with *Trypanosoma equiperdum* in the *Terrestrial Code*, it would be advisable to, first, (re)assess the compliance of these infections with the criteria for the inclusion of diseases, infections and infestations in the OIE list – based on the procedure presented in section 8.1.a) of this report.

The Commission recommended including the assessment of *T. evansi* and *T. equiperdum* against the criteria described in Chapter 1.2. of the *Terrestrial Code* in the terms of reference of the next *ad hoc* Group on animal African Trypanosomoses.

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<sup>2</sup> World Organisation for Animal Health (OIE). (2016). – Handbook for the management of High Health, High Performance horses. OIE, Paris, France, 74pp. Available at: [www.oie.int/fileadmin/Home/eng/Our\\_scientific\\_expertise/docs/pdf/Chevaux/HHP\\_Handbook\\_December\\_2016\\_V3.pdf](http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/Chevaux/HHP_Handbook_December_2016_V3.pdf) (accessed on 5 October 2018). (This publication was developed based on Chapter 4.16. of the *Terrestrial Code*.)

## 4. *Ad hoc* and Working Groups

### 4.1. Meeting reports for endorsement

#### a) *Ad hoc* Group on animal African trypanosomoses: 6-8 March 2018

Following the request from OIE Members, this *ad hoc* Group was convened to develop a *Terrestrial Code* chapter on animal African trypanosomoses to support Member Countries in their efforts to control and eliminate the disease.

The Commission commended the *ad hoc* Group for the progress made after its first meeting and agreed with the outline proposed for the chapter.

The Commission suggested seeking the Wildlife Working Group's opinion on the role of wildlife and feral animals in the epidemiology of the disease. The *ad hoc* Group was also encouraged to consider the criteria described in Chapter 1.2. of the *Terrestrial Code* when reviewing the case definition of Article 8.Y.1.

The Commission extensively discussed the proposal to declare a country or zone free from infection only in susceptible domestic animals, regardless of the status of susceptible wildlife, even in the presence of competent vectors. The Commission took note of the rationale provided in the report of the *ad hoc* Group, but considered that should this provision be included in the draft chapter, it should be further justified, including examples of country (countries) or zone(s) that managed to eliminate the disease in the domestic species despite the presence of infection in wildlife and in the presence of competent vectors.

The Commission discussed the *ad hoc* Group's recommendations for the importation of live animals from infected countries. Those recommendations include quarantine and laboratory testing not only in the country of origin but also at the destination, aiming at mitigating the risk posed by the reactivation of infection in a carrier animal. The Commission recognised that, in these circumstances, the negative predictive value of quarantine and testing at origin may be low, and thus may not be sufficient to reduce the risk to a negligible level prior to shipment. The Commission emphasised that the *Terrestrial Code* provides recommendations for safe international trade based on risk mitigation measures applied in the country of origin. Therefore, the Commission did not support the inclusion of recommendations for the importation of live animals from infected countries in the draft chapter.

The Commission discussed the merit and feasibility of drafting provisions for the importation of live susceptible animals directly for slaughter (in line with Article 11.5.8. of the *Terrestrial Code*) and on compartmentalisation. The Commission proposed to include these two topics in the terms of reference of the next *ad hoc* Group.

The Commission agreed on the proposed outline of the draft articles on surveillance, including vector surveillance.

The endorsed report of the *ad hoc* Group is attached as [Annex 7](#).

#### b) *Ad hoc* Group on prioritisation of diseases for which vaccines could reduce antimicrobial use in cattle, sheep and goats: 7–9 May 2018

The *ad hoc* Group was convened to complete the work started in 2015 by another *ad hoc* Group that dealt with the prioritisation of diseases for which vaccines could reduce antimicrobial use in animals, which focussed on pigs, poultry and fish. The aim of the *ad hoc* Group was to provide guidance on the prioritisation of diseases for which the use of improved and new vaccines could reduce antimicrobial use in cattle, sheep and goats, and to make recommendations for targeted research programmes.

The Commission congratulated the *ad hoc* Group on its work and endorsed the report.

The Commission noted that the work the OIE is doing on research prioritisation is already guiding research funding in some countries and encouraged the OIE to better clarify that some diseases that are not considered a priority at the global level might still be considered a high priority at the regional level.

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

**c) *Ad hoc* Group on antimicrobial resistance: 3–5 July 2018**

The Commission considered and endorsed the report of the *ad hoc* Group on Antimicrobial Resistance.

The Commission was informed that the meeting was organised in three parts. The first part dealt with the revision of the OIE List of Antimicrobial Agents of Veterinary Importance, also improving coherence between the WHO and OIE Lists with respect to terminology used for antimicrobial classification. The second part covered the OIE database on the use of antimicrobial agents in animals, encompassing the preliminary results of the third phase of data collection on antimicrobial agents intended for use in animals, an update on annual biomass and analysis planned for this third phase, the presentation of the template for the fourth phase, and conversion of the data from the spreadsheet format to a database system. The third part was dedicated to the Second OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents in Animals<sup>3</sup>: Putting Standards into Practice and poster selection.

The endorsed *ad hoc* Group report is attached as [Annex 9](#).

**d) *Ad hoc* Group on Bovine Spongiform Encephalopathy risk assessment: 3–5 July 2018**

The Commission reviewed and endorsed the report of the *ad hoc* Group on Bovine Spongiform Encephalopathy (BSE) risk assessment, which initiated the revision of the risk-based provisions for the categorisation of official BSE risk status.

The Commission commended the work of the *ad hoc* Group in two specific areas: firstly, in strengthening the risk assessment methodology which supports the categorisation of BSE risk status, and in particular, for taking into consideration different husbandry and farming practices and the associated likelihood of exposure to and recycling of the BSE agent; and secondly, for reconsidering the systematic impact of the occurrence of an indigenous case of classical BSE in cattle born less than 11 years ago on an officially recognised BSE negligible risk status.

The Commission noted that the revision of the risk-based provisions for the categorisation of official BSE risk status will be continued by this Group and by an *ad hoc* Group on BSE surveillance.

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

**e) *Ad hoc* Group on alternatives for surveillance for demonstration of freedom from FMD and recovery periods: 28-30 August 2018**

The Commission reviewed and endorsed the report of the *ad hoc* Group on alternatives for surveillance for demonstration of freedom from FMD and recovery periods.

The Commission appreciated that options were being proposed in support of an early recovery of FMD free status, with or without vaccination, where emergency vaccination without the subsequent slaughter of all vaccinated animals would be applied.

In addition, the Commission agreed with the opinion of the *ad hoc* Group that FMD surveillance should aim at demonstrating the absence of FMDV transmission rather than infection in vaccinated animals, and recommended that Chapter 8.8. of the *Terrestrial Code* be further reviewed to ensure that this surveillance objective is reflected consistently throughout the chapter.

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<sup>3</sup> [http://www.oie.int/amr2018/wp-content/uploads/2018/10/A\\_AMR\\_draftProgramme\\_15102018\\_v.3\\_ND.pdf](http://www.oie.int/amr2018/wp-content/uploads/2018/10/A_AMR_draftProgramme_15102018_v.3_ND.pdf)

The Commission concurred with the observation of the *ad hoc* Group that the questionnaires provided in Chapters 1.7. to 1.12. of the *Terrestrial Code* were primarily designed to support the compilation of information for initial applications for the recognition of official status, and agreed that it would be valuable to consider developing specific questionnaires to be followed for applications for the recovery of official disease free status.

The endorsed report of the *ad hoc* Group is attached as Annex 11.

#### **4.2. Planned *ad hoc* Groups and confirmation of proposed agendas**

The Commission took note of the dates of the *ad hoc* Group and Working Group meetings scheduled to be held before the next Commission meeting in February 2019, as listed below.

The Commission reviewed and agreed with the proposed agenda of the Working Group on Wildlife.

- a) *Ad hoc* Group on Bovine Spongiform Encephalopathy surveillance: 3–5 October 2018
- b) *Ad hoc* Group on evaluation of African horse sickness status: 17 October 2018 (teleconference)
- c) *Ad hoc* Group on evaluation of Foot and Mouth Disease status: 22–25 October 2018
- d) *Ad hoc* Group on evaluation of Bovine Spongiform Encephalopathy status: 29–30 October 2018
- e) *Ad hoc* Group on evaluation of Contagious Bovine Pleuropneumonia status: 13–14 November 2018
- f) *Ad hoc* Group on Bovine Spongiform Encephalopathy risk assessment (second meeting): 20–22 November 2018
- g) *Ad hoc* Group on evaluation of Peste des Petits Ruminants status: 27 November 2018 (teleconference)
- h) *Ad hoc* Group on evaluation of Classical Swine Fever status: 4–6 December 2018
- i) *Ad hoc* Group on antimicrobial resistance: 16–18 January 2019
- j) *Ad hoc* Group on animal African trypanosomoses: 15–17 January 2019 (to be confirmed)
- k) Working Group on Wildlife: 4–7 December 2018

### **5. Official disease status**

#### **5.1. Expert missions to Members requested by the Commission**

##### **a) State of play and prioritisation**

The Commission reviewed and prioritised the missions for the maintenance of disease status and the endorsement of official control programmes to be performed. The prioritised list of missions would be confirmed following consultation with the Director General of the OIE.

##### **b) Follow-up of past missions: action plans and progress reports**

The Commission considered the mission reports of countries that recently hosted an OIE expert mission and also reviewed the progress reports submitted by countries on the implementation of the recommendations from previous missions.

- ***India (endorsed official control programme for FMD)***

The Commission considered the detailed report of the FMD mission conducted in June 2018 to monitor the progress along India's official control programme for FMD, which was endorsed in May 2015.

The Commission commended India for the significant progress achieved since the endorsement of its official control programme for FMD. The Commission also took note of the recommendations of the mission to further strengthen the control programme and was informed that India had submitted an updated plan for 2019 to 2024. The Commission advised that India should report on the progress made on the recommendations of the mission when reconfirming its endorsement in November 2018.

The Commission agreed that the endorsement should be maintained.

- ***People's Republic of China (endorsed official control programme for FMD)***

The Commission was updated on the main outcomes of the FMD mission conducted in July 2018 to monitor the progress of the official control programme for FMD of the People's Republic of China (China), which was endorsed in May 2015.

The Commission commended China for the significant progress achieved since the endorsement of its official control programme for FMD. In addition, it took note of the recommendations of the mission to further strengthen the control programme and advised that China responds to questions raised in the report, submits an updated plan incorporating the recommendations of the mission and reports on the progress made when reconfirming its endorsement in November 2018.

The Commission agreed that the endorsement should be maintained.

- ***Kazakhstan (zones free from FMD with vaccination)***

An OIE mission took place in Kazakhstan in May 2017 prior to the granting of the official recognition of five zones free from FMD with vaccination. The Commission reviewed the report provided by Kazakhstan on the progress made regarding the implementation of the recommendations of this OIE mission. The Commission commended Kazakhstan on the progress made and noted that, as per regular procedures for the maintenance of officially free status, more detailed information on FMD surveillance was expected in support of Kazakhstan's annual reconfirmations of its FMD free zones.

- ***Madagascar (FMD free status without vaccination)***

Madagascar has been officially recognised as an FMD free country without vaccination since 2003. An OIE mission took place in April 2017 in order to assess the continuous compliance of Madagascar with the requirements of the *Terrestrial Code* in light of a potential increased risk of FMDV introduction due to recent disease outbreaks in the region. The Commission reviewed the report provided by Madagascar informing it on the progress made regarding the implementation of the recommendations of this OIE mission. The Commission observed that the implementation of some recommendations had been delayed in 2018 due to the lack of available funding. The Commission emphasised that all recommendations pertaining to the strengthening of control of movements should be given a high priority. The implementation of these recommendations will be thoroughly reviewed by the Commission in February 2019.

- ***Romania (CSF)***

An OIE mission took place in Romania in May 2017 prior to the granting of the official recognition of the CSF free country status. At its September 2017 meeting, the Commission suggested adding and broadening the recommendations of the previous mission to include strengthening the biosecurity in the backyard holdings, considering the recent outbreaks of African swine fever in domestic pigs. The Commission reviewed the report provided by Romania informing it of the progress made regarding the implementation of the recommendations of the OIE mission and addressing the issues previously raised by the Commission. The Commission considered the information provided by Romania to be insufficient to demonstrate that biosecurity in the backyard holdings had been strengthened. In addition, the Commission noted that the spread of African swine fever in Romania may indicate that insufficient biosecurity was in place. In February 2018, the Commission recommended a follow-up mission be conducted to monitor the implementation of these measures in the field. The Commission reiterated this recommendation and emphasised that this mission should be given a high priority.

- **Bulgaria (CSF)**

An OIE mission took place in Bulgaria in September 2017 prior to the granting of the official recognition of the country CSF free status. The Commission reviewed the report provided by Bulgaria describing the progress made regarding the implementation of the recommendations of this OIE mission. The Commission commended Bulgaria on the progress made and on the quality of the information provided. Whilst the Commission previously recommended that a follow-up mission take place within one year to monitor the implementation of the recommendations in the field, based on the satisfactory information provided by Bulgaria, it now indicated that such a mission should no longer be regarded to be a high priority, and encouraged Bulgaria to maintain its efforts.

## 5.2. Specific update on official disease status

### a) Follow-up of some countries having an endorsed official control programme

The discussions of the Commission on the endorsed official control programmes for FMD of India and the China are captured under Section 5.1.b) of the report

### b) Cessation of vaccination in a FMD free with vaccination zone

- **Chinese Taipei (FMD)**

The Commission took note of the official communication from Chinese Taipei to the OIE on the cessation of vaccination in the FMD free zone with vaccination covering Taiwan, Penghu and Matsu areas to change from FMD free with vaccination status to FMD free without vaccination status. The future application for the new status should be submitted to the OIE within 24 months of the cessation of vaccination, in accordance with Article 8.8.3. of the *Terrestrial Code*. The current officially recognised FMD free status with vaccination of this zone of Chinese Taipei will be maintained unchanged until compliance with Article 8.8.2. is approved by the OIE.

### c) Update on situation of official status of countries/zones

- **Haiti (FMD)**

Following the Commission's recommendation made during its February 2018 meeting with regard to Haiti's reconfirmation of its FMD free status, Haiti submitted the requested document showing the arrangements for laboratory diagnosis with an OIE Reference Laboratory (or other competent laboratory for FMD diagnostic tests). Whilst acknowledging the submission of the requested information by Haiti, the Commission strongly recommended that Haiti conduct simulation exercise(s) for collecting and sending samples to the OIE Reference Laboratory for FMD. The Commission also strongly encouraged Haiti to continue its efforts in providing training to relevant personnel and sectors on the detection and reporting of clinical suspicions of FMD.

- **Kyrgyzstan (AHS)**

Following a mission in Kyrgyzstan in April 2018 to monitor compliance with the *Terrestrial Code* provisions for the maintenance of its African horse sickness (AHS) free country status, the Commission was informed that, based on the review of the mission report via electronic consultation, the AHS status had been suspended with effect from 22 May 2018.

- **Mauritius (FMD)**

The Commission took note that the FMD free status of Mauritius had been suspended for more than two years and, according to the requirements of the *Terrestrial Code*, official recognition of its FMD free status would have to follow the provisions of Articles 8.8.2. or 8.8.3.

- **Other (FMD)**

The Commission considered an application from a Member for the recovery of its FMD free status. In accordance with the Standard Operating Procedures for official recognition of disease status, the Commission forwarded this application to seek the opinion of the *ad hoc* Group for evaluation of FMD status of Members prior to its consideration at its meeting.

Upon reviewing the application and additional information submitted by the Member as well as the recommendations of the *ad hoc* Group, the Commission unanimously commended the Member for the great efforts it had made in responding to the FMD outbreaks in the containment zone as well as for the transparency of the information provided. The Commission had serious concerns about the feasibility of the maintenance of the FMD free status due to the challenges encountered – also acknowledged by the country – in controlling the movements at the border with a neighbouring country with undetermined FMD status.

Considering this concern, the Commission requested additional information to be submitted by the Member in order to make an informed assessment.

### **5.3. Annual reconfirmations and other official status related issues**

#### **a) Selection of status for comprehensive review of 2018 annual reconfirmations**

The Commission selected the list of Members' 2018 annual reconfirmations for comprehensive review during the Commission's upcoming meeting in February 2019. The selection was based on a set of criteria described in the SOPs. The Commission will review a total of 43 annual reconfirmations during its February 2019 meeting.

### **5.4. Standards related to official status recognition**

#### **a) Procedure for official status of non-contiguous territories**

The procedure for the official recognition of disease status of non-contiguous territories as part of a country already recognised with an OIE official disease status was endorsed by the Commission at its last meeting in February 2018.

The Commission discussed whether an option for faster recovery (i.e. less than two incubation periods in case of establishment of a containment zone) should be considered in case of an outbreak in a non-contiguous territory which would lead to the suspension of the official status of the whole territory being recognised. Considering that generally, animals and animal products move without restrictions between the non-contiguous territory and the mainland, the Commission recommended that the current provisions of the *Terrestrial Code*, including that relating to the establishment of a containment zone, should apply.

#### **b) BSE testing methods and maintenance of BSE official risk status**

In order to better monitor compliance of the BSE diagnostic methods in use by Members having an officially recognised BSE risk status with the recommendations of the *Terrestrial Manual*, the Commission recommended that, from November 2018, Members should document the BSE diagnostic methods used in their reconfirmation for BSE risk status.

## **6. Global Control and eradication strategies**

### **6.1. Foot and Mouth Disease. Global Control Strategy**

The Commission was updated on the activities that had been conducted since its February 2018 meeting in the framework of the Global FMD Control Strategy and under the umbrella of the Global Framework for the progressive control of Transboundary Animal Diseases (GF-TADs).

The Commission was informed of the change in the composition of the GF-TADS FMD Working Group. Dr Neo Mapitse replaced Dr Laure Weber-Vintzel and Dr Bouna Diop replaced Dr Silvia Kreindel.

The 3rd Regional Roadmap Meeting on the Foot-and-Mouth Disease Progressive Control Pathway for Eastern Africa was held in Entebbe, Uganda, on 3–5 July 2018. A total of 44 participants, including OIE Delegates and their FMD country focal points, were drawn from 12 countries. Representatives of Regional Economic Communities, the East African Community and Intergovernmental Authority on Development, African Union – Interafrican Bureau for Animal Resources, Pan African Veterinary Vaccine Center of the African Union, Food and Agriculture Organization of the United Nations (FAO)–OIE FMD Reference Centres were also present. The report and the recommendations of the meeting are published on the GF-TADS website<sup>4</sup>.

The first FMD roadmap meeting for Central Africa will take place in Cameroon on 25–27 September 2018. The outcome of this first meeting should assist participant countries in preparing mid- and long-term action plans for FMD control in the region. In addition, the GF-TADS FMD Working Group is planning to organise the next West Eurasia roadmap in Iran in early 2019 to commemorate the 10th anniversary of the first roadmap in the region.

The Commission commended the Working Group for the publication of the second edition of the FMD-progressive control pathway (PCP) guidelines. The revised guidelines clarify the PCP approach and the acceptance process of the PCP stages at the regional level, and propose an integrated path from stage 0 of the PCP to the OIE recognition of FMD freedom without vaccination. This second edition also included a revision of the critical competences of the OIE Tool for the Evaluation of the Performance of Veterinary Services (OIE PVS tool) that are relevant for each of the PCP-FMD stages. The Commission was informed on the ongoing work to amend the questionnaires that are used for countries self-assessment prior the roadmaps meeting. A web-based tool to facilitate the use of the questionnaires and the ease with which the analysis of the countries' responses would also be created.

Finally, the Commission was made aware of the main activities planned for the first semester of the 2019 that would be included in the 2019–2020 action plan that is being finalised. This action plan will be presented to the Commission during its February 2019 meeting.

## **6.2. Peste des Petits Ruminants. Global Control and Eradication Strategy**

The Commission was informed on the ongoing activities and progress of the PPR Global Control and Eradication Strategy (GCES).

The Commission was updated on the current status of the PPR GCES, which was adopted during the International Conference on PPR organised by FAO and the OIE in Abidjan, Côte d'Ivoire, in April 2015. The Commission was reminded that following the establishment of the FAO–OIE joint PPR Secretariat in FAO Headquarters in Rome, Italy, in April 2016, the first five-year PPR Global Eradication Programme (GEP) was developed and launched in October 2016. From 2015 to 2017, the first round of PPR regional roadmap meetings was finalised for all the nine regions identified in the GCES and in parallel, in 2017, the second round was initiated with the organisation of meetings for four regions, namely Central Asia, the Middle East, Central Africa and South Asia. Through the PPR GEP, support has been provided to countries to formulate their PPR national strategic plans. In addition, in June 2017 the inaugural meeting of the PPR Advisory Committee was held at OIE Headquarters in Paris, and, in April 2018, the PPR Global Research and Expertise Network was launched in Vienna, Austria. The second meeting of the PPR Advisory Committee will take place in October 2018 in Rome.

The Commission was also informed of the PPR Global Conference that took place in Brussels, Belgium, on 6–7 September 2018 with a high level of Ministerial attendance. Through a Ministerial Declaration, more than 45 countries renewed their political commitment to globally eradicate PPR by 2030 and encouraged resource partners to join the fight against the disease.

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<sup>4</sup> [www.gf-tads.org/fmd/fmd/en/](http://www.gf-tads.org/fmd/fmd/en/).

The Commission commended the numerous activities implemented so far under the GCES but stressed that some countries had undertaken vaccination for several years without achieving eradication, which could trigger donor scepticism. Therefore, concerted efforts and detailed epidemiological assessments would be required to serve as a showcase for effective vaccination campaigns.

Finally, the Commission took note that PPR has recently reached the European Union Member States with Bulgaria reporting its first ever case of infection in June 2018.

### **6.3. Rabies. Global Strategic Plan to End Human Deaths from Dog-mediated Rabies. Zero by 30**

The Commission was updated on the latest development for the implementation of the Global Strategic Plan to end human death from dog-mediated rabies by 2030, that was published in May 2018.

The partner organisations (World Health Organization [WHO], FAO, the OIE and the Global Alliance for Rabies Control) are aiming to leverage existing tools and expertise in a coordinated way to empower, engage and enable countries to eliminate dog-mediated rabies.

The first phase for the implementation of the Global Strategic Plan (2018–2019) is focusing on building a strong foundation for rabies elimination by preparing and improving normative tools and structures to catalyse action in 29 target countries. Core activities include resource mobilisation, supporting countries in preparing robust, budgeted, effective and sustainable national rabies elimination plans following a One Health approach, and facilitating the coalescence of these plans into a coordinated regional effort. The Ministers of Agriculture and Health from the targeted countries would be formally invited to sign a statement to reaffirm their commitment to prioritising rabies prevention in their national plans and work with human and animal health stakeholders to eliminate rabies deaths nationally by 2030.

The Commission was also informed of the memorandum of understanding signed by FAO, WHO, and the OIE<sup>5</sup> to formalise and strengthen their cooperation to combat health threats associated with interactions between humans, animals and the environment. In addition to antimicrobial resistance and avian influenza, rabies elimination remains a priority for the Tripartite, and there is a new focus on health services strengthening.

## **7. Liaison with other Commissions**

### **7.1. Terrestrial Animal Health Standard Commission**

#### **a) Procedure for the evaluation of disease against the listing criteria of *Terrestrial Code* chapter 1.2.**

The Commission assessed the draft proposal prepared by OIE Headquarters to establish an SOP for the decision to list/delist pathogenic agents in Chapter 1.3. of the *Terrestrial Code*, according to the criteria for listing provided in the *Terrestrial Code* Chapter 1.2. on the criteria for the inclusion of diseases, infections and infestations in the OIE List.

Under the proposed procedure, when the need or the request of adding/removing pathogenic agents to the OIE List arises, the assessment of the agent against listing criteria should be through a specific, written analysis structured to provide the recent context (*i.e.* global or regional situation) and a summary of evidence for each criterion in Chapter 1.2 of the *Terrestrial Code*. This assessment would be led by OIE Headquarters with the technical support of the OIE Reference Centres or of the subject-matter experts through online consultation or by convening an *ad hoc* Group.

The Commission proposed that scientific evidence to assess pathogenic agents against listing criteria be provided by subject-matter experts, ensuring a geographical balance. It also recognised that some expertise (e.g. for assessing economic impact) might lie outside the OIE Reference Centres. The outcome of such consultation should be evaluated by experts responsible for

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<sup>5</sup> [http://www.oie.int/fileadmin/Home/eng/Media\\_Center/docs/pdf/onehealthportal/MoU\\_Tripartite\\_Signature\\_May\\_30\\_2018.pdf](http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/onehealthportal/MoU_Tripartite_Signature_May_30_2018.pdf)

surveillance systems from the different regions of the OIE, in order to ensure an appropriate assessment of the impact.

The conclusions of the expert consultation, including the analysis against listing criteria supported by the scientific literature, would be considered by the Commission and annexed to its report. Members would be invited to provide comments on the summary of the discussion and the recommendation, before proposing the modification of the Chapter 1.3 of the *Terrestrial Code*.

The Commission considered requesting the Director General of the OIE to convene an *ad hoc* Group for reviewing the current OIE List and assessing some pathogenic agents that were put on hold (e.g. porcine epidemic diarrhoea, theileriosis, chronic wasting disease, dourine), but concluded that it would be difficult to convene an *ad hoc* Group with the adequate expertise to assess all the diseases adequately. In addition, the Commission considered the possible risk of bias in the assessment due to the presence of only one expert on a specific disease in the Group.

The Commission pointed out that including a pathogenic agent in the OIE List should respond to a significant and ongoing impact on animal health, and not just to a short-term health impact.

The Commission supported the OIE proposal, but noted that, while the proposed process would sensibly reduce the subjectivity of the evaluation, a certain degree of subjectivity is unavoidable. It also pointed out that the proposed process would be demanding in terms of time and resources for the OIE and the Commission.

The Commission's opinion and the updated proposal for the procedure for evaluation were sent to the Code Commission for consideration and would be further discussed during the joint meeting of both commissions in February 2019.

**b) Chapter 8.16. Infection with rinderpest virus (recovery status)**

The Commission was informed on the proposal to update the *Terrestrial Code* Chapter 8.16 on infection with rinderpest virus, in line with requests received from country representatives and other stakeholders during the development of the Global Rinderpest Action Plan (GRAP). These changes would include provisions for “vaccinate to live” as a means to recover freedom from disease. The update process would be initiated by the FAO–OIE Joint Advisory Committee (JAC) for Rinderpest and the draft chapter would be presented to the Commission at its next meeting, in February 2019.

**c) Chapter 10.4. Infection with avian influenza virus. Report of the meeting of the *ad hoc* Group on avian influenza: June 2018**

The Commission commended the work done by the *ad hoc* Group that was convened to undertake a revision of Chapter 10.4. and considered the report and the amended chapter that had been drafted. The Commission took note of the opinion of the *ad hoc* Group regarding low pathogenicity avian influenza not matching the criteria described in Chapter 1.2. of the *Terrestrial Code*. The Commission supported the proposal to only include high pathogenicity avian influenza viruses in the case definition of Chapter 10.4. The Commission also agreed on the importance of including low pathogenic avian influenza in the six-monthly report to the OIE.

The Commission supported the *ad hoc* Group proposal to reduce the incubation period to 14 days, based on available scientific literature. For disease control purposes, the Commission agreed a time of two incubation periods be considered.

The Commission discussed the proposal of the *ad hoc* Group on the use of vaccination against high pathogenicity avian influenza in poultry. The Commission agreed on the proposal, recognising that Differentiating Infected from Vaccinated Animals (DIVA) tests are now available to distinguish between vaccinated and infected animals.

The Commission agreed with the *ad hoc* Group's proposal to not refer to ‘backyard poultry’ in the definition of “poultry”. For the purpose of this chapter, the Commission concurred that if the birds are kept in a single household and their products are only used in the same household, these birds do not pose a risk for the spread of the disease and, therefore, they should not be considered poultry.

The Commission also supported the modification proposed in the surveillance articles.

The Commission considered its participation in the process of amending this chapter relevant and expressed its interest in continuing its involvement in the process.

**d) Temporary protection zone. Chapter 4.3. on Zoning and compartmentalisation**

The President and 1st Vice-President of the Commission and the Code Commission held a meeting on 11 September 2018 to discuss the concept of temporary protection/preventive zone that was first circulated for Member comments after the Specialist Commissions meetings in September 2017. The meeting was chaired by the OIE Deputy Director General for International Standards and Science, Dr Matthew Stone.

The main objective of the meeting was to consider the Member comments received after circulating the draft concept, to explore its links with currently existing concepts of the *Terrestrial Code* (i.e. protection zone, containment zone) and to agree on the best approach to further develop and communicate the new concept to Members.

The strategic drivers of the temporary protection/preventive zone, the relevance of its inclusion in the horizontal chapter (i.e. Chapter 4.3. of the *Terrestrial Code*) and whether it should be applicable to all diseases or only to those diseases for which the OIE recognises an official status were extensively discussed.

It was agreed that OIE Headquarters would draft a discussion paper, based mainly on the current concept of “protection zone”, exploring the application and impact of the concept related to different diseases. This paper would be reviewed by both Commissions during the February 2019 meetings.

**e) Chapter 1.1. Notification of disease, infections and infestations, and provision of epidemiological information**

The OIE World Animal Health Information and Analysis Department had identified the need for a clarification of the term “new strain” used in point 3 of Article 1.1.3 of the *Terrestrial Code* that described Members’ obligations to report immediate disease events.

The Commission took note of the opinion expressed by the Biological Standards Commission. The Commission pointed out that in order to clarify point 3 of Article 1.1.3. of the *Terrestrial Code*, it would be necessary to take into consideration the differences between the occurrence of a completely unknown “new strain” which may overlap with the Glossary definition of an “emerging disease”, and the occurrence of an existing and known strain in a new country or zone.

Article 1.1.3. of the *Terrestrial Code* states that provisions for immediate notification are in accordance with relevant disease-specific chapters. Therefore, the Commission proposed that specific guidance about what should be considered a “strain” should be provided in the relevant disease-specific chapters. The Commission recognised that adding this new information would have a direct implication on Member obligations concerning immediate notification.

The Commission acknowledged that not all listed diseases had a dedicated chapter, and asked the OIE to provide support in identifying the most urgent diseases needing a clarification for the term ‘strain’ in the case definition.

The Commission noted that upcoming *ad hoc* Groups on specific diseases should be consulted and requested that the case definition of the disease-specific *Terrestrial Code* chapters be updated.

**7.2. Biological Standards Commission**

**a) Use of cattle tongue epithelium in the production of FMD vaccine**

The Commission considered a letter sent by a Member clarifying certain aspects of the use of cattle tongue epithelium in the production of FMD vaccine.

The Commission took note of the Biological Standard Commission's opinion and concurred that the method met the criteria for quality and agreed that it could be retained in the *Terrestrial Manual*.

The Commission reiterated its position expressed at its meeting in September 2017 and highlighted the fact that the use of epithelium cells could lead to increased levels of non-structural proteins (NSPs) in vaccinated animals impairing the FMD surveillance in a vaccinated population.

The Commission continued to support the cautionary words contained in the *Terrestrial Manual* Chapter 2.1.18. on FMD and in Chapter 3.7.2. on the minimum requirements for the production and quality control of vaccines, and encouraged Members to phase out this production method.

## **8. Conferences, workshops, meetings, missions**

The Commission was updated on the main conclusions of some of the Conferences and meetings that the OIE was involved in since last February's meeting.

### **8.1. 9th and 10th meeting of the SGE ASF**

The Commission was updated on the main recommendations of the last two meetings of the Standing Group of Experts on African swine fever in Europe (SGE ASF) that took place in Kiev, Ukraine, and Paris, France, in March and May 2018, respectively.

### **8.2. Scoping meeting on the issues and implications of guidance on international trade and transport of insects, London, the UK, 19-21 June 2018**

Insects are currently used for a variety of purposes, including biological control, research and food/feed production. The international trade in insects appears to be steadily growing, both in terms of geographical distribution and trade volumes. A large number of species are traded, including vectors capable of transmitting human and animal diseases. Despite the possible risks that these could pose to public and animal health, there is a lack of international standards and guidance on this type of trade, particularly for health certification and shipping requirements. This also causes disparity in trade conditions and possibly unjustified barriers between countries.

The Imperial College of London convened a scoping meeting on the issues and implications of guidance on the international trade of insects. The participants were experts and representatives of international organisations, national regulatory bodies, research centres and insect production organisations.

The meeting highlighted several information gaps, and it was concluded that additional information should be collected and analysed, to assess the need for further action. A better understanding of trade movements of insects and their possible role in the spread of infectious diseases would assist in assessing the risk posed by this type of trade, and the need for standards to ensure its safety.

The Commission was informed that the OIE is considering the recruitment of an intern to collect and analyse data on this issue, to assist in assessing the risk posed by this form of trade. The Commission welcomed the proposal and asked to be kept informed of any progress.

### **8.3. OIE Conference on Antimicrobial Resistance. Putting Standards into Practice. Morocco, Oct 2018**

The Commission was updated on progress in organising the 2nd OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents in Animals. Putting Standards into Practice in Marrakesh, Morocco, on 29–31 October 2018. The aim of the conference is to increase understanding of antimicrobial resistance (AMR) in order to facilitate the development of policies and the sustainable control of AMR. The conference will bring together OIE Delegates, OIE National Focal Points for Veterinary Products, ministers, experts, professionals, policy-makers, international organisations and donors. To highlight current efforts and address emerging needs, oral and poster presentations would focus on the impact of economics, policies and action plans on the fight against antimicrobial resistance. A number of the invited speakers would represent the Tripartite (WHO, the OIE and FAO) to give presentations about experiences and updates on ongoing projects.

## 9. Disease control specific issues

### 9.1. Rapid screening of bovine carcasses to determine the absence of FMDv (PCR test on lymph nodes)

The Commission acknowledged receipt of an expert opinion proposing a rapid screening method for bovine carcasses to determine the absence of FMDV. The Commission considered that the methodology could add confidence and facilitate safe international trade.

The Commission recognised the value of the proposed method, but considered the current provisions for matured, deboned meat included in Chapter 8.8. of the *Terrestrial Code* to be sufficient to guarantee safe trade of bovine meat from infected countries or zones.

### 9.2. Evaluation of *M. caprae* and *M. tuberculosis* match the OIE listing criteria of *Terrestrial Code* Chapter 1.2.

The Commission reviewed the opinion provided by a panel of experts which had been requested to provide advice on the question of whether *Mycobacterium caprae* and *Mycobacterium tuberculosis* fulfil the listing criteria of Chapter 1.2. of the *Terrestrial Code*.

The Commission concurred with the experts' opinion that *M. caprae* meets all of the listing criteria.

The Commission noted that little information is available on the impact of *M. tuberculosis* and agreed with the experts on the fact that, for *M. tuberculosis*, no transmission between animals or from animals to humans had been reported. Thus, the presence of the pathogen in several countries could not be considered as international spread, as its diffusion does not depend on live animals or their products, vectors or fomites.

The Commission discussed the interpretation of point 1 of Article 1.2.1. of the *Terrestrial Code* and noted that if the transmission of the pathogenic agent (via live animals or their products, vectors or fomites) is proven between two countries, this should be considered as international spread.

The Commission concluded that despite the fact that the mycobacterium complex is composed of *M. bovis*, *M. caprae* and *M. tuberculosis*, for the purpose of the *Terrestrial Code*, only *M. bovis* and *M. caprae* should be considered in the case definition.

The expert panel assessment of *M. caprae* and *M. tuberculosis* against the listing criteria described in Chapter 1.2. of the *Terrestrial Code* is included as [Annex 12](#).

### 9.3. Prion disease in dromedary camels in Algeria

The Commission took note of the recent detection of a prion disease in dromedary camels (*Camelus dromedarius*) in Algeria (Babelhadj *et al.*, 2018)<sup>6</sup> and discussed if this event should be considered an emerging disease based on its impact on the camel population or public health.

The Commission decided to seek the expert opinion of the *ad hoc* Groups on Bovine Spongiform Encephalopathy and on Camel Diseases. Should this event be considered an emerging disease, the Commission would also request the experts to provide recommendations for the correct monitoring of the event in potentially affected countries.

### 9.4. Resistance to antiparasitics

The Commission was updated on the OIE activities on antiparasitics since its last meeting in February. A training seminar for Focal Points for Veterinary Products for the American Region was held from 1 to 3 August in Tecámac, Mexico. The conclusion was that urgent actions led by the OIE are needed to tackle the problem of antiparasitic resistance. All training seminars from the different regions confirmed that there is strong interest among Members to work together on this issue.

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<sup>6</sup> [https://wwwnc.cdc.gov/eid/article/24/6/17-2007\\_article](https://wwwnc.cdc.gov/eid/article/24/6/17-2007_article)

The Commission was informed that an article titled “Update from the field concerning antiparasitical resistance” will be published in the September issue of *OIE News*.

The establishment of an electronic Working Group by inviting representatives from all Regions to take part (with geographical balance) is proposed, with the objective of preparing a document for possible publication on the responsible and prudent use of antiparasitics.

#### **9.5. Definition of a seasonally vector-free period**

In its meetings in September 2017 and February 2018, the Commission discussed the concerns expressed by some Members on the need to assess if the concept of a vector-borne disease seasonal free period is still scientifically justified and, if it is, to specify the scientific criteria to define it, in particular referring to the *Terrestrial Code* Chapter 8.3. on infection with bluetongue virus and Chapter 1.5. on surveillance for arthropod vectors of animal diseases. During these meetings, the Commission encouraged further scientific investigation on the validity of seasonal freedom and on the criteria that may define such a period, so as to provide evidence supporting the decision on whether or not to amend the relevant *Terrestrial Code* chapters.

The OIE proposed conducting a literature review and to use it as a basis for consultation with the OIE Reference Laboratories and Collaborating Centres on the matter. It is expected that the literature review would provide information on the scientific basis to assess the validity of vector-borne disease seasonal freedom, support the development of criteria influencing and defining vector-borne disease seasonal freedom. It would also help in the assessment of the potential impact of climate change on criteria influencing seasonal freedom.

The Commission welcomed the OIE initiative and noted that the outcome of this exercise would support the control of other vector-borne diseases (*e.g.* African horse sickness).

### **10. For the Commission information**

#### **10.1. Update on rinderpest activities**

An update on rinderpest post-eradication activities implemented since the last meeting was provided.

The Global Rinderpest Action Plan (GRAP) will be jointly published by FAO and the OIE in the fourth quarter of 2018. A prototype version of the GRAP was launched at the FAO–OIE Stakeholder Conference, held at FAO headquarters, in Rome, Italy, on 29–30 March 2018, after the GRAP was tested in two regional tabletop exercises, in Nairobi, Kenya, on 21–23 November 2017, and in Colombo, Sri Lanka, on 13–15 March 2018.

The Commission was informed that the modernisation of the Electronic Rinderpest Reporting System (ERRS), which allows Members to do their annual reporting on rinderpest virus containing materials (RVCM), and the development of the Rinderpest Virus Tracking System, which enables Rinderpest Holding Facilities (RHF) to update their inventories in real time, had been successfully concluded. The results of the 2018 reporting would be presented by the President of the Commission at the 87th General Session of the World Assembly of Delegates.

The FAO–OIE Joint Advisory Committee for Rinderpest (JAC) had its 13th meeting on 12–13 June 2018 at the headquarters of the International Atomic Energy Agency, in Vienna, Austria. In addition to discussing the aforementioned subjects, the JAC issued a recommendation for the OIE to propose for designation as RHF, the two institutes whose applications were pending, at the next General Session of the World Assembly of Delegates. An application for the production of rinderpest vaccine (LA–AKO) and bulk antigen, at the FAO–OIE designated RHF Category B in Japan, was reviewed and recommended for approval.

#### **10.2. Project update: replacement International Standard Bovine Tuberculin**

The Commission received an update on an ongoing OIE project to replace the OIE’s International Standard Bovine Tuberculin (ISBT).

An OIE *ad hoc* Group of bovine tuberculosis (bTB) experts is coordinating a project to develop and evaluate a replacement for the OIE's ISBT. The ISBT is used as a reference standard for quality control tests for purified protein derivative (PPD) bovine tuberculins that are used in bTB surveillance, diagnosis, and export certification. The current reference standard was produced in 1986 and is becoming depleted.

In the studies, two candidate tuberculins will be tested in guinea pigs and cattle, in comparison with the current ISBT, to evaluate and calibrate the candidate tuberculins' potency and specificity, as well as their overall 'fitness for purpose'. A Preliminary Evaluation in guinea pigs has now been completed with satisfactory results, and a larger International Collaborative Study is scheduled to take place in September 2018 to June 2019 where the performance of the two candidate tuberculins will be further assessed in guinea pigs as well as experimentally infected cattle and naturally sensitised 'reactor' cattle to further evaluate 'fitness for purpose'.

When the tests are completed, provided the data are satisfactory, the *ad hoc* Group will prepare a summary report and submit it for approval/endorsement through the OIE governance processes, including adoption by OIE Delegates at the OIE General Session, and a report will be submitted for publication in a peer-reviewed journal. The National Institute for Biological Standards and Control (NIBSC) could then begin distributing the new ISBT.

### **10.3. Update on the SIRCAH STAR-IDAZ International Research Consortium**

The Commission was updated on the recent activities performed by the STAR-IDAZ International Research Consortium on Animal Health (IRC), which is a forum of public and private R&D programme owners/managers aiming to coordinate research on animal health at the international level and to improve the control tools for a list of priority diseases/issues. To date, the consortium has 25 partners, which include national funding bodies as well as industry, international research organisations and donors. The STAR-IDAZ IRC is governed by an Executive Committee, composed of one representative from each partner, including the OIE, which works under the guidance of a Scientific Committee, consisting of independent experts. A Secretariat (SIRCAH), funded by the European Commission, was established in 2016 to support the IRC activities, and is co-hosted by the OIE.

Every year, the Executive Committee selects priority diseases to target for activities in the coming year. Priority diseases are diseases that have a significant impact at the global level and still need research in order to develop adequate control tools. In 2017, the selected diseases/horizontal issues were: ASF, bTB, brucellosis, helminths, Porcine Reproductive and Respiratory Syndrome (PRRS) and vaccinology. In 2018, new priorities were added: diagnostics, innovative anti-infective approaches (which would include alternatives to antibiotics), FMD and vector-borne diseases. Geographically balanced working groups of experts are being established to perform gap analyses and draw research roadmaps on the selected diseases/issues. The first research roadmaps (vaccine development for bTB, brucellosis and PRRS) have been delivered by the working groups and are published on the STAR-IDAZ IRC website.

The STAR-IDAZ established regional networks in Europe, the Americas, Asia and Australasia, and Africa and the Middle East. Periodic meetings are organised so as to update information about research activities and priorities, as well as to increase research coordination in the different regions.

## **11. Programme and priorities**

### **11.1. Update and prioritisation of the work plan**

The Commission updated its work programme, identified the priorities and scheduled the dates for the various *ad hoc* Group meetings which would be accessible to Members on the OIE website.

The updated work programme is attached as [Annex 13](#).

**12. Adoption of the report**

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

**13. Date of next meeting**

The next meeting of the Scientific Commission is scheduled for 18–22 February 2019.

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.../Annexes



**REPORT OF THE MEETING  
OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES  
Paris, 10–14 September 2018**

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**Agenda**

**Opening**

**1. Welcome and Induction Session**

**2. Adoption of the agenda**

**3. Terrestrial Animal Health Code**

**3.1. Member Country comments received for SCAD consideration**

- a) Glossary
- b) Chapter 1.4. Animal health surveillance
- c) Chapter 1.6. Procedures for self-declaration and for official recognition by the OIE
- d) Chapter 4.4. Application of compartmentalisation
- e) Chapter 4.X. Vaccination
- f) Chapter 4.Y. Official control of listed and emerging diseases
- g) Chapter 8.14. Infection with rabies virus
- h) Chapter 15.1 Infection with African swine fever virus

**3.2. Other considerations**

- a) Revision of Terrestrial Code chapters on OIE listed diseases of relevance to equids:
  - Chapter 12.2. Contagious equine metritis
  - Chapter 12.6. Infection with equine influenza virus
  - Chapter 12.7. Equine piroplasmiasis
- b) Draft Chapter 8.X. Infection with *Trypanosoma evansi* (non equine surra) and Chapter 12.3. Infection with Trypanozoon in equids

**4. Ad hoc and Working Groups**

**4.1. Meeting reports for endorsement**

- a) *Ad hoc* Group on animal African trypanosomoses: 6-8 March 2018
- b) *Ad hoc* Group on prioritisation of diseases for which vaccines could reduce antimicrobial use in cattle, sheep and goats: 7-9 May 2018
- c) *Ad hoc* Group on antimicrobial resistance: 3-5 July 2018
- d) *Ad hoc* Group on Bovine Spongiform Encephalopathy risk assessment: 3-5 July 2018
- e) *Ad hoc* Group on alternatives for surveillance for demonstration of freedom from FMD and recovery periods: 28-30 August 2018

**4.2. Planned *ad hoc* Groups and confirmation of proposed agendas**

- a) *Ad hoc* Group on Bovine Spongiform Encephalopathy surveillance: 3-5 October 2018
- b) *Ad hoc* Group on evaluation of African horse sickness status: 17 October 2018 (teleconference)
- c) *Ad hoc* Group on evaluation of Foot and Mouth Disease status: 22-25 October 2018
- d) *Ad hoc* Group on evaluation of Bovine Spongiform Encephalopathy status: 29-30 October 2018
- e) *Ad hoc* Group on evaluation of Contagious Bovine Pleuropneumonia status: 13-14 November 2018
- f) *Ad hoc* Group on Bovine Spongiform Encephalopathy risk assessment (second meeting): 20-22 November 2018
- g) *Ad hoc Group* on evaluation of Peste des Petits Ruminants status: 27 November 2018 (teleconference)
- h) *Ad hoc* Group on evaluation of Classical Swine Fever status: 4-6 December 2018
- i) *Ad hoc* Group on antimicrobial resistance: 16-18 January 2019
- j) *Ad hoc* Group on animal African trypanosomoses: 15-17 January 2019 (to be confirmed)
- k) Working Group on Wildlife: 4-7 December 2018

**5. Official disease status**

**5.1. Expert missions to Members requested by the Commission**

- a) State of play and prioritisation
- b) Follow-up of past missions: action plans and progress reports

**5.2. Specific update on official disease status**

- a) Follow-up of some countries having an endorsed official control programme
- b) Cessation of vaccination in a FMD free with vaccination zone
- c) Update on situation of countries/zones

**5.3. Annual reconfirmations and other official status related issues**

- a) Selection of status for comprehensive review of 2018 annual reconfirmations

**5.4. Standards related to official status recognition**

- a) Procedure for official status of non-contiguous territories
- b) BSE testing methods and maintenance of BSE official risk status

**6. Global Control and eradication strategies**

**6.1. Foot and Mouth Disease. Global Control Strategy**

**6.2. Peste des Petits Ruminants. Global Control and Eradication Strategy**

**6.3. Rabies. Global Strategic Plan to End Human Deaths from Dog-mediated Rabies. Zero by 30.**

**7. Liaison with other Commissions**

**7.1. Terrestrial Animal Health Standard Commission**

- a) Procedure for the evaluation of disease against the listing criteria of *Terrestrial Code* chapter 1.2.
- b) Chapter 8.16. Infection with rinderpest virus (recovery status)
- c) Chapter 10.4. Infection with avian influenza virus. Report of the meeting of the *ad hoc* Group on avian influenza: June 2018
- d) Temporary protection zone. Chapter 4.3. on Zoning and compartmentalisation
- e) Chapter 1.1. Notification of disease, infections and infestations, and provision of epidemiological information.

**7.2. Biological Standards Commission**

- a) Use of cattle tongue epithelium in the production of FMD vaccine

**8. Conferences, workshops, meetings, missions**

**8.1. 9<sup>th</sup> and 10<sup>th</sup> meeting of the SGE ASF**

**8.2. Scoping meeting on the issues and implications of guidance on international trade and transport of insects, London, the UK, 19-21 June 2018**

**8.3. OIE Conference on Antimicrobial Resistance. Putting Standards into Practice. Morocco, Oct 2018**

**9. Disease control specific issues**

**9.1. Rapid screening of bovine carcasses to determine the absence of FMDv (PCR test on lymph nodes)**

**9.2. Evaluation if *M. caprae* and *M. tuberculosis* match the OIE listing criteria of *Terrestrial Code* Chapter 1.2.**

**9.3. Prion disease in dromedary camels in Algeria**

**9.4. Resistance to antiparasitics**

**9.5. Definition of a seasonally vector free period**

**10. For the Commission information**

10.1. Update on rinderpest activities

10.2. Project update: replacement International Standard Bovine Tuberculin

10.3. Update on the SIRCAH STAR-IDAZ International Research Consortium

**11. Programme and priorities**

11.1. Update and prioritisation of the work plan

**12. Adoption of the report**

**13. Date of next meeting**

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

**Paris, 10–14 September 2018**

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**List of Participants**

**MEMBERS**

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**Dr Cristóbal Zepeda** (*President*)  
APHIS Attaché, Brazil  
7500 Brasilia Place  
Dulles, VA 20189-7500  
UNITED STATES OF AMERICA  
Tel: +55 61 3312 7725  
[Cristobal.zepeda@aphis.usda.gov](mailto:Cristobal.zepeda@aphis.usda.gov)

**Dr Baptiste Dungu** (*Vice-President*)  
26 Dalrymple Crescent  
Edinburgh EH9 2NX  
Scotland  
UNITED KINGDOM  
Tel.: +212 523 30 31 32  
Fax: +212 523 30 21 30  
[b.dungu@mci-santeanimale.com](mailto:b.dungu@mci-santeanimale.com)

**Dr Misheck Mulumba** (*Member*)  
Agricultural Research Council  
Private Bag X05  
Onderstepoort 0110  
Pretoria  
SOUTH AFRICA  
Tel: +27 12 529 9338  
[mulumbam@arc.agric.za](mailto:mulumbam@arc.agric.za)

**Dr Kris De Clercq** (*Vice-President*)  
Sciensano  
Department of Virology  
Section Epizootic Diseases  
Groeselenberg 99  
B-1180 Ukkel  
BELGIUM  
Tel.: +32 2 379 0400  
[kris.declercq@sciensano.be](mailto:kris.declercq@sciensano.be)

**Dr Silvia Bellini** (*Member*)  
Responsible of the Unit Surveillance  
and Control  
Istituto Zooprofilattico Sperimentale  
della Lombardia e dell'Emilia  
Romagna "Bruno Ubertini"  
Via Bianchi 9  
25124 Brescia  
ITALY  
Tel: +39 30 2290590  
[silvia.bellini@izsler.it](mailto:silvia.bellini@izsler.it)

**Dr Zengren Zheng** (*Member*)  
Chief Scientist & Deputy  
Director of China Animal Health  
and Epidemiology Center (CAHEC)  
No. 369 Nan Jing Road  
Qingdao  
PEOPLE'S REPUBLIC OF CHINA  
[Zhengzr62@126.com](mailto:Zhengzr62@126.com)

**OIE HEADQUARTERS**

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**Dr Elisabeth Erlacher-Vindel**  
Head  
Science & New Technologies (SNT)  
Department  
[e.erlacher-vindel@oie.int](mailto:e.erlacher-vindel@oie.int)

**Dr Gregorio Torres**  
Chargé de mission  
SNT Department  
[g.torres@oie.int](mailto:g.torres@oie.int)

**Dr Stefano Messori**  
Chargé de mission  
SNT Department  
[s.messori@oie.int](mailto:s.messori@oie.int)

**Dr Neo Mapitse**  
Head  
Status Department  
[n.mapitse@oie.int](mailto:n.mapitse@oie.int)

**Dr Min Kyung Park**  
Deputy Head  
Status Department  
[m.park@oie.int](mailto:m.park@oie.int)

**Dr Morgane Dominguez**  
Project Officer  
Status Department  
[m.dominguez@oie.int](mailto:m.dominguez@oie.int)

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**Rationale for the amendments to:**

**CHAPTER 1.4. ANIMAL HEALTH SURVEILLANCE  
provided by the Scientific Commission**

**Article 1.4.1. Introduction and objectives**

The Commission disagreed with a Member proposal to include references to zoonotic agents. The term “infection”, as defined in the Glossary, already includes references to the presence of a pathogenic agent in the body of humans or animals.

**Article 1.4.4. Surveillance methods**

The Commission took note of a Member proposal to clarify that relevant and robust scientific evidence should underpin the weighting of any risk factors used in a surveillance based on a non-probability sampling. The Commission considered this concept to be implicit in the current provision. However, for additional clarity, it proposed to amend the text specifying that the extrapolation of results for non-probability sampling to the study and target population needs to take into consideration the relative weight of risk factors.

The Commission agreed with a Member proposal that “risk-based sampling” can be either probability or non-probability based. Consequently, it was added to the list of probability-based sampling methods.

The Commission disagreed with a Member proposal to amend the text by adding that likelihood, consequence and overall risk should be assessed and documented, as this does not add value to the current provision.

The Commission agreed with the proposal of some Members to clarify that sentinel units could be used for the surveillance of re-emerging diseases, as it could be the case for diseases such as Rift Valley fever.

The Commission considered the current definition of syndromic surveillance was adequate. It captures the essence of syndromic surveillance, which is detecting signals that could be indicative of the occurrence of infection or infestation. The Commission disagreed with a Member proposal to draft new text to further describe syndromic surveillance. It noted the title of the section was amended to refer to syndromic surveillance instead of syndromic data. Therefore, the Commission proposed to delete reference to software, as this is more relevant for syndromic data than syndromic surveillance.

The Commission agreed with a Member comment on the importance of laboratory quality control and quality assurance systems for ensuring valid analysis of data and proposed to modify the text accordingly.

**Article 1.4.5. Early warning systems**

In response to a Member request concerning the early warning system definition, the Commission referred to its opinion on this same topic expressed in the Glossary (c.f. 3.1.a), and proposed providing more details on the components of an early warning system in this article.

One Member proposed amending point 4) of Article 1.4.5. by deleting the provision of a legal obligation for relevant stakeholders to report suspected or confirmed cases of notifiable or emerging diseases to the Veterinary Authority. The Commission noted this provision was already present in the adopted definition of early detection system. The Commission disagreed with the proposal as it would impact negatively on disease notification.

In agreement with some Member comments, the Commission proposed to delete the bullet points under point 4), since these might be considered too prescriptive, some major parts are partly covered already in the revised chapter, and could ultimately result in delays with notifications, as stakeholders would be obliged to collect all elements before submitting them.

The Commission agreed with the comments of some Member on the list under point 5bis) as, according to these Members, it may be incomplete and could be perceived as prescriptive. The Commission proposed to delete the list and suggested that the OIE consider the elaboration of the guidelines for disease outbreak investigation. However, should the list be retained, the Commission agreed with the proposal of some Members to add the words “and exit” before the word “pathways” as epidemiological investigations would normally consider both source (of incursion) and spread (to other animals/groups/holdings/areas). The Commission proposed to also consider the movement of animal products in the list to under point 5bis), as this could have an important impact on disease surveillance.

The Commission disagreed with a Member proposal to add a paragraph clarifying the two procedures for the declaration of freedom (self-declaration and official recognition by the OIE), as this Chapter deals with surveillance for demonstrating the absence of diseases (infection/infestation) regardless of the administrative procedure. In addition, the description of the procedures for claiming freedom are already well detailed in Chapter 1.6. of the *Terrestrial Code*.

#### **Article 1.4.6. Surveillance for freedom from an infection or infestation**

In response to a Member comment, the Commission confirmed its previous opinion with regard to the impact of vaccination on the disease status of a country or zone. It reiterated that, unless otherwise specified in the relevant listed disease-specific chapter, the vaccination of animals should not affect the status of the country or zone. However, it was agreed that the absence of vaccination should remain among the requisites for claiming historical freedom. The Commission suggested amending point 2b i) accordingly.

The Commission disagreed with a Member proposal that a country or zone could always be considered free from a disease when infection is present in wildlife, providing effective measures have been implemented to prevent the transmission of infection to the domestic population. While recognising that for some diseases (*e.g.* classical swine fever) infection in wildlife does not impact the country or zone official disease status, for most diseases the presence of disease in wildlife would impede the country in fulfilling the provisions of freedom. The Commission made a remark that point 2a) applies only unless otherwise specified in the disease-specific chapter.

The Commission disagreed with one Member who proposed historical freedom be recognised if the infection or infestation was absent for ten years, whether or not prerequisites listed in point 2a) are complied with. It was noted that the Member did not provide scientific justification for reducing the time. It was agreed that, should scientific evidence be made available, this provision could be reviewed.

The Commission, while agreeing that frequency and duration of surveillance should be appropriate to the epidemiology of the pathogen, disagreed with a Member proposal to amend the text, as this was already considered part of the pathogen-specific surveillance.

**Rationale for the amendments to:**

**CHAPTER 4.Y. OFFICIAL CONTROL OF LISTED AND EMERGING DISEASES  
provided by the Scientific Commission**

**Article 4.Y.4. Surveillance and early warning system**

The Commission agreed with the proposal of some Members to relocate some of the information contained in this article to Article 1.4.5. on early warning systems to provide guidance on what needs to be done in response to suspected cases.

**Article 4.Y.5. General considerations when managing an outbreak**

The Commission disagreed with a Member proposal to add “surveillance and tracing (forwards and backwards) from known infected properties or animals” among the options for stopping the spread of infection, as surveillance *per se* does not stop the spread of infection. The Commission also agreed with a Member proposal to add “vector control” among the options for stopping the spread of infection.

**Article 4.Y.6. Culling of animals and disposal of dead animals and animal products**

The Commission, in accordance with one Member proposal, agreed that for some diseases (*e.g.* anthrax) shedding of the agent does not always cease after the death of the animal. Additionally, and in order to improve clarity of the article, the Commission suggested deleting the reference to “active” spread.

Noting that human beings may themselves serve as fomites, not just their clothes and footwear, the Commission proposed to modify the text as proposed by a Member. For consistency, the Commission suggested the same amendment be made in Article 4.Y.8.

The Commission noted that there was not a definition in the *Terrestrial Code* for infectious and contagious diseases. It pointed out that contagious diseases are transmitted through contact, while infectious disease could be transmitted by other means (*e.g.* vectors). The Commission disagreed with the proposal of some Members to refer to “infectious disease(s)” instead of “contagious disease(s)” throughout the chapter, as the terms are not synonymous.

The Commission concurred with two Members comments that pointed out that in some circumstances animals outside of establishments might be included in the stamping-out policies. The Commission agreed with a Member proposal to broaden the definition to a defined zone instead of to limit it to all establishments.

**Article 4.Y.8. Biosecurity**

The Commission agreed with the proposal of some Members to add reference to disinfection as a measure of biosecurity.

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**Rationale for the amendments to:**

**CHAPTER 8.14. INFECTION WITH RABIES VIRUS  
provided by the Scientific Commission**

**Article 8.14.1. General provisions**

The Commission disagreed with a Member proposal to define rabies as a group of diseases. It noted that it is well accepted by the international rabies expert community that rabies is a single disease and not a group of diseases.<sup>1</sup>

The Commission noted that, for the purpose of this chapter, a ‘case’ is defined as an infection with rabies virus, which was formerly named as ‘classical rabies virus, genotype-1’. In order to increase the clarity of the chapter and to exclude other lyssaviruses from the case definition, the Commission proposed adding a statement saying that, for the purposes of this chapter, only rabies virus is to be considered.

The Commission agreed with the proposal of some Members to amend the text to clarify that virus shedding lasts until death.

In response to a Member, the Commission proposed to clarify that ‘dog population’ was referring to *Canis familiaris*.

The Commission, in response to a Member request, stressed that the objective of the epidemiological studies is to provide evidence that virus circulation in the dog species is independent from other animal species.

**Article 8.14.2. Country or zone free from infection with rabies virus**

The Commission pointed out that rabies is always associated with clinical signs and disagreed with a Member proposal to include animals not showing clinical signs as part of the laboratory and epidemiological investigation. In addition, in the context of declaring freedom, the Commission noted that the aim is to investigate all animals showing clinical signs so as to increase the confidence of the freedom claim.

The Commission disagreed with a Member request to provide further clarification on the field investigations, as these are described in Chapter 1.4. of the *Terrestrial Code*.

Some Members expressed concerns about the impact that an imported case may have on the disease status of a country or zone. The Commission concurred with the opinion expressed by the *ad hoc* Group stating that should an imported case be detected outside of the quarantine station, the country or zone should not lose its free status, providing that an appropriate epidemiological investigation to rule out the presence of secondary cases is implemented and documented. The Commission did not consider it necessary to make reference to the minimum time that may elapse to gather sufficient evidence to rule out the presence of secondary cases.

In response to a Member request to define “at-risk animals”, the Commission proposed to delete reference to “at risk”, as it did not add any value to the provision.

**Article 8.14.2ter. Country or zone free from dog-mediated rabies**

In the context of a country or zone free from dog-mediated rabies, surveillance should be primarily focused on the dog population. The Commission disagreed with a Member proposal to add reference to wildlife in point 1b) of this article.

The Commission disagreed with a Member comment on the need to specify the target animals subject to surveillance, as this article only refers to dog-mediated rabies. Spillover infection from wildlife should not be considered dog-mediated rabies.

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<sup>1</sup> World Health Organization (WHO) (2018). – WHO Expert Consultation on Rabies: third report. WHO Technical Report Series, No. 1012. WHO, Geneva, Switzerland.

The Commission agreed with a Member proposal to consider a minimum time requirement of 24 months for the duration of the implementation of a stray dog population management programme, which is in line with the duration of the required surveillance. It also agreed to clarify that such a programme should be maintained.

#### **Article 8.14.5. Recommendations for importation of dogs, cats and ferrets from countries or zones considered infected with rabies virus**

The Commission disagreed with a Member proposal that primary vaccination should be received no less than 6 months prior to shipment. It was well documented by the *ad hoc* Group that if a dog, cat or ferret reaches a rabies antibody threshold of 0.5 IU/ml, it should be considered protected and safe for importation, regardless of the timing of vaccination. Thus, the Commission considered a minimum of 30 days appropriate to ensure that a vaccinated animal reaches the expected antibody threshold after vaccination.

The Commission considered several comments from some Members and agreed to modify the text to clarify that the antibody test is not only linked to the day of shipment but also to the day of vaccination. The Commission noted that antibody level testing should happen at least one month after vaccination, and that a minimum of three months should elapse between testing and shipment, in order to ensure that the detected antibodies were elicited by the vaccination and not by a possible natural infection. Therefore, a minimum of four months should elapse between vaccination and shipment.

#### **Article 8.14.6. Recommendations for importation of other susceptible animals from countries or zones considered infected with rabies virus**

In accordance with some Member comments, the Commission noted that the provisions in this article are more lenient than for dogs, cats and ferrets (Article 8.14.5.). The Commission took note of the justification provided by the *ad hoc* Group for amending this article. However, it was pointed out that for carnivores other than dogs, cats and ferrets a licensed rabies vaccine is not available on the market and that serological assays had been validated for dogs and cats only, so that the threshold of seropositivity of 0.5 IU/ml may not apply to other species. Therefore, the Commission proposed to reinstate the previous structure of the adopted chapter that had two separated articles, one for the importation of domestic ruminants, equids, camelids and suids, and one for the importation of wildlife (Articles 8.14.7. and 8.14.9. respectively). Those articles could include different provisions for the different species.

#### **Article 8.14.8. OIE endorsed official control programme for dog-mediated rabies**

The Commission took note of a comment suggesting the inclusion of a monitoring and surveillance plan specific to the movement of dogs involved in the meat trade. It assessed the risk posed by the movement of dogs intended for consumption. It was noted that this is a practice in some countries only and that the control of animal movement (also in connection with the movement of dogs for the dog-meat trade) should be an integral part of any dog rabies elimination programme. The Commission suggested that, if dog movement for meat trade purposes exists, it should be described under point 4c) ‘dog population management including stray dog control’ as part of the country dog movement control policy.

#### **Article 8.14.9. General principles of surveillance**

The Commission agreed with the proposal of some Members to add “any change in behaviour followed by death within 10 days” to the criteria used to define a suspected case.

The Commission agreed with the proposal of some Members to state that animals (especially carnivores and bats) found dead are recognised as an important source of information for rabies surveillance, and proposed to add a sentence to this effect under point 2b).

The Commission agreed with a Member comment on the risk posed by the movement of dogs intended for consumption. As was stated above, the Commission highlighted that the control of dog movement, regardless of its purpose, should be an important component of any rabies disease programme. The Commission did not consider it necessary to amend the text.

**Rationale for the amendments to:**

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

**Article 15.1.1bis. Safe commodities**

In response to a comment suggesting the deletion of the reference to meat in a sealed container as a safe commodity as well as updating the Fo value for the inactivation of African swine fever virus in meat, the Commission took note of European Food Safety Authority (EFSA) opinion on African swine fever (ASF) supporting the view that canned meat can be considered a safe commodity. However, the Commission questioned if canned meat and meat in a hermetically sealed container should be considered the same commodity as proposed in the amended chapter.

The Commission consulted the International Food Safety and Quality Network website<sup>1</sup> where it is indicated that ready-to-eat food should have an Fo value between 8 and 15. However, the Commission did not have access to a scientific reference to support the suggested modification.

In a typical canning process, the centre of the can is heated to 121°C for 3 min ( $F_0 = 3$ )<sup>2</sup> for long life and 70°C for pasteurisation. Adkin *et al.* (2004)<sup>3</sup> considered the survival time of ASF as well as that of classical swine fever (CSF), FMD and swine vesicular disease (SVD) in canned meat to be 0 days.

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

The Commission disagreed with a Member proposal to require the Veterinary Authority to have knowledge of and authority over feral pigs, and made reference to the definition of “feral animals” in the Glossary of *Terrestrial Code*.

**Article 15.1.3. Country or zone free from ASF**

The Commission disagreed with a Member proposal to specify that risk mitigation measures other than those described in the chapter could be implemented if determined by a risk analysis. The Commission emphasised that the principle of equivalence is a general principle of the *Terrestrial Code* (Chapter 5.3. of the *Terrestrial Code*) and therefore, it was not necessary to amend the text.

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<sup>1</sup> [www.ifsqn.com/](http://www.ifsqn.com/)

<sup>2</sup> [www.fao.org/docrep/010/ai407e/AI407E22.htm](http://www.fao.org/docrep/010/ai407e/AI407E22.htm)

<sup>3</sup> Adkin A., Coburn H., England T., Hall S., Hartnett E., Marooney C., Wooldridge M., Watson E., Cooper J., Cox T. & Seaman M. (2004). – Risk assessment for the illegal import of contaminated meat and meat products into Great Britain and the subsequent exposure of GB livestock (IIRA): foot and mouth disease (FMD), classical swine fever (CSF), African swine fever (ASF), swine vesicular disease (SVD). Veterinary Laboratories Agency, New Haw, United Kingdom.



**REPORT OF THE MEETING OF THE OIE AD HOC GROUP  
ON ANIMAL AFRICAN TRYPANOSOMOSSES  
Paris, 6–8 March 2018**

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The first meeting of the OIE *ad hoc* Group on Animal African Trypanosomoses (hereafter referred to as the Group) was held at the OIE Headquarters in Paris from 6 to 8 March 2018.

**1. Opening of the meeting**

Dr Matthew Stone, Deputy Director General of the OIE for International Standards and Science, welcomed the Group members and the representatives from the Scientific Commission for Animal Diseases (Scientific Commission) and the Terrestrial Animal Health Standards Commission (Code Commission).

Dr Stone informed the Group that their Terms of Reference were based on a request of the African Union to include a chapter in the *Terrestrial Animal Health Code (Terrestrial Code)* on animal African trypanosomoses. He emphasised that the purpose of the *Terrestrial Code* is to support disease control, to provide recommendations for surveillance, and to promote safe international trade avoiding unjustified trade barriers. He pointed out the importance of providing scientific rationale for all the proposed provisions in the draft chapter. Finally, he stressed the need for all the members of the Group to consider *Terrestrial Code* Chapter 1.2. *Criteria for the inclusion of diseases, infections and infestations in the OIE list* when considering the hosts and pathogenic agents to be included in the case definition. He also reminded the experts of the ongoing work to draft chapters on equine trypanozoon and non-equine surra.

Dr Stone emphasised that the members of the Group were nominated by the Director General of the OIE according to their internationally recognised expertise and geographically balanced representation, but they were not representing their own countries or institutions in the meeting. He noted that all members of the Group were asked to declare any actual or potential conflict of interest and respect the confidentiality of the process.

**2. Appointment of the chairperson and rapporteur, and adoption of the agenda**

The meeting was chaired by Dr Rob Bagnall, and Dr Vincent Delespaux was appointed as rapporteur with the support of the OIE Secretariat. The draft agenda was adopted by the Group.

The Terms of Reference and adopted agenda, and List of Participants are presented as Appendices I and II, respectively of this report.

**3. Update on the current knowledge of the epidemiology, diagnostic and control strategies of animal African trypanosomoses (excluding both non-equine surra and equine *Trypanozoon*)**

Presentations entitled *The Epidemiology and Impact of Animal African Trypanosomoses*, *Animal African Trypanosomoses, Taxonomy and Diagnostic Methods*, and *Animal African Trypanosomoses Control Measures* were given by Dr Marc Desquesnes, Dr Vincent Delespaux and Dr Issa Sidibe, respectively.

Reference was also made by Dr Giuliano Cecchi to the recently developed concept of the Progressive Control Pathway (PCP) for animal African trypanosomoses (Diall *et al.*, 2017).

#### 4 Draft Terrestrial Animal Health Code Chapter 8.Y. Animal African trypanosomoses

The Group extensively discussed the scope of the new *Terrestrial Code* chapter and took into consideration the existing *Terrestrial Code* draft chapters 8.X. Infection with *Trypanosoma evansi* (non-equine surra) and Chapter 12.3. *Infection with Trypanozoon in equids (dourine, equine surra)*, which had already been circulated twice for Member Country comments.

The Group considered the comments of some Members Countries received on the draft *Terrestrial Code* chapter 8.X. and 12.3. and also extensively discussed the trypanosomes taxonomy and current diagnostic limitations.

The Group acknowledged that, in the majority of endemic countries, the diagnosis of the disease is mainly based on the identification of the parasite by direct examination techniques. However, the Group agreed that serology for antibody detection would be the most sensitive diagnostic method to determine the disease status of a country or zone.

It was highlighted that co-infection with several trypanosome species in the same animal could exist. Therefore, once IgG is detected by a species-specific ELISA<sup>1</sup> (*T. vivax* ELISA, *T. congolense* ELISA, *T. brucei* ELISA, or *T. evansi* ELISA), an animal should be considered as infected with animal African trypanosome(s), regardless of the species identified because other species may also exist.

On the other hand, it was also noted, that with appropriate surveillance and using molecular laboratory techniques in an appropriate number of samples, a country or zone could be able to gather sufficient epidemiological evidence to substantiate claims regarding the absence of certain species of trypanosomes.

Although some members of the Group felt that only one chapter that took account of all the different species of *Trypanosoma* was necessary, the Group noted that the main purpose of the draft *Terrestrial Code* chapter should be to support Members Countries in their efforts to control the disease while ensuring safe international trade. The Group proposed to limit the scope of the chapter to infection with animal trypanosomes of African origin in multiple host species, which would exclude infection with *T. evansi* (surra) and *T. equiperdum* (dourine).

##### Article 8.Y.1. General Provisions

The Group pointed out the range of trypanosome species that were considered of African origin by the scientific literature and also the diversity of potential hosts. The Group agreed that the chapter should focus on those species and domestic and wildlife hosts of epidemiological importance.

The Group assessed the different trypanosomes of African origin against the listing criteria defined in the *Terrestrial Code* chapter 1.2. It was decided, that for the purpose of this chapter, animal trypanosomes of African origin should be restricted to *T. congolense*, *T. simiae*, *T. godfreyi*, *T. vivax*, and *T. brucei*. The Group also agreed that the “susceptible animals” should be domestic and wild animals belonging to the following families: bovidae, suidae, equidae, camelidae, canidae and felidae as well as non-human primates.

The Group discussed the challenge of differentiating a species of Trypanosome within the three subgenera of the *Salivaria* section, namely Trypanozoon, Duttonella and Nannomonas; the Group suggested that a case of animal trypanosomes of African origin should be defined as either:

- i) a susceptible animal where a pathogenic agent of the Duttonella (*T. vivax*), Nannomonas (*T. congolense*, *T. simiae*, *T. godfreyi*) or Trypanozoon (*T. brucei*) subgenera has been identified; or
- ii) the presence of antibodies has been detected in a sample from a susceptible animal showing clinical signs consistent with animal trypanosomoses of African origin or which had an epidemiological link to a confirmed case in any of the susceptible animal species.

The Group considered peer-reviewed publications (Eisler *et al.*, 2001) and discussed the length of incubation periods of the disease. It was noted that the incubation period depends on different factors, including the host and the trypanosome species. The Group suggested that for the purpose of this chapter the incubation period should be 90 days.

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<sup>1</sup> ELISA: enzyme-linked immunosorbent assay

The Group was of the opinion that Member Countries should not impose bans on the trade in commodities of domestic and captive wild susceptible animals in response to a notification of infection with animal trypanosomes of African origin in wild susceptible animals if they were traded in accordance with the relevant Articles of the chapter.

#### Article 8.Y.2 Safe commodities

The Group considered *Terrestrial Code* Chapter 2.2. *Criteria applied by the OIE for assessing the safety of commodities*.

The Group agreed that pasteurised milk and milk products, hair, wool and fibre, gelatine, horns, hooves and claws, meat products, and hides and skins that have undergone standard processing procedures should be considered safe commodities.

The Group took note of the risk posed by fresh meat (Mandal *et al.*, 2017; Van Vinh Chau *et al.*, 2016). It was agreed that non-processed meat may pose a very low but not negligible risk and therefore meat should not be considered a safe commodity.

#### Article 8.Y. 3. Country or zone free from infection with animal trypanosomes of African origin

The Group considered several epidemiological scenarios for a country or zone to be declared free from the infection. The Group considered several scientific publications (Maudlin *et al.*, 2004a; Van den Bossche & De Deken, 2004; Warnes *et al.*, 1999), and agreed on the possibility and feasibility of implementing effective vector protection measures and physical separation between domestic and wildlife population.

It was suggested that a country or zone could be declared free from the infection only in susceptible domestic animals, regardless of the status of susceptible wildlife, even in the presence of competent vectors.

The Group took note of the scientific rationale of Article 15.1.3 on country or zone free from African swine fever virus and decided to follow a similar approach. The Group drafted provisions for historical freedom, freedom in all susceptible animals and freedom only in susceptible domestic and captive wild animals.

With regards to the time elapsed since the last detected case, the Group noted that, in field conditions, the persistence of antibodies (IgG) would range from 4 to 6 months (Desquesnes *et al.*, 2003). The Group also considered the challenge of conducting an epidemiological investigation, which should include serological surveys, to rule out the presence of the infection by antibody detection. Therefore, the Group agreed that 2 years would be the minimum time that should elapse for a country to be able to gather sufficient scientific evidence to substantiate freedom, providing that (i) the disease was notifiable in the entire country, (ii) an appropriate surveillance was in place and (iii) commodities from susceptible animals were imported following the recommendations of this chapter.

The Group took into consideration the role of vectors in the epidemiology of the disease and agreed to add a paragraph on the need to conduct specific entomological surveillance, as well as surveillance in zones neighbouring an infected country or zone.

#### Article 8.Y.4 Recovery of free status

The Group discussed the possibility of providing a 'fast-track' recovery procedure and took note of the Articles on recovery of free status of different existing disease-specific chapters of the *Terrestrial Code*.

The Group pointed out that appropriate treatment of infected animals would reduce the parasitaemia and would therefore reduce the risk of transmission.

The Group proposed that, if appropriate biosecurity measures are in place, the free status could be recovered earlier than 2 years provided that surveillance has been carried out during at least 180 days (2 maximum incubation periods) after the infected animals have been killed or slaughtered.

The Group also proposed that a country or zone could recover the free status 6 months after an appropriate treatment (Maudlin *et al.*, 2004b) was administered to the infected animals.

The Group discussed whether or not a test (ELISA) to detect either antigens or antibodies following treatment should be recommended for the recovery of the status. The Group took into consideration that antibodies could be present up to 6 months after treatment and that the presence of antibodies should not always be considered as an indication of infectivity. The Group decided to postpone this discussion to the next meeting. The Group agreed to draft provisions for the international trade of commodities that were not considered 'safe commodities'. It took note of the commodity-based trade articles of already existing disease-specific chapters of the *Terrestrial Code*.

Article 8.Y.5. Recommendations for importation from countries or zones free from infection with animal trypanosomes of African origin

Susceptible animals

The Group proposed that for the importation of susceptible animals from free countries or zones, the Veterinary Authorities should require the presentation of an international veterinary certificate attesting that: (1) the animals showed no clinical sign of animal trypanosomoses of African origin on the day of shipment; (2) the animals were kept in a country or zone free from animal trypanosomes of African origin since birth or was introduced in accordance with the provisions of the chapter Article 8.Y.6.

Article 8.Y.6 Recommendations for importation from countries or zones infected with animal trypanosomes of African origin

Susceptible animals

The Group proposed that for the importation of susceptible animals from infected countries or zones, the Veterinary Authorities should require the presentation of an international veterinary certificate attesting that the animals: (1) were kept in a fly-proof quarantine station isolated for at least 30 days prior to the shipment; (2) were subjected to a pathogenic agent identification test and an antibody detection ELISA adapted to the epidemiological situation with negative results on samples collected at the entrance of the quarantine station and at least 30 days after the first test; (3) were transported in a fly-proof vessel/vehicle to the place of shipment; (4) showed no clinical sign of animal trypanosomoses of African origin during the quarantine period and on the day of shipment.

The Group pointed out the significance of reactivation of parasitaemia after a period of stress such as transport (Desquesnes, 2004). Therefore, while acknowledging that recommending risk mitigation measures in the country of destination was not the normal practice of the *Terrestrial Code*, it was considered justified to recommend further risk mitigation measures (30 days of isolation period in a quarantine station and laboratory testing) in the importing country. The Group added an extra 30 days to the quarantine period in case a positive animal was detected during the isolation period, providing the positive animal was killed and the carcass properly disposed of. Consequently, a total quarantine of 90 days was suggested.

Article 8.Y.7. Recommendations for importation of semen from countries or zones free from animal trypanosomes of African origin

The Group proposed that for the importation of semen from free countries or zones, the Veterinary Authorities of the importing countries should require the presentation of an international veterinary certificate attesting that the semen came from a donor free from the pathogens and was collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 8.Y.8. Recommendations for importation of semen from countries or zones infected with animal trypanosomes of African origin

The Group proposed that for the importation of semen from infected countries or zones, the Veterinary Authorities of the importing countries should require the presentation of an international veterinary certificate attesting that the semen came from a donor free from the pathogens and will remain free based on the fact that the semen were collected in a fly-proof artificial insemination centre.

The Group noted the 90-day isolation period and test scheme recommended in Article 8.Y.6. It was suggested that the donor should be kept in isolation at least 90 days prior to semen collection and that an identification test and an antibody detection ELISA should be carried out at the entrance in the artificial insemination centre and at least 90 days after the first tests. The Group emphasised that the serological test should be adapted to the epidemiological situation of the country to ensure an appropriate sensitivity of the results.

The Group recommended that semen should also be collected, processed and stored in accordance with Chapters 4.5. and 4.6.

Article 8.Y.9. Recommendations for importation from countries or zones free from animal trypanosomes of African origin

For *in-vivo* derived embryos and for *in-vitro* produced embryos

The Group proposed that for the importation of embryos from free countries or zones, the Veterinary Authorities of the importing countries should require the presentation of an international veterinary certificate attesting that (1) the donor female was proven to be non-infected with the pathogens; (2) the semen used complied with the relevant articles of the chapter; and (3) the embryos were collected, processed and stored in accordance with Chapters 4.7. or 4.9, as relevant.

Article 8.Y.10. Recommendations for importation from countries or zones infected with animal trypanosomes of African origin

For *in-vivo* derived embryos and for *in-vitro* produced embryos

The Group proposed that for the importation of embryos from infected countries or zones, the Veterinary Authorities of the importing countries should require the presentation of an international veterinary certificate attesting that the embryos came from a donor female free from the pathogens and not at risk of infection based on the fact that the collection were carried out in a fly-proof collection centre.

Based on the recommendation for trade of semen from an infected country or zone, the Group recommended that the female donor should be kept in isolation for at least 90 days prior to the collection and that an identification test and an antibody detection ELISA should be carried out at the time of entry to the collection centre and at least 90 days after the first tests. The embryos should also be collected, processed and stored in accordance with Chapters 4.7. and 4.9., as relevant.

Article 8.Y.11. Recommendations for importation of fresh meat from countries or zones free from animal trypanosomes of African origin

The Group proposed that for the importation of fresh meat from free countries or zones, the Veterinary Authorities of the importing countries should require the presentation of an international veterinary certificate attesting that the fresh meat of susceptible animals came from animals free from the pathogens, slaughtered in an approved slaughterhouse/abattoir and subjected to ante- and post-mortem inspections with favourable results.

Article 8.Y.12. Recommendations for importation of fresh meat from countries or zones infected with animal trypanosomes of African origin

The Group proposed that for the importation of fresh meat from infected countries or zones, the Veterinary Authorities of the importing countries should require the presentation of an international veterinary certificate attesting that the fresh meat of susceptible animals came from animals that had been slaughtered in an approved slaughterhouse/abattoir and had been subjected to ante- and post-mortem inspections with favourable results.

The Group pointed out that the risk of cross-contamination after slaughter was negligible. It also noted that based on the experience of the members of the Group, the parasites are not expected to survive in meat that is kept at 4°C for more than 5 days. The Group also agreed that other effective inactivation procedures may exist and be used and therefore included this possibility in the Article.

Article 8.Y.13 General Principles of surveillance and Article 8.Y.14 General conditions and methods for surveillance

The Group took into consideration the Articles on surveillance of *Terrestrial Code* Chapter 8.3. *Infection with bluetongue virus* to develop the articles on surveillance for animal trypanosomes of African origin.

The Group highlighted the importance of considering wildlife and feral susceptible animals, as well as domestic and captive wild animals, when designing a surveillance system of animal trypanosomoses of African origin. The Group also agreed that the specific surveillance recommendations should aim at supporting Member Countries in their efforts to control the disease as well as those Member Countries aiming at demonstrating absence of infection.

The Group considered different surveillance strategies and diagnostic methods available. It was agreed that according to the purpose of the surveillance, clinical, parasitological, serological and molecular surveillance should be taken in consideration.

The Group stressed that serological surveillance for the detection of antibodies against animal trypanosomoses is key to demonstrating absence of infection. It was suggested that the presence of maternal antibodies should be considered as they could be detected in the offspring up to 6 months of age (Dwinger *et al.*, 2011). The Group stressed that any positive diagnostic result should be followed-up to rule out the presence of infection.

## 5. Other matters

Based on the Group's draft *Terrestrial Code* chapter proposal, it was recommended to amend the *Terrestrial Code* Chapter 1.3. *Diseases, infections and infestations listed by the OIE* to remove Trypanosomosis (tsetse-transmitted) from the List and to include infection with animal trypanosomes of African origin.

The Group took note of the request made by the Specialist Commissions after their February 2018 meetings to provide its expert opinion on the merit of merging infection with *T. evansi* (surra) in a single multispecies *Terrestrial Code* chapter. The Group acknowledged that surra is globally accepted as a single disease. In addition, the Group stressed that the risk mitigation measures would be very similar regardless of the host.

The Group also acknowledged the diagnostic challenge of differentiating horses infected with *T. evansi* (surra) from those infected with *T. equiperdum*, but also noted the epidemiological differences of the two diseases.

Based on the above, the Group was of the opinion that three *Terrestrial Code* chapters could be drafted:

1. Infection with animal trypanosomoses of African origin – several host and pathogen species
2. Infection with *T. evansi* – several host species
3. Infection with *T. equiperdum* –equine.

The Group could not finalise the draft chapter during the 3-day meeting and listed the pending issues that would need to be addressed before finalising the draft chapter:

1. Vector surveillance;
2. Sentinel surveillance;
3. Surveillance for demonstration of freedom;
4. Surveillance for recovery of freedom;
5. Whether or not compartmentalisation should be considered.

Another meeting could be convened by the Director General to finalise the drafting of the chapter and to consider the feedback from Specialist Commissions after their September 2018 meetings.

## 6. Adoption of the report

The *ad hoc* Group reviewed the draft report provided by the rapporteur and agreed to circulate it electronically for comments before the final adoption

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.../Appendices

Appendix I**MEETING OF THE OIE AD HOC GROUP ON ANIMAL AFRICAN TRYPANOSOMOSES**  
**Paris, 6–8 March 2018**

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**Terms of Reference**

1. Excluding both non-equine surra (infection with *T. evansi*) and equine *Trypanozoon* (infection with *T. evansi*, *T. b. equiperdum* and *T. brucei*), consider the latest scientific evidence regarding the epidemiology and control strategies for animal African trypanosomoses with a focus on the tsetse-transmitted trypanosomes. The draft chapter may include, but not be limited to:
  - a. The case definition for animal African trypanosomoses considering the listing criteria of the *Terrestrial Code* Chapter 1.2.
  - b. The elements for a national control programme for animal African trypanosomoses
  - c. The requirements for a country or zone to declare freedom from animal African trypanosomoses
  - d. The recommendations for the safe international trade of animals susceptible to animal African trypanosomoses
  - e. Specific recommendations for the surveillance of animal African trypanosomoses taking into consideration the *Terrestrial Code* Chapter 1.4 on animal health surveillance and Chapter 1.5 on surveillance for arthropod vectors of animal diseases

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**Agenda**

1. Opening of the meeting
  2. Appointment of chairperson and rapporteur, and adoption of the agenda
  3. Update on the current knowledge of the epidemiology, diagnostic and control strategies of animal African trypanosomoses (excluding both non-equine surra and equine *Trypanozoon*)
  4. Draft *Terrestrial Animal Health Code* Chapter 8.Y *Animal African trypanosomoses*
  5. Other matters
  6. Adoption of the report
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Appendix II**MEETING OF THE OIE AD HOC GROUP ON ANIMAL AFRICAN TRYPANOSOMOSES**

Paris, 6–8 March 2018

**List of Participants****MEMBERS**

**Marc Desquesnes**  
UMR177-Intertryp (CIRAD-IRD)  
CIRAD-bios  
Campus international de Baillarguet  
TA A-17 / G  
34398 Montpellier Cedex 5  
FRANCE  
[marc.desquesnes@cirad.fr](mailto:marc.desquesnes@cirad.fr)

**William Shereni**  
Tsetse Control Division  
Department of Livestock and Veterinary  
Services  
Ministry of Lands, Agriculture and  
Rural Resettlement,  
ZIMBABWE  
[shereni2005@yahoo.com](mailto:shereni2005@yahoo.com)

**Issa Sidibe**  
Insectary and Tsetse and  
Trypanosomiasis Programme  
IBD-CETT 01 BP 1087  
Bobo-Dioulasso 01  
BURKINA FASO  
[sambo@fasonet.bf](mailto:sambo@fasonet.bf)

**Mary Isabel Gonzatti**  
Simon Bolivar University Department  
of Cellular Biology Miranda  
VENEZUELA  
[mgonzat@usb.ve](mailto:mgonzat@usb.ve)

**Rob Bagnall**  
Former Deputy Director Veterinary  
Services KwaZulu Natal  
Hemel en Aarde Estate  
Hermanus, 7200  
SOUTH AFRICA  
[robbagnall@telkomsa.net](mailto:robbagnall@telkomsa.net)

**Vincent Delespaux**  
Scientific coordinator  
Vrije Universiteit Brussel (VUB),  
Brussels  
BELGIUM  
[vincent.delespaux@vub.be](mailto:vincent.delespaux@vub.be)

**OTHER PARTICIPANTS**

**Giuliano Cecchi**  
Subregional Office for Eastern Africa  
Food and Agriculture Organization of the United Nations  
(FAO)  
CMC Road, Bole Sub City, Kebele 12/13  
P O Box 5536, Addis Ababa  
ETHIOPIA  
[Giuliano.Cecchi@fao.org](mailto:Giuliano.Cecchi@fao.org)

**Jose Ramón Franco Miguell**  
*(Invited but could not attend)*  
Medical Officer  
Human African Trypanosomiasis Programme  
Innovative & Intensified Disease Management  
World Health Organization (WHO)  
Geneva, SWITZERLAND  
[francoj@who.int](mailto:francoj@who.int)

**SPECIALIST COMMISSION REPRESENTATIVES**

**Baptiste Dungu**  
Member of the Scientific Commission for Animal diseases  
MCI-Santé Animale  
26 Dalrymple Crescent  
Edinburgh EH9 2NX  
UNITED KINGDOM  
[b.dungu@mci-santeanimale.com](mailto:b.dungu@mci-santeanimale.com)

**Emmanuel Couacy-Hyman**  
Member of the Terrestrial Animal Health Standards  
Commission  
Virologist – Epidemiologist  
Laboratoire Centrale de Pathologie Animale  
BP 206 - Bingerville  
COTE D'IVOIRE  
[chymann@hotmail.com](mailto:chymann@hotmail.com)

**OIE HEADQUARTERS**

**Matthew Stone**  
Deputy Director General  
12 rue de Prony, 75017 Paris  
FRANCE  
Tel: 33 - (0)1 44 15 18 88  
Fax: 33 - (0)1 42 67 09 87  
[m.stone@oie.int](mailto:m.stone@oie.int)

**Gregorio Torres**  
Chargé de mission  
Science and New Technologies  
Department  
[g.torres@oie.int](mailto:g.torres@oie.int)

**François Diaz**  
Chargé de mission  
Science and New Technologies  
Department  
[f.diaz@oie.int](mailto:f.diaz@oie.int)

## Appendix III

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**REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON PRIORITISATION OF DISEASES  
FOR WHICH VACCINES COULD REDUCE ANTIMICROBIAL USE IN CATTLE, SHEEP, AND GOATS  
Paris, 7 -9 May 2018**

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**1. Opening**

The OIE *ad hoc* Group on Prioritisation of Diseases for which Vaccines could reduce Antimicrobial Use in cattle, sheep, and goats met from 7 to 9 May 2018 at the OIE Headquarters in Paris, France.

Dr Matthew Stone, Deputy Director General International Standards and Science of the OIE, welcomed the participants and introduced the OIE, its mission, its standard setting and animal health reporting activities, and its approach to providing scientific advice. He commented on the growing OIE efforts toward increasing transparency in the animal health situation globally, also through the development of guidelines and recommendations on priority areas for Veterinary Services at the international level.

Dr Stone reaffirmed the OIE position that antimicrobials are essential tools for protecting and maintaining animal health and welfare when used responsibly and prudently, and that the use of antimicrobials for growth promotion is to be avoided, as it is contrary to the principle of prudent use.

Dr Stone highlighted the growing importance of combatting antimicrobial resistance (AMR) and the OIE contribution to the international efforts to fight it, also in the framework of the Global Action Plan on AMR. He explained that the work is mainly distributed on two pillars, the development of a monitoring and evaluation framework, for which the OIE is refining, with its Tripartite partners, the WHO and the FAO, a set of indicators to be used at the global level to support Members in establishing their national action plans, and the development of a stewardship framework, addressing research and development (R&D), prudent use and access. As part of its standard setting mandate, the OIE established standards for the Harmonisation of national antimicrobial resistance surveillance and monitoring programmes and for the Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals in its Terrestrial Animal Health Code, which were recently revised and will be proposed for adoption at the upcoming General Session in May 2018, together with the updated OIE List of Agents of Veterinary Importance. An OIE *ad hoc* Group on AMR, which was formed in 2000, and has met periodically since that time, has overseen the development and revision of these standards and recommendations.

The second OIE annual report on the use of antimicrobial agents intended for use in animals was published in 2017. Dr Stone commented that the number of Members engaged with the data collection is increasing, and that the report offered several reporting options for Members, allowing quantitative reporting of antimicrobial use. Another important element of the OIE AMR activities was the training of the OIE National Focal Points for Veterinary Products, which are provided to build capacities and knowledge, including on the market authorisation process and to drive Focal Point engagement in the national action plans.

Dr Stone informed the Group that the OIE is involved in the activities of the STAR-IDAZ International Research Consortium, a forum of public and private R&D programme owners/managers aiming to coordinate research on animal health at global level, for which it co-hosts the Secretariat. This collaboration would facilitate the uptake of the Group recommendations by research funders, ensuring impact. Similarly, the collaboration with GALVmed would support the picking up on the recommendations to develop specific vaccination which suits their mandate.

## 2. Appointment of chairperson and rapporteurs, and adoption of the agenda

The Group appointed Dr Cyril Gay as the chairperson of the meeting and Professor David Jordan agreed to act as rapporteur.

The Agenda, which was adopted without changes, and the List of Participants are presented in [Appendices I and II](#) of this report, respectively.

## 3. Background to the meeting

Dr Elisabeth Erlacher-Vindel, Head of the Science and New Technologies Department, provided background information on the reasons for convening the *ad hoc* Group. To address requests from several Countries and organisations for information on where to target research to reduce the use of antimicrobials in animals, in 2015 the OIE convened a first *ad hoc* Group aiming to identify priority diseases in chickens, swine and fish. The current Group represented a follow up on this approach, to identify priority diseases for cattle, sheep, and goats.

Dr Erlacher-Vindel explained the rationale and work performed by the first *ad hoc* Group and presented the process that was followed for agreeing on the tables for reporting and for ranking priorities. She suggested that the new Group might want to consider improving the definition of categorisation of research priorities.

Dr Erlacher-Vindel highlighted that the work of these *ad hoc* Groups is part of the provision of scientific advice activities of the OIE and is not directly related to its standard-setting activities. She emphasised that the focus of the discussions should not be on vaccine development itself, but rather on the capacity of reducing the use of antimicrobial agents through vaccination. While it was recognised that other practices need to be also implemented to reduce antimicrobial use, only vaccination should be covered by the Group.

The participants introduced themselves to the Group and presented relevant background information from their specific fields of expertise.

## 4. Review and address the Terms of Reference for the *ad hoc* Group meeting

The Group heard the background information presented by the participants and considered the draft Terms of Reference (ToR) (attached in [Appendix III](#) of this report).

The Group discussed considering water buffalo in the ToR. It was finally decided that, although water buffalo is an important species in some regions, for the time being this *ad hoc* Group should focus on *Bos taurus* and *Bos indicus* only, since these species are more globally farmed than other bovidae. The Group agreed that no inter-species prioritisation should be performed.

The Group proposed minor adjustment to the ToR for the meeting.

The Group noted that, while regional perspectives should be taken into consideration for some aspects, bacterial and non-bacterial diseases should be ranked based on their importance at global level. The ToR were amended accordingly.

The Group agreed that, while the cost of vaccine was important, it was more appropriate to refer to ‘barrier to adoption’, which encompasses cost-prohibition and also includes vaccine distribution. The ToR were amended accordingly.

The Group recognised that some vaccines have marginal benefit and are based on older technologies, and this can result in high use of antimicrobials. The availability of modern technologies and knowledge might be utilised to deliver enhanced vaccines, but would require significant investment in research and development.

The Group discussed on which particular stakeholders and interested parties should be considered as the target audience for the report. It was agreed that, in particular, public funders are a key stakeholder, and there were examples of uptakes of the recommendations of the first *ad hoc* Group by public funders. The Group noted that the report would also help public and private research and development institutions to prioritise their investment. Furthermore, the report would be a useful resource for national and international policy makers in animal health. It was pointed out that, especially for diseases that are not financially attractive

targets for investments by pharmaceuticals companies (*e.g.* neglected diseases), donor support would be critical to ensure vaccine development.

The Group agreed that zoonotic agents that do not cause disease in animals, and thus do not directly lead to use of antimicrobial agents use in animals, were out of the scope of the current *ad hoc* Group.

## 5. Refine template and criteria for the ranking of diseases

The possibility of dividing the Group into two subgroups, one looking at cattle and the other one at small ruminants, was considered. The participants presented their expertise on the different species: since most experts had experience in several of the species covered by the ToR, it was agreed that it would be more effective to conduct the work with the Group as a whole.

The Group agreed that cattle, sheep, and goats were to be discussed separately.

The Group discussed about targeting dairy and meat cattle separately and agreed that this would create additional and unnecessary complexity to the tables. It was agreed that references would be made in the report if a specific priority applied to a specific subgroup only (*e.g.* if the identified priorities relate to dairy or meat animals, or to feedlot or grass-fed animals). This same principle was applied to sheep and goats.

The participants discussed the adoption of the template and guiding criteria for the ranking of diseases used by the *ad hoc* Group convened on this subject in 2015.

Although it was recognised that not all antimicrobial agents would have the same relevance from an antimicrobial resistance (AMR) viewpoint, the Group decided to highlight diseases for which the highest volumes of antimicrobials would be used, in the context of the rate of disease occurrence.

The Group noted that, in many cases, a reduction of use of antimicrobial agents in cattle, sheep, and goats could be achieved by effective vaccines against a viral or parasitic disease, since the clinical signs of infection with some of these pathogens are often similar to bacterial diseases, and bacterial infections can develop secondarily, thus necessitating antimicrobial agent therapy.

The Group agreed that the focus should be on identification of diseases where a new or improved vaccine would have the maximum effect on reducing the use of antimicrobial agents in cattle, sheep, and goats.

The Group discussed and agreed that the following criteria would be applied for ranking research priorities:

- High priority: The agent or the disease/syndrome results in a high use of antimicrobial agents and there are no readily available vaccines, or the vaccines are suboptimal in terms of efficacy or safety or practicality, or are cost-prohibitive.
- Medium priority: The agent or the disease/syndrome results in a medium use of antimicrobial agents and there are no readily available vaccines, or the vaccines are suboptimal in terms of efficacy or safety or practicality, or are cost-prohibitive.
- Low priority: The agent or the disease/syndrome results in a low use of antimicrobial agents, regardless of whether a vaccine is readily available and effective.

The Group ranked the vaccine research priorities for each syndrome/pathogen based firstly on the use of antimicrobial agents as above. The Group then adjusted this preliminary ranking based upon current vaccine availability and quality, and on the technical knowledge necessary to develop or improve vaccines to reduce antimicrobial use.

The Group decided to separate the diseases entailing high and medium use of antimicrobials from the ones which implies lower use by listing the diseases in two separate tables, with the latter ones noted in Appendices. This will help simplify the tables and better emphasise the priorities. Nevertheless, the Group highlighted that some diseases that are scored as having low use of antimicrobials at a global level, might still be a considered a high priority at a regional level.

The Group proposed that a focus for research should include studies to demonstrate that vaccine could reduce use of antimicrobial agents under field condition, as this information might serve to increase the uptake of existing vaccines that are underutilised.

It was noted that, in some cases, vaccines might exist but are not used due to lack of availability (*e.g.* problems linked to delivery system, registration, access). This problem is more common in some regions, where antimicrobial agents are more accessible to farmers than vaccines and where veterinarians and veterinary paraprofessionals guidance is lacking, ultimately leading to poor antimicrobial stewardship. Poor access to diagnostic services may also contribute to poor antimicrobial stewardship. In these circumstances, the culture of preventive vaccination often receives relatively little emphasis, and farmers primarily rely on therapeutic antimicrobial products. The Group agreed that, while it would be interesting to identify regional-specific barriers to adoption of vaccines leading to a reduction in the use of antimicrobial agents, this was out of the scope of the Group ToR.

It was noted that, for many pathogens, effective vaccines already exist. However, the degree, breadth, level of global distribution, consistency of supply, or duration of protection afforded was not optimal, thus providing a barrier to the uptake of the vaccine.

## 6. Rank diseases for the two focus areas

### 6.1. Key principles adopted

In order to facilitate identification of infections where new or improved vaccines would have the maximum potential to reduce antimicrobial use, a number of categories were investigated:

1. Identification of the most prevalent and important bacterial infections in cattle, sheep, and goats that are associated with high antimicrobial use.
2. Identification of common non-bacterial infections in cattle, sheep, and goats showing clinical signs that trigger empirical antimicrobial treatment (*e.g.* for diarrhoea) and which also result frequently in bacterial co-infection.
3. An assessment of antibiotic use in response to the syndromic indication or diagnosed disease. This was categorised as high, medium or low in the context of considered use compared with the total use of antimicrobial agents in that animal species.
4. The availability of a vaccine(s), and if available, their effectiveness.
5. The potential for a new or improved vaccine to reduce the need for antimicrobial treatment.

Also considered out of scope were autogenous vaccines, primarily because of lack of broad applicability across regions, registration variability and the absence of global efficacy data.

### 6.2. Limitations

As a consequence of adopting the above criteria, it became evident that there were many data gaps. For example, key information such as a current list of all available vaccines that have marketing authorisation, amount of antimicrobials used for different infections, and the relative incidence of different infections worldwide are not available. In addition, since only a few scientific studies, if any, have investigated the use of antimicrobial agents related to viral diseases, relying solely on objective quantitative data was not feasible. Lastly, the large number of diseases assessed was such that it was not possible to perform a comprehensive bibliographic review.

Based on the above limitations, conclusions of the report are based on considerations weighted primarily on the participating experts' professional knowledge and advice.

Due to its global focus, regional and national differences could not be accommodated by this report. Nevertheless, the report provides a framework for regions and countries to adopt a similar process for prioritising diseases.

### 6.3. Cattle diseases

#### Respiratory

The bovine respiratory disease complex (BRD) is a multifactorial disease attracting high level of antimicrobial use in cattle, especially in feedlots. For vaccine development, a syndromic, multi-pathogen, approach would be preferable to address all animal health risks. The Group suggested that regulatory agencies' performance requirements for licensing of vaccines might not reflect how these vaccines subsequently perform in the field. The need for DIVA (Differentiating Infected from Vaccinated Animals) vaccines was discussed. However, BRD is primarily a production-limiting disease rather than a regulated disease for domestic or international trade. Thus, the experts agreed that incorporating DIVA functionality in vaccines for BRD would have a low relevance, and would be unlikely used to support decisions on domestic or international trade. Where evidence of compliance with vaccination is needed, other opportunities exist.

The major organisms involved are:

- a. *Mannheimia haemolytica*: Regarded as a primary pathogen and features a lack of cross protection among different strains;
- b. *Pasteurella multocida*: Regarded both as a primary and a secondary pathogen. It was recognised that the existing vaccines notably have marginal efficacy and there is a potential lack of cross protection among *P. multocida* field isolates;
- c. *Histophilus somni*: Regarded as an opportunistic pathogen, that is less common and for which it was difficult to know the efficacy of the available vaccines under field conditions;
- d. Bovine viral diarrhoea virus (BVDV): Considered by the group to be the viral pathogen that elicits the most significant use of antimicrobial agents in BRD;
- e. *Mycoplasma bovis*: The Group agreed that the role in BRD was lower than for other pathogens, and that although it was found with increasingly higher occurrence, its role as a causal agent in BRD was uncertain;
- f. Parainfluenza virus 3 (PI3), BHV-1 (IBR): Both these viruses were recognised as being lesser contributors to antimicrobial use, and existing vaccines are effective and safe. For IBR, DIVA vaccines have been shown to be useful for eradicating the disease in several countries of Europe;
- g. Bovine respiratory syncytial virus (BRSV): Adequate vaccines are available;
- h. Bovine coronavirus: Recognised as an emerging respiratory pathogen. While a vaccine is available, its efficacy is uncertain.

Apart from BRD, the Group considered another respiratory disease as within the scope, Contagious Bovine Pleuropneumonia (CBPP, *Mycoplasma mycoides subsp. mycoides*). CBPP is one of the most relevant diseases in Africa, where it entails high use of antimicrobial agents, which could lead to establishment of a carrier state. Vaccines have low efficacy, their access is limited to official control programmes, and have short duration of immunity and safety issues (residual virulence).

*Dictyocaulus viviparus* (lungworm) was also considered as relevant to cattle health, but the use of antimicrobials was not considered high enough to warrant including this pathogen in the list.

#### Mastitis

The main causal agents of cattle mastitis were considered: *Streptococcus agalactiae*, *Streptococcus uberis*, Coagulase negative *Staphylococci*, *Staphylococcus aureus*, *Escherichia coli*, and *Mycoplasma bovis*. The Group agreed that antimicrobial use for mastitis was higher in modern, intensive dairy production as compared to grass-based production. Most of these agents provoked high use of antimicrobials, with the exception of *E. coli*, and *M. bovis*. The Group agreed that it was common practice to treat the disease and select for less susceptible animals through culling practices, rather than

to prevent it through vaccination. The occurrence of multiple strains, the lack of cross-protection of available vaccines, and the difficulty of building a specific immune response at the site of infection were identified as a current difficulty. The Group recognised that other pathogens could provoke mastitis, but have a low impact on antimicrobial use, and thus were not discussed.

One hurdle associated with the development of mastitis vaccines for cattle is the broad coverage provided by the current dairy antimicrobial treatment strategies. Dry cow therapies provide control against a number of different contagious and environmental pathogens. From a herd perspective, development of a vaccine against individual pathogens will not eliminate the need for control of the other pathogens often found in infected cows. Development of combination vaccines that address the common mastitis pathogens would offset this issue, but represents a difficult technical challenge that would require a significant investment in research and development.

### Lameness

Lameness is a priority issue for the dairy sector, together with mastitis. The Group identified interdigital and digital dermatitis as the dominant lameness syndromes attracting antimicrobial use. *Fusobacterium necrophorum* is the main causal agent in cattle. It provokes significant use of antimicrobials, and vaccines are not globally available. *Trueperella pyogenes* and *Treponema spp.* were also discussed. While both these agents are often present in lame cows, their role as causative agents for lameness needs further investigation.

### Enteric

Enteric diseases are an important cause of antimicrobial use, especially in feedlot systems. *Fusobacterium necrophorum* entails high use of antimicrobials, especially in feedlots, arising from acidosis. No vaccines are labelled for enteric disease/acidosis/liver abscesses; and off-label use of *F. necrophorum* vaccines designed for other diseases provides limited efficacy.

*Salmonella enterica* is a notable zoonotic disease involving antimicrobial resistance. The disease's greatest effects on animals are in dairy calves soon after birth, which are exposed to the challenge before the onset of immunity that might be derived from vaccination. *Salmonella spp.* vaccines are available to address the prevalent subspecies/serotypes in the various regions (e.g. *S. enterica* serotype Dublin, *S. enterica* serotype Newport, *S. enterica* serotype Typhimurium). These vaccines are generally used in herd programmes to control the level of *Salmonella spp.* bioburden within the vaccinated herd, leading to lower levels of *Salmonella spp.* exposure to the new animals entering in the herd. This then results in a lower level of the disease.

Enterotoxigenic *E. coli* provokes a high use of antimicrobials, especially in dairy farms. Effective vaccines do exist, but are not available in every region.

Bovine rotavirus and bovine coronavirus are also causal agents of neonatal diarrhoea in calves, which may be treated with antimicrobials because the cause of symptoms is frequently undifferentiated. Rotavirus infections, being more prevalent than coronavirus, are likely to attract higher use of antimicrobials. In both cases, effective vaccines exist, even if with limited geographic availability.

Johne's disease (*Mycobacterium avium subsp. paratuberculosis*) was judged to entail medium use of antimicrobials. The condition is often undiagnosed or misdiagnosed, and maybe mistaken for other forms of bacterial enteritis. Vaccine availability is geographically limited, and existing products present several drawbacks. The Group agreed that DIVA vaccines would provide advantages for disease management, trade and movement of animals.

*Cryptosporidium parvum* and *Eimeria spp.* were viewed to provoke medium use of antimicrobial agents, being higher in regions where syndromic treatment is provided without relying on diagnostics. Currently, no vaccines are available. In a similar manner, helminths were also considered as contributing to inappropriate antimicrobial use, and this is likely to vary between different regions, depending on the quality of veterinary services. The Group agreed to assign helminths-vaccine research as a high priority because of the additional advantage of reducing anthelmintic resistance. *Trueperella pyogenes* was considered out of scope, due to the low use of antimicrobials at a global level, and/or the availability of effective vaccines. BVDV was also excluded, since there was an acknowledgement that BVDV is no longer considered an important enteric pathogen.

### Systemic

The Group discussed several pathogens causing infections of a systemic nature:

- *P. multocida* (Haemorrhagic septicaemia): Provokes high use of antimicrobials, even though the existing vaccines appear effective. Thus, research into vaccine for this agent was not deemed a priority;
- *Leptospira spp.*: Entails medium use of antimicrobials, and the Group observed that regional differences in serovars act to limited vaccine availability and use;
- *Bacillus anthracis*: Prophylactic antimicrobial treatment in affected herds is performed in some regions, leading to medium antimicrobial use, even though effective vaccines are available.

### Reproductive

Metritis/endometritis syndrome associated with *T. pyogenes*, *E. coli*, and *F. necrophorum* was considered. The Group agreed that this syndrome entails high use of antimicrobials, and that existing vaccines are not registered for metritis.

### Cutaneous

The Group discussed about *Dermatophilus congolensis* (rain scald), which causes severe skin infections in cattle. This pathogen entails medium use of antimicrobials under certain climatic conditions, and no vaccines are available.

### Vector-borne

Vector-borne pathogens in cattle were considered. *Anaplasma marginale* was considered a major contributor to antimicrobial use; vaccines are effective but have limitations in availability and administration. *Ehrlichia ruminantium* (heartwater) is present in several regions, where it imposes high antimicrobial use. High use of antimicrobials and absence of vaccine for *Trypanosoma spp.* were noted, and major research challenges were identified for vaccine development for these pathogens. Theileriosis (due to *T. parva* and *T. annulata*, depending on the region) is a major issue in some regions, where it causes high use of antimicrobials. Nevertheless, the impact on antimicrobial use at global level is medium. Vaccines are available for some but not all of the main *Babesia spp.* causing disease in cattle (*B. bigemia*, *B. divergens*, *B. bovis*), which entails a medium use of antimicrobials.

The Group highlighted that, in some regions, antimicrobial use is associated with tick infestation to control tick-borne pathogens. Vaccines exist against some individual tick species (*i.e. Rhipicephalus microplus*); vaccines against multiple species of ticks could be a useful tool for reducing antimicrobial use.

The Group also discussed several transboundary diseases, *i.e. Mycobacterium bovis*, *Brucella abortus*, bluetongue virus, foot-and-mouth disease virus, lumpy skin disease virus, and *Coxiella burnetii*, and agreed that antimicrobial treatment was largely uncommon for these diseases. Several *Clostridium* species were considered also, but were not addressed further for the same reason. Nevertheless, in some regions antimicrobial treatment might be applied (due to lack of diagnosis), but without major impact on antimicrobial use at global level.

Pathogens/diseases which entail high and medium use of antimicrobial agents in cattle are reported in Table 1. Other relevant pathogens/diseases which entail low use of antimicrobials are reported in Appendix IV.

**Table 1: Pathogens/diseases which entail high and medium use of antimicrobial agents and for which vaccines would significantly reduce the need for antibiotic use in cattle**

Key syndrome / Disease	Primary pathogen(s)	Antimicrobial Use [High, Medium, Low]	Commercial vaccine exists* [Yes/No]	Major constraints to use of vaccine / vaccine development	Vaccine Research Priority [High, Medium, Low]
<b>Respiratory</b>	<i>Mannheimia haemolytica</i> (Bovine Respiratory Disease Complex, BRD)	High	Yes	<ul style="list-style-type: none"> <li>Timely delivery (time of vaccination in relation to natural challenge)</li> <li>Onset of immunity (one dose versus two doses)</li> <li>Differences in serotype</li> <li>Potential lack of cross-protection</li> <li>Leukotoxin content in some vaccines is not controlled</li> </ul>	High
	<i>Pasteurella multocida</i> (BRD)	High	Yes	<ul style="list-style-type: none"> <li>Timely delivery</li> <li>Marginal efficacy</li> <li>Potential lack of cross-protection</li> </ul>	High
	<i>Mycoplasma mycoides subsp. mycoides small colony</i> (Contagious Bovine Pleuropneumonia, CBPP)	High	Yes	<ul style="list-style-type: none"> <li>Marginal efficacy</li> <li>Short duration of immunity</li> <li>Safety (live vaccine with residual virulence)</li> <li>Access limited to official control programmes</li> </ul>	High
	<i>Histophilus somni</i> (BRD)	High	Yes	<ul style="list-style-type: none"> <li>Timely delivery</li> <li>Adverse reactions when used in large combinations</li> <li>Basic research needed on epidemiology and pathogenesis</li> </ul>	Medium
	Bovine Virus Diarrhoea Virus (BRD)	High	Yes	<ul style="list-style-type: none"> <li>Timely delivery</li> <li>Maternal antibody interference</li> <li>Not all vaccines protect against Type 1 and Type 2, and Hobi-like viruses</li> </ul>	Medium
	<i>Mycoplasma bovis</i> (BRD)	Medium	Yes	<ul style="list-style-type: none"> <li>Timely delivery</li> <li>Limited efficacy</li> <li>Vaccine not available in all countries</li> <li>More research needed on epidemiology and pathogenesis</li> <li>Lack of challenge model</li> <li>Co-infections</li> </ul>	High
<b>Mastitis</b>	<i>Streptococcus agalactiae</i>	High	Yes	<ul style="list-style-type: none"> <li>Marginal efficacy</li> <li>Strain variation</li> <li>Lack of cross-protection</li> <li>Multiple doses needed for efficacy</li> </ul>	High
	<i>Streptococcus uberis</i>	High	Yes	<ul style="list-style-type: none"> <li>Marginal efficacy</li> <li>Strain variation</li> <li>Lack of cross-protection</li> <li>Multiple doses needed for efficacy</li> </ul>	High
	Coagulase negative <i>Staphylococci</i>	High	Yes	<ul style="list-style-type: none"> <li>Marginal efficacy</li> <li>Strain variation</li> <li>Lack of cross-protection</li> <li>Multiple doses needed for efficacy</li> </ul>	High
	<i>Staphylococcus aureus</i>	High	Yes	<ul style="list-style-type: none"> <li>Marginal efficacy</li> <li>Strain variation</li> <li>Lack of cross-protection</li> <li>Multiple doses needed for efficacy</li> </ul>	High

Key syndrome / Disease	Primary pathogen(s)	Antimicrobial Use [High, Medium, Low]	Commercial vaccine exists* [Yes/No]	Major constraints to use of vaccine / vaccine development	Vaccine Research Priority [High, Medium, Low]
Lameness (interdigital and digital dermatitis)	<i>Fusobacterium necrophorum</i>	High	Yes	<ul style="list-style-type: none"> <li>• Cost prohibitive</li> <li>• Limited efficacy</li> <li>• Limited availability</li> </ul>	High
Enteric	<i>Fusobacterium necrophorum</i>	High	Yes	<ul style="list-style-type: none"> <li>• No products labelled for this application. When used off-label, limited efficacy for enteric diseases/acidosis/liver abscess</li> </ul>	High
	<i>Salmonella enterica subsp. enterica</i>	High	Yes	<ul style="list-style-type: none"> <li>• Predominant serotypes (e.g. Typhimurium, Dublin) vary between geographic regions</li> <li>• Lack of cross-protection between serotypes</li> <li>• In dairy calves, exposure precedes onset of active immunity following vaccination</li> <li>• Limited availability</li> </ul>	Medium
	Enterotoxigenic <i>Escherichia coli</i>	High	Yes	<ul style="list-style-type: none"> <li>• Effective vaccines available for predominant strains</li> </ul>	Low
	Rotavirus	High	Yes	<ul style="list-style-type: none"> <li>• Reasonable efficacy of vaccine</li> <li>• Limited geographic availability</li> </ul>	Low
	Helminth enteric parasites	Medium	No	<ul style="list-style-type: none"> <li>• Need research in vaccine technology for multi-cellular parasites</li> </ul>	High
	<i>Cryptosporidium parvum</i>	Medium	No	<ul style="list-style-type: none"> <li>• Research and development investment needed</li> </ul>	Medium
	<i>Mycobacterium avium subspecies paratuberculosis</i> (Johne's disease)	Medium	Yes	<ul style="list-style-type: none"> <li>• Existing vaccines have safety and performance issues (including potential cross reactions on TB test)</li> <li>• Require new vaccine technologies</li> <li>• Need DIVA vaccine</li> <li>• User safety</li> <li>• Injection site reactions from experimental vaccines</li> <li>• Limited distribution</li> </ul>	Medium
	<i>Eimeria spp.</i>	Medium	No	<ul style="list-style-type: none"> <li>• Research and development investment needed</li> </ul>	Medium
	Bovine coronavirus	Medium	Yes	<ul style="list-style-type: none"> <li>• Satisfactory efficacy of vaccines</li> <li>• Limited geographic availability</li> </ul>	Low
Systemic	<i>Pasteurella multocida</i> (haemorrhagic septicaemia)	High	Yes	<ul style="list-style-type: none"> <li>• Satisfactory vaccines, but issues with availability</li> </ul>	Low
	<i>Leptospira spp.</i>	Medium	Yes	<ul style="list-style-type: none"> <li>• Limited efficacy, due to regional differences in serovars</li> </ul>	Medium
	<i>Bacillus anthracis</i> (anthrax)	Medium	Yes	<ul style="list-style-type: none"> <li>• Effective vaccines available</li> </ul>	Low
Reproductive	<i>Trueperella pyogenes</i>	High	No	<ul style="list-style-type: none"> <li>• No vaccine labelled for metritis</li> </ul>	High
	<i>Fusobacterium spp.</i>	High	No	<ul style="list-style-type: none"> <li>• No vaccine labelled for metritis</li> </ul>	High
	<i>Escherichia coli</i>	High	No	<ul style="list-style-type: none"> <li>• No vaccine labelled for metritis</li> </ul>	High
Cutaneous	<i>Dermatophilus congolensis</i> (rain scald)	Medium	No	<ul style="list-style-type: none"> <li>• Lack of a challenge model</li> <li>• Difficult to grow the pathogen for vaccine production</li> </ul>	Medium

Key syndrome / Disease	Primary pathogen(s)	Antimicrobial Use [High, Medium, Low]	Commercial vaccine exists* [Yes/No]	Major constraints to use of vaccine / vaccine development	Vaccine Research Priority [High, Medium, Low]
Vector-borne	<i>Anaplasma marginale</i>	High	Yes	<ul style="list-style-type: none"> <li>Vaccine production based on live animal infection</li> <li>Limited availability</li> <li>Difficult administration</li> <li>Adequate efficacy</li> </ul>	High
	<i>Ehrlichia ruminantium</i> (heartwater)	High	Yes	<ul style="list-style-type: none"> <li>Low production capacity</li> <li>Lack of strain specificity</li> <li>Vaccine production based on live animal infection</li> <li>Limited availability</li> <li>Difficult administration</li> <li>Adequate efficacy</li> </ul>	High
	<i>Trypanosoma spp.</i>	High	No	<ul style="list-style-type: none"> <li>Antigenic variation for African Animal Trypanosomosis (AAT)</li> </ul>	High
	Bluetongue virus	Medium	Yes	<ul style="list-style-type: none"> <li>Strain specific vaccine</li> <li>Partial cross-protection</li> <li>Potential reversion to virulence for live attenuated vaccines</li> <li>Caution for use in pregnant animals</li> </ul>	High
	<i>Babesia spp.</i>	Medium	Yes	<ul style="list-style-type: none"> <li>Vaccines not available for all species</li> <li>Low production capacity</li> <li>Vaccine production based on live animal</li> <li>Limited availability</li> <li>Difficult administration</li> <li>Adequate efficacy</li> </ul>	Medium
	<i>Theileria parva</i>	Medium	Yes	<ul style="list-style-type: none"> <li>Infection and treatment method (ITM) vaccine</li> <li>Adequate efficacy</li> <li>Difficult administration</li> <li>Residual virulence</li> <li>Limited availability</li> <li>Cost</li> </ul>	Medium
	<i>Theileria annulata</i>	Medium	Yes	<ul style="list-style-type: none"> <li>Cold chain required</li> <li>Low production capacity</li> <li>Limited availability</li> </ul>	Medium
	Ticks	Medium	Yes	<ul style="list-style-type: none"> <li>Limited species coverage</li> <li>Vaccine only available in limited countries</li> </ul>	Medium

\* does not cover autogenous vaccines

#### 6.4. Sheep Diseases

##### Respiratory

Ovine respiratory disease is a multifactorial disease attracting a high level of antimicrobial use in sheep, especially in grain-fed systems. *M. haemolytica* (regarded as a primary pathogen) and *P. multocida* (regarded as a primary or secondary pathogen) are the main agents involved, and attract a high use of antimicrobials. Most of the existing vaccines target both agents, but have marginal efficacy. *Mycoplasma ovipneumoniae* can also play an important role in the syndrome. In contrast to cattle, viral agents (*i.e.* PI3) were considered as lesser contributors.

The virus causing peste des petits ruminants (PPR) was considered. While PPR is a systemic disease, respiratory complications are one of the major clinical signs and thus antimicrobial agents are used. Vaccines are effective and safe. The experts highlighted that there was a relatively low use of vaccines in some endemic countries when there is low compliance with official programmes. DIVA and combination vaccines are available. Despite the impact of the disease, the Group agreed that its relevance in terms of research priority for development of vaccine to reduce antimicrobial use would be low.

### Mastitis

*Mycoplasma agalactiae*, one of the causal agents of classical contagious agalactia (an OIE listed disease), was considered. The disease is present in several regions and is becoming more widespread. While vaccines are available, the disease provokes medium antimicrobial use.

The main causal agents of sheep mastitis were considered to be *M. haemolytica*, Coagulase-negative *Staphylococci*, and *Staphylococcus aureus*. The Group agreed that antimicrobial use for this syndrome was generally medium in sheep, depending on the farming practices (*i.e.* higher in intensive production). Unlike cattle, vaccines for these causes of mastitis do exist and are effective. However, their uptake is low due to lack of awareness of vaccine options. While the Group recognised that there are other pathogens that could provoke mastitis in sheep, they have low impact on antimicrobial use, and so were not considered further.

### Lameness

Lameness is a priority issue for sheep production, and provokes significant use of antimicrobial agents. Ovine virulent footrot (*Dichelobacter nodosus*) was discussed: commercial multi-strain vaccines provide short duration and offer poor cross-serotype protection. However, farm-specific vaccines customised to one or two serogroups that are present, although expensive, provide highly effective immune response and can cure infected sheep. Research is underway to overcome interference resulting in short duration immunity induced by multi-strain vaccines, by developing a common-antigen vaccine. No vaccine is available for *F. necrophorum* (foot scald, foot abscess), provoking high use of antimicrobials. Vaccines exist for *Trueperella pyogenes* (foot scald), and *Corynebacterium pseudotuberculosis* (foot abscess), but have limited efficacy. Nevertheless, these diseases have less impact on antimicrobial use as compared to footrot.

### Enteric

Enterotoxigenic *E. coli* provoke high use of antimicrobials, especially for young sheep. Effective vaccines exist but appear to receive little use, since antimicrobials are convenient and used on a syndromic basis. Johne's disease (*M. avium subsp. paratuberculosis*) entails medium use of antimicrobials on account of it being mistaken for other forms of bacterial enteritis. Existing vaccines have user-safety issues and can provoke adverse reactions at the site of injection. The Group agreed that DIVA vaccines would perhaps assist in disease management and trade and movements of vaccinated animals. *Cryptosporidium parvum* and *Eimeria spp.* provoke medium use of antimicrobial agents. Helminths entail low use of antimicrobials, and were thus not considered by the Group. Unlike cattle, *F. necrophorum* and *S. enterica* entails lower use of antimicrobials, due to lower occurrence of disease due to these agents. Reasonably effective vaccines exist for rotavirus and *Clostridium perfringens*, which provoke low antimicrobials use.

### Systemic

Ovine caseous lymphadenitis (*Corynebacterium pseudotuberculosis*) was considered the only systemic disease for which antimicrobial use in sheep was high at a global level. While vaccines are available, their efficacy is variable.

Several other pathogens, for which a medium consumption of antimicrobials was identified, were considered (*i.e.* *Bibersteinia trehalosi*, *Pasteurella multocida*, *Campylobacter jejuni*, *Chlamydophila spp.*, and Sheep pox virus). Other pathogens (*i.e.* *C. burnetii*, *Salmonella abortusovis*, and *Brucella ovis*) were considered by the Group, and it was decided that they had a low priority due to the relatively low impact on antimicrobial use at global level.

### Vector-borne

Vector-borne pathogens in sheep were considered. *Ehrlichia ruminantium* (heartwater) is present in several regions, where it is believed to attract high antimicrobial use.

Bluetongue virus (BTV) was discussed. Antimicrobial agents are used early in bluetongue outbreaks, especially in countries where the viruses are endemic and a firm diagnosis of the cause of sickness is delayed. Current vaccination control is complicated by the diverse nature of BTV and the potential that

vaccines containing the relevant strains are not available in the country at the time of the outbreak. A cross-protective vaccine covering the full range of serotypes would help minimise antimicrobial use, but is technically challenging.

The impact of *Anaplasma phagocytophilum*, *Theileria spp.* of small ruminants, *Trypanosoma spp.*, and *Babesia spp.* on antimicrobial use was considered not significant, and these pathogens were not further discussed.

Reproductive syndromes were discussed by the Group, and it was agreed that none of the pathogens entailed sufficiently high antimicrobial use at a global level as to be further considered.

Pathogens/diseases which entail high and medium use of antimicrobial agents in sheep are reported in Table 2. Other relevant pathogens/diseases which entail low use of antimicrobials are report in [Appendix V](#).

**Table 2: Pathogens/diseases which entail high and medium use of antimicrobial agents and for which vaccines would significantly reduce the need for antibiotic use in sheep**

Key syndrome / Disease	Primary pathogen(s)	Antimicrobial Use [High, Medium, Low]	Commercial vaccine exists* [Yes/No]	Major constraints to use of vaccine / vaccine development	Vaccine Research Priority [High, Medium, Low]
Respiratory	<i>Mannheimia haemolytica</i>	High	Yes	<ul style="list-style-type: none"> <li>Timely delivery</li> <li>Onset of immunity (one dose versus two doses)</li> <li>Differences in serotype</li> <li>Potential lack of cross-protection between serotypes</li> <li>Leukotoxoid content in some vaccines is not controlled</li> </ul>	High
	<i>Pasteurella multocida</i>	High	Yes	<ul style="list-style-type: none"> <li>Timely delivery</li> <li>Marginal efficacy</li> <li>Potential lack of cross-protection</li> </ul>	High
	<i>Mycoplasma ovipneumoniae</i>	High	No	<ul style="list-style-type: none"> <li>Limited efficacy</li> <li>Lack of cross protection</li> </ul>	High
	Peste des petits ruminants virus	High	Yes	<ul style="list-style-type: none"> <li>Effective and safe vaccines available</li> <li>Need combination vaccines with other respiratory pathogens</li> <li>Relatively low use of vaccine in some endemic countries when official programmes have low compliance</li> <li>DIVA vaccines needed</li> </ul>	Low
Mastitis	<i>Mycoplasma agalactiae</i> (contagious agalactia)	Medium	Yes	<ul style="list-style-type: none"> <li>Live attenuated vaccine efficacious, inactivated vaccine suboptimal</li> <li>Potential reversion to virulence</li> <li>Notifiable disease</li> </ul>	Medium
	<i>Mannheimia haemolytica</i>	Medium	Yes	<ul style="list-style-type: none"> <li>Effective vaccine available</li> <li>Low demand for vaccine</li> <li>Lack of awareness</li> </ul>	Low
	Coagulase negative <i>Staphylococci</i>	Medium	Yes	<ul style="list-style-type: none"> <li>Effective vaccine available</li> <li>Strain variation</li> <li>Lack of cross-protection</li> <li>Multiple doses needed for efficacy</li> </ul>	Low
	<i>Staphylococcus aureus</i>	Medium	Yes	<ul style="list-style-type: none"> <li>Effective vaccine available</li> <li>Strain variation</li> <li>Lack of cross-protection</li> <li>Multiple doses needed for efficacy</li> </ul>	Low

Key syndrome / Disease	Primary pathogen(s)	Antimicrobial Use [High, Medium, Low]	Commercial vaccine exists* [Yes/No]	Major constraints to use of vaccine / vaccine development	Vaccine Research Priority [High, Medium, Low]
<b>Lameness</b>	<i>Dichelobacter nodosus</i> (ovine virulent footrot)	High	Yes	<ul style="list-style-type: none"> <li>Short duration of immunity</li> <li>No cross-serotype protection</li> <li>Vaccine antigen interference in large combination vaccines</li> <li>Cost prohibitive farm-specific mono-valent and bi-valent vaccines</li> <li>Vaccine only available in limited countries</li> </ul>	High
	<i>Fusobacterium necrophorum</i> (foot scald)	High	No	<ul style="list-style-type: none"> <li>Limited efficacy of experimental vaccines</li> </ul>	High
	<i>Trueperella pyogenes</i> (foot abscess)	Medium	Yes	<ul style="list-style-type: none"> <li>Limited efficacy</li> </ul>	Medium
	<i>Corynebacterium pseudotuberculosis</i> (foot abscess)	Medium	Yes	<ul style="list-style-type: none"> <li>Limited efficacy</li> </ul>	Medium
<b>Enteric</b>	Enterotoxigenic <i>Escherichia coli</i>	High	Yes	<ul style="list-style-type: none"> <li>Effective vaccines available for predominant strains</li> </ul>	Low
	<i>Mycobacterium avium</i> subspecies <i>paratuberculosis</i> (Johne's disease)	Medium	Yes	<ul style="list-style-type: none"> <li>Need DIVA vaccine</li> <li>User safety</li> <li>Injection site reactions</li> </ul>	Medium
	<i>Cryptosporidium parvum</i>	Medium	No	<ul style="list-style-type: none"> <li>Research and development investment needed</li> </ul>	Medium
	<i>Eimeria</i> spp.	Medium	No	<ul style="list-style-type: none"> <li>Research and development investment needed</li> </ul>	Medium
<b>Systemic</b>	<i>Corynebacterium pseudotuberculosis</i> , <i>C. spp.</i>	High	Yes	<ul style="list-style-type: none"> <li>Vaccines available, but variable efficacy</li> </ul>	Medium
	<i>Bibersteinia trehalosi</i>	Medium	Yes	<ul style="list-style-type: none"> <li>Lack of cross protection</li> </ul>	Medium
	<i>Pasteurella multocida</i> (haemorrhagic septicaemia)	Medium	Yes	<ul style="list-style-type: none"> <li>Limited availability</li> <li>Satisfactory efficacy</li> </ul>	Medium
	<i>Campylobacter jejuni</i>	Medium	Yes	<ul style="list-style-type: none"> <li>Limited efficacy</li> <li>Limited availability</li> </ul>	Medium
	<i>Chlamydophila</i> spp.	Medium	Yes	<ul style="list-style-type: none"> <li>Satisfactory efficacy</li> <li>Caution for use in pregnant animals</li> <li>Vaccine covers <i>C. abortus</i></li> </ul>	Low
	Sheep Pox Virus	Medium	Yes	<ul style="list-style-type: none"> <li>Satisfactory efficacy in sheep</li> </ul>	Low
<b>Vector-borne</b>	<i>Ehrlichia ruminantium</i> (heartwater)	High	Yes	<ul style="list-style-type: none"> <li>Low production capacity</li> <li>Lack of strain specificity</li> <li>Vaccine production based on live animal infection</li> <li>Limited availability</li> <li>Difficult administration</li> <li>Adequate efficacy</li> </ul>	High
	Bluetongue virus	Medium	Yes	<ul style="list-style-type: none"> <li>Strain specific vaccine</li> <li>Partial cross-protection</li> <li>Potential reversion to virulence for live attenuated vaccines</li> <li>Caution for use in pregnant animals</li> </ul>	High

\* does not cover autogenous vaccines

## 6.5. Goat Diseases

### Respiratory

Caprine respiratory disease is a multifactorial disease resulting in high level of antimicrobial use. *M. haemolytica* (regarded as a primary pathogen) and *P. multocida* (regarded as a primary or secondary pathogen) are the main agents involved, and these attract high use of antimicrobials. Most of the vaccines target both agents, but are limited in availability and/or efficacy. There is maybe some variation in breed resistance to *M. haemolytica*, occurring in some regions. Similar to sheep, viral agents (*i.e.* PI3) were considered as lesser contributors to disease occurrence in goats.

Contagious Caprine Pleuropneumonia (caused by *Mycoplasma capricolum subsp. capripneumoniae*) was discussed as important cause of respiratory disease in some regions, and as provoking high use of antimicrobials. While vaccines are generally considered as efficacious, there are issues of suboptimal potency, efficacy and supply. Other small-ruminant *Mycoplasma* species complicate the epidemiology of the disease.

Peste des petits ruminants virus causes systemic disease in goats, but respiratory complications are a major feature and cases might be treated with antimicrobials. While vaccines are effective and safe, there is relatively low use of vaccines in some endemic regions, where official programmes have low compliance. DIVA and combination vaccines are available.

### Mastitis

The main causal agents of goat mastitis were considered: *M. agalactiae*, *Mycoplasma mycoides subsp. capri*, *Mycoplasma capricolum*, *Mycoplasma putrefaciens*, *M. haemolytica*, Coagulase negative *Staphylococci*, and *S. aureus*. The Group agreed that antimicrobial use for this syndrome was generally medium in goats, depending on the farming practices (higher in intensive production). Except for mycoplasmas, vaccines are mostly available and effective, but the uptake is low due to lack of awareness of vaccine options. Although antimicrobial use is medium for mycoplasmas, therapy has low effectiveness and could lead to establishment of carrier status. While the Group recognised that there are other pathogens that could provoke mastitis in goats, they have low impact on antimicrobial use, and were not discussed further.

### Lameness

Lameness is a priority issue for goat production, provoking significant use of antimicrobial agents. Vaccines for virulent footrot (*D. nodosus*) for goats are not available, and sheep vaccine causes severe reactions when administered to goats. No vaccine is also available for *F. necrophorum*, which is the only pathogen entailing high antimicrobial use. As for sheep, vaccines exist for *T. pyogenes* (foot scald, foot abscess) and *C. pseudotuberculosis* (foot abscess) but present efficacy limitations. However, these pathogens have a lower impact on antimicrobial use as compared to footrot.

### Enteric

Enteric diseases of goats were considered. This syndrome was not recognised as being a major cause of antimicrobial use in goats. *Eimeria spp.* provoke medium use of antimicrobial agents. Johne's disease (*M. avium subsp. paratuberculosis*) entails low use of antimicrobials. Helminths entail low use of antimicrobials, and were therefore not considered.

### Systemic

Similar to sheep, *Corynebacterium pseudotuberculosis* was considered the only systemic pathogen for which high antimicrobial use occurs for goats. Suboptimal efficacy of the available vaccines was recognised as an issue in this species. Several other pathogens, attracting medium consumption of antimicrobials, were considered (*i.e.* *B. trehalosi*, *C. jejuni*, *Chlamydophila spp.*, and Goat pox virus). In the case of *C. burnetii*, low antimicrobial use excluded it from further consideration.

### Vector-borne

Vector-borne pathogens in goats were considered. Only *Ehrlichia. ruminantium* (heartwater) was considered as having a significant impact on antimicrobial use.

Reproductive syndromes were discussed by the Group. It was agreed that none of the pathogens entailed antimicrobial use high enough at a global level as to be further considered.

Pathogens/diseases which entail high and medium use of antimicrobial agents in goats are reported in Table 3. Other relevant pathogens/diseases which entail low use of antimicrobials are report in Appendix VI.

**Table 3: Pathogens/diseases which entail high and medium use of antimicrobial agents and for which vaccines would significantly reduce the need for antibiotic use in goats**

Key syndrome / Disease	Primary pathogen(s)	Antimicrobial Use [High, Medium, Low]	Commercial vaccine exists* [Yes/No]	Major constraints to use of vaccine / vaccine development	Vaccine Research Priority [High, Medium, Low]
Respiratory	<i>Mannheimia haemolytica</i>	High	Yes	<ul style="list-style-type: none"> <li>Timely delivery</li> <li>Onset of immunity (one dose versus two doses)</li> <li>Differences in serotype</li> <li>Potential lack of cross-protection</li> <li>Leukotoxoid content in some vaccines is not controlled</li> </ul>	High
	<i>Pasteurella multocida</i>	High	Yes	<ul style="list-style-type: none"> <li>Timely delivery</li> <li>Marginal efficacy</li> <li>Potential lack of cross-protection</li> </ul>	High
	<i>Mycoplasma capricolum subsp. capripneumoniae</i> (Contagious caprine pleuropneumonia, CCPP)	High	Yes	<ul style="list-style-type: none"> <li>Suboptimal production process (low yield)</li> <li>Vaccine is efficacious, but issues of suboptimal potency</li> <li>Other small ruminant <i>Mycoplasma spp.</i> complicate epidemiology</li> </ul>	High
	Peste des Petits Ruminants Virus (PPR)	High	Yes	<ul style="list-style-type: none"> <li>Effective and safe vaccines available</li> <li>Need combination vaccines with other respiratory pathogens</li> <li>Relatively low use of vaccine in some endemic countries, when official programmes have low compliance</li> <li>DIVA vaccine needed</li> </ul>	Low
Mastitis	<i>Mycoplasma agalactiae</i>	Medium	Yes	<ul style="list-style-type: none"> <li>Live attenuated vaccine efficacious, inactivated vaccine suboptimal</li> <li>Potential reversion to virulence</li> <li>Notifiable disease</li> <li>Carrier animals</li> </ul>	Medium
	<i>Mycoplasma mycoides subsp. capri</i>	Medium	No	<ul style="list-style-type: none"> <li>Limited efficacy of experimental vaccines</li> </ul>	Medium
	<i>Mycoplasma capricolum</i>	Medium	No	<ul style="list-style-type: none"> <li>Limited efficacy of experimental vaccines</li> </ul>	Medium
	<i>Mycoplasma putrefaciens</i>	Medium	No	<ul style="list-style-type: none"> <li>Limited efficacy of experimental vaccines</li> </ul>	Medium
	<i>Mannheimia haemolytica</i>	Medium	Yes	<ul style="list-style-type: none"> <li>Effective vaccine available</li> <li>Low demand for vaccine</li> <li>Lack of awareness</li> </ul>	Low
	Coagulase negative <i>Staphylococci</i>	Medium	Yes	<ul style="list-style-type: none"> <li>Effective vaccine available</li> <li>Strain variation</li> <li>Lack of cross-protection</li> <li>Multiple doses needed for efficacy</li> </ul>	Low
	<i>Staphylococcus aureus</i>	Medium	Yes	<ul style="list-style-type: none"> <li>Effective vaccine available</li> <li>Strain variation</li> <li>Lack of cross-protection</li> <li>Multiple doses needed for efficacy</li> </ul>	Low

Key syndrome / Disease	Primary pathogen(s)	Antimicrobial Use [High, Medium, Low]	Commercial vaccine exists* [Yes/No]	Major constraints to use of vaccine / vaccine development	Vaccine Research Priority [High, Medium, Low]
<b>Lameness</b>	<i>Fusobacterium necrophorum</i> (foot scald)	High	No	• Limited efficacy of experimental vaccines	High
	<i>Dichelobacter nodosus</i> (virulent footrot)	Medium	No	• Severe reactions to sheep vaccine	High
	<i>Trueperella pyogenes</i> (foot abscess)	Medium	Yes	• Limited efficacy	Medium
	<i>Corynebacterium pseudotuberculosis</i> (foot abscess)	Medium	Yes	• Limited efficacy	Medium
<b>Enteric</b>	<i>Eimeria spp.</i>	Medium	No	• Research and development investment needed	Medium
<b>Systemic</b>	<i>Corynebacterium pseudotuberculosis</i> , <i>C. spp.</i>	High	Yes	• Vaccines available, but variable efficacy	Medium
	<i>Bibersteinia trehalosi</i>	Medium	Yes	• Lack of cross protection	Medium
	<i>Campylobacter jejuni</i>	Medium	Yes	• Limited efficacy • Limited availability	Medium
	<i>Chlamydophila spp.</i>	Medium	Yes	• Satisfactory efficacy • Caution for use in pregnant animals • Vaccine covers <i>C. abortus</i>	Low
	Goat pox virus	Medium	Yes	• Satisfactory efficacy in goats	Low
<b>Vector-borne</b>	<i>Ehrlichia ruminantium</i> (heartwater)	High	Yes	• Low production capacity • Lack of strain specificity • Vaccine production based on live animal infection • Limited availability • Difficult administration • Adequate efficacy	High

\* does not cover autogenous vaccines

## 7. Agree on an overall priority list of animal diseases where availability of vaccines could reduce the use of antimicrobials taking into account technical and financial constraints to vaccine usage

The Group emphasised that there was a fundamental need for significant investment to use cutting-edge technologies to address the significant gaps in the available vaccines needed to address antimicrobial resistance.

It was also recognised that Public-Private-Partnerships would be essential to bridge researchers and vaccine manufacturers to achieve the above goal.

The Group agreed that effective vaccines for the diseases listed in Tables 1-3 could substantially reduce the use of antimicrobial agents in cattle, sheep, and goats. It was acknowledged that notable scientific and technical hurdles exist. However, an overarching investment in vaccine research could have a significant impact, particularly if the research addressed the following seven gaps (not listed in order of priority):

1. Efficacy consistent with control needs;
2. Maternal antibody interference;
3. Cross-protection or inclusion of relevant strains in vaccine formulations;
4. Occurrence of immunological interference in multivalent vaccines;
5. Induction of mucosal immunity for respiratory, enteric and mastitis pathogens;

6. Duration of immunity;
7. Onset of immunity.

## **8. Any other issues**

The Group recommended that communication of the outcomes of the Group should be pursued apart from the publication of the final report.

The Group suggested the report be distributed for consideration to funders of research, global animal health research organisations (*e.g.*, STAR-IDAZ IRC), and that global vaccine research networks be supported to pool resources and expertise to address gaps for each of the priority diseases listed in Tables 1-3.

It was acknowledged that in some regions, even if vaccines are available, the lack of defined vaccination programme makes the uptake of such tools limited.

## **9. Finalisation and endorsement of the draft report**

The Group adopted the report.

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.../Appendices

Appendix I

**AD HOC GROUP ON PRIORITISATION OF DISEASES  
FOR WHICH VACCINES COULD REDUCE ANTIMICROBIAL USE IN CATTLE, SHEEP, AND GOATS  
Paris, 7 – 9 May 2018**

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**Agenda**

1. Opening
2. Appointment of chairperson and rapporteurs
3. Background of the meeting
4. Review and address the Terms of reference for the *ad hoc* Group meeting
5. Refine template and criteria for the ranking of diseases
6. Rank diseases for the two focus areas
  - a. Cattle diseases
  - b. Sheep and goat diseases
7. Agree overall priority list of animal diseases where availability of vaccines could reduce the use of antimicrobials taking into account technical and financial constraints to vaccine usage
8. Any other issues
9. Finalisation and endorsement of the draft report

Appendix II

**AD HOC GROUP ON PRIORITISATION OF DISEASES  
FOR WHICH VACCINES COULD REDUCE ANTIMICROBIAL USE IN CATTLE, SHEEP, AND GOATS  
Paris, 7 – 9 May 2018**

**List of Participants**

**MEMBERS**

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**Professor Peter Borriello**  
(invited but could not attend)  
Chief Executive Officer  
Veterinary Medicines Directorate  
Woodham Lane, New Haw,  
Addlestone, Surrey KT15 3NB  
UNITED KINGDOM  
[p.borriello@vmd.defra.gsi.gov.uk](mailto:p.borriello@vmd.defra.gsi.gov.uk)

**Dr Michel Bellaïche**  
Kimron Veterinary Institute  
Bet Dagan, P.O.Box 12  
50250  
ISRAEL  
[michelb@moag.gov.il](mailto:michelb@moag.gov.il)

**Professor David Jordan**  
New South Wales Department of Primary  
Industries,  
Wollongbar,  
NSW,  
AUSTRALIA  
[david.jordan@dpi.nsw.gov.au](mailto:david.jordan@dpi.nsw.gov.au)

**Dr Gérard Moulin**  
ANSES Fougères  
Agence Nationale du Médicament Vétérinaire  
8 rue Claude Bourgelat - Parc d'Activités de la  
Grande Marche - Javené CS 70611  
35306 Fougères  
FRANCE  
[gerard.moulin@anses.fr](mailto:gerard.moulin@anses.fr)

**Dr Roland Larson**  
62 Stockenström Street, Graaff-reinet, 6280  
Location Graaff-Reinet, Camdeboo Local  
Municipality,  
Cacadu District Municipality, Eastern Cape,  
SOUTH AFRICA  
[larsonroland@telkomsa.net](mailto:l Larsonroland@telkomsa.net)

**Dr Vish Nene**  
International Livestock Research Institute (ILRI)  
Old Naivasha Road,  
P. O. Bo 30709,  
Nairobi 00100  
KENYA  
[v.nene@cgiar.org](mailto:v.nene@cgiar.org)

**Dr Cyril G. Gay**  
USDA - Animal Production and Protection  
Veterinary Medical Science  
Animal Health and Safety  
Room 4-2110  
5601 Sunnyside Ave.  
Beltsville, MD, 20705-5148  
UNITED STATES OF AMERICA  
[cyril.gay@ars.usda.gov](mailto:cyril.gay@ars.usda.gov)

**Observers**

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**Mr Vaughn E. Kubiak**  
HealthforAnimals  
168 Avenue de Tervueren  
1150 Brussels  
[e.kubiak@zoetis.com](mailto:e.kubiak@zoetis.com)

**Dr Geert Vertenten**  
HealthforAnimals  
168 Avenue de Tervueren  
1150 Brussels  
[geert.vertenten@merck.com](mailto:geert.vertenten@merck.com)

**Representative Scientific Commission for Animal Diseases**

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**Dr Baptiste Dangu**  
26 Dalrymple Crescent  
Edinburgh EH9 2NX  
Scotland  
UNITED KINGDOM  
[b.dangu@mci-santeanimale.com](mailto:b.dangu@mci-santeanimale.com)

**OIE Headquarters**

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**Dr Matthew Stone**  
Deputy Director General International Standards and  
Science  
12 rue de Prony  
75017 Paris  
FRANCE  
[oie@oie.int](mailto:oie@oie.int)

**Dr Elisabeth Erlacher-Vindel**  
Head of the Science and New Technologies  
Department  
[e.erlacher-vindel@oie.int](mailto:e.erlacher-vindel@oie.int)

**Dr Stefano Messori**  
Chargé de mission  
Science and New Technologies Department  
[s.messori@oie.int](mailto:s.messori@oie.int)

**Dr Glen Gifford**  
Chargé de mission  
Science and New Technologies Department  
[g.gifford@oie.int](mailto:g.gifford@oie.int)

Appendix III

**AD HOC GROUP ON PRIORITISATION OF DISEASES  
FOR WHICH VACCINES COULD REDUCE ANTIMICROBIAL USE IN CATTLE, SHEEP, AND GOATS  
Paris, 7 – 9 May 2018**

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**Terms of Reference**

**Background**

To address the threat of antimicrobial resistance, the WHO with the support of the OIE and FAO drafted a Global Action Plan on Antimicrobial Resistance. In the development of this plan, the use of vaccines to prevent diseases and to reduce the prevalence of infections was considered as being one of the possible options to reduce the use of antimicrobial agents at the global level.

The OIE convened, in 2015, an *ad hoc* Group to provide guidance on the prioritisation of diseases for which the use of already available and new vaccines could reduce antimicrobial use in animals, as well as to make recommendations for targeted research programmes for improved and new vaccines. The *ad hoc* Group focussed its activities on chickens, swine and fish. To complete this work, the OIE has agreed to convene a second *ad hoc* Group to prioritise diseases for which vaccines could reduce antimicrobial use in domestic ruminants (cattle, sheep, and goats).

**Purpose**

The *ad hoc* Group will provide guidance on prioritisation of diseases for which the use of already available and new vaccines could reduce antimicrobial use in domestic ruminants (cattle, sheep, and goats).

**Terms of Reference**

1. Consider diseases for which the availability and use of appropriate vaccines could reduce antimicrobial use in domestic ruminants (cattle, sheep, and goats).
2. Rank bacterial and non-bacterial diseases in domestic ruminants (cattle, sheep, and goats) by animal group, which cause the highest use of antimicrobials in the animal species concerned.
3. Refine the ranking by considering relevant factors impacting vaccine development, effectiveness or implementation of vaccination (examples could include but are not limited to the feasibility to develop vaccines, factors affecting the effectiveness of vaccines, such as number of implicated pathogens/strains, specific host immune reactions, general immune status related factors, or other factors that might reduce implementation of vaccination, such as current vaccine costs).

**Expected output of the *ad hoc* Group**

The development of a list of ranked priority diseases to guide research on vaccine development or improvement for domestic ruminants (cattle, sheep, and goats) with the overall aim of decreasing the use of antimicrobial agents at the global level.

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Appendix IV

**Table 1 - Appendix. Pathogens/diseases which entail low use of antimicrobial agents and for which vaccines would reduce the need for antibiotic use in cattle**

Key syndrome / Disease	Primary pathogen(s)	Antimicrobial Use [High, Medium, Low]	Commercial * vaccine exists [Yes/No]	Major constraints to use of vaccine / vaccine development	Vaccine Research Priority [High, Medium, Low]
<b>Respiratory</b>	Parainfluenza-3 virus (Bovine Respiratory Disease Complex, BRD)	Low	Yes	<ul style="list-style-type: none"> <li>Adequate efficacy, relative to the impact of the disease</li> </ul>	Low
	Bovine Herpesvirus-1 / Infectious Bovine Rhinotracheitis (IBR) virus (BRD)	Low	Yes	<ul style="list-style-type: none"> <li>Adequate efficacy and safety</li> <li>DIVA vaccine available</li> <li>Eradicated from some countries in Europe</li> </ul>	Low
	Bovine Respiratory Syncytial Virus (BRD)	Low	Yes	<ul style="list-style-type: none"> <li>Adequate efficacy and safety relative to the impact of the disease – sufficient to prevent secondary bacterial infection</li> </ul>	Low
	Bovine Coronavirus (BRD)	Low	Yes	<ul style="list-style-type: none"> <li>Emerging respiratory pathogen</li> <li>Originally developed for enteric disease. Efficacy not fully established for BRD</li> <li>More research needed on epidemiology and pathogenesis</li> </ul>	Low
	<i>Dictyocaulus viviparus</i>	Low	Yes	<ul style="list-style-type: none"> <li>Live irradiated larvae</li> </ul>	Low
<b>Mastitis</b>	<i>Escherichia coli</i>	Low	Yes	<ul style="list-style-type: none"> <li>Marginal efficacy</li> <li>Multiple doses needed for efficacy</li> </ul>	Low
	<i>Mycoplasma bovis</i>	Low	No	<ul style="list-style-type: none"> <li>Vaccines for respiratory disease available, but not effective for mastitis</li> </ul>	Low
<b>Lameness (interdigital and digital dermatitis)</b>	<i>Trueperella pyogenes</i>	Low	No	<ul style="list-style-type: none"> <li>Uncertain role of organism in disease and production loss</li> <li>Limited efficacy (experimental vaccines)</li> </ul>	Low
	<i>Treponema spp.</i>	Low	No	<ul style="list-style-type: none"> <li>Uncertain role of organism in disease and production loss</li> <li>Limited efficacy (experimental vaccines)</li> </ul>	Low
<b>Enteric</b>	<i>Clostridium perfringens</i>	Low	Yes	<ul style="list-style-type: none"> <li>Vaccines have satisfactory efficacy</li> </ul>	Low

\* does not cover autogenous vaccines

## Appendix V

**Table 2 - Appendix Pathogens/diseases which entail low use of antimicrobial agents and for which vaccines would reduce the need for antibiotic use in sheep**

Key syndrome / Disease	Primary pathogen(s)	Antimicrobial Use [High, Medium, Low]	Commercial vaccine exists* [Yes/No]	Major constraints to use of vaccine / vaccine development	Vaccine Research Priority [High, Medium, Low]
<b>Respiratory</b>	Parainfluenza-3 virus	Low	Yes	<ul style="list-style-type: none"> <li>Adequate efficacy relative to the impact of the disease</li> </ul>	Low
<b>Enteric</b>	<i>Fusobacterium necrophorum</i>	Low	No	<ul style="list-style-type: none"> <li>Vaccine available for footrot, but not labelled for this application</li> </ul>	Low
	<i>Salmonella enterica subsp. enterica</i>	Low	Yes	<ul style="list-style-type: none"> <li>Effective vaccines available but low use, due to low prevalence of disease</li> <li>Dominant serotypes vary between geographic regions</li> <li>Lack of cross-protection</li> <li>Limited availability</li> </ul>	Low
	<i>Clostridium perfringens</i>	Low	Yes	<ul style="list-style-type: none"> <li>Vaccines have satisfactory efficacy</li> </ul>	Low
	Rotavirus	Low	Yes	<ul style="list-style-type: none"> <li>Reasonable efficacy of vaccine</li> <li>Limited geographic availability*</li> </ul>	Low
<b>Systemic</b>	<i>Coxiella burnetii</i>	Low	Yes	<ul style="list-style-type: none"> <li>Available in few countries</li> <li>Satisfactory efficacy</li> <li>Cost prohibitive</li> </ul>	Low
	<i>Salmonella abortusovis</i>	Low	No	<ul style="list-style-type: none"> <li>Disease present in few countries</li> </ul>	Low
	<i>Brucella ovis</i>	Low	Yes	<ul style="list-style-type: none"> <li>Satisfactory efficacy</li> <li>Caution in use for older animals that will test positive</li> </ul>	Low

\* does not cover autogenous vaccines

Appendix VI

**Table 3 - Appendix Pathogens/diseases which entail low use of antimicrobial agents and for which vaccines would reduce the need for antibiotic use in goats**

Key syndrome / Disease	Primary pathogen(s)	Antimicrobial Use [High, Medium, Low]	Commercial * vaccine exists [Yes/No]	Major constraints to use of vaccine / vaccine development	Vaccine Research Priority [High, Medium, Low]
<b>Respiratory</b>	Parainfluenza-3 virus	Low	Yes	<ul style="list-style-type: none"> <li>• Adequate efficacy, relative to the impact of the disease</li> </ul>	Low
<b>Enteric</b>	<i>Mycobacterium avium subspecies paratuberculosis</i> (Johne's disease)	Low	Yes	<ul style="list-style-type: none"> <li>• Vaccination may interfere with diagnostic tests for Johne's disease</li> <li>• Strong reaction with <i>Mycobacterium spp.</i></li> </ul>	Low
<b>Systemic</b>	<i>Coxiella burnetii</i>	Low	Yes	<ul style="list-style-type: none"> <li>• Available in few countries</li> <li>• Satisfactory efficacy</li> <li>• Cost prohibitive</li> </ul>	Low

\* does not cover autogenous vaccines



**REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON ANTIMICROBIAL RESISTANCE**  
**Paris, 3-5 July 2018**

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**1. Opening**

The OIE *ad hoc* Group on Antimicrobial Resistance (hereafter referred to as ‘the Group’) met from 3 to 5 July 2018 at the OIE Headquarters in Paris, France.

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

The adopted Agenda and List of Participants are presented in Appendices I and II of this report, respectively. The Group elected Dr Herbert Schneider as the chair, and Drs Chris Teale and Carolee Carson as rapporteurs.

**3. Roundtable from the participants on any new issues of interest for the Group**

Information was shared within the Group on antimicrobial use and antimicrobial resistance topics of common interest.

**4. Revision of the OIE List of antimicrobial agents of veterinary importance in animals including ionophores**

The Group focussed primarily on a technical review of the OIE List (herein designated the ‘List’), with the intent of proposing updates taking into consideration the 2016 WHO Critically Important Antimicrobials for Human Medicine, and improving coherence between the WHO and OIE Lists with respect to terminology used for antimicrobial classification. The Group also consulted the OIE Global Database on Antimicrobial Agents Intended for Use in Animals, utilising the information to inform the technical review of the List.

The Group reviewed the List and addressed specific aspects as follows:

1. **Novobiocin:** The Group discussed whether the class name ‘aminocoumarin’ vs. ‘coumarin’ would be more appropriate. The Group noted variable naming of this class in the literature and suggested using ‘aminocoumarin’ to align with the WHO List.
2. **Aminocyclitols:** The Group discussed whether aminocyclitols should be a sub-class of aminoglycosides or a separate class. The Group proposed that the aminocyclitol spectinomycin should be in a separate class from the aminoglycosides and that spectinomycin should not be grouped together with streptomycin and dihydrostreptomycin. The Group proposed that ‘Aminocyclitols’ would come before ‘Aminoglycosides’ in the List. For streptomycin and dihydrostreptomycin they would fall under the heading ‘Aminoglycosides’ and before ‘Aminoglycosides +2 deoxystreptamine’. For aminocyclitols, the Group noted that there was a need to add text in the column ‘Specific comments’ and proposed ‘Used for respiratory infections in cattle and enteric infections in multiple species’. The Group suggested to retain the same categorization for the aminocyclitols and aminoglycosides (VCIA)<sup>1</sup>.

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<sup>1</sup> According with the OIE List of Antimicrobial Agents of Veterinary Importance, antimicrobial agents are classified in three categories: Veterinary Critically Important Antimicrobial Agents (VCIA), Veterinary Highly Important Antimicrobial Agents (VHIA) and Veterinary Important Antimicrobial Agents (VIA).

3. **Fusidic acid:** The Group reviewed the classification of fusidic acid. The Group suggested using the class “fusidane” as per information in recent text books (Antimicrobial Therapy in Veterinary Medicine, 4th edition, S. Giguère and al., Blackwell Publishing, 2006) and the OIE Rev sci tech (2012) keeping “fusidic acid” as the example.
4. **Ionophores:** The Group reviewed the classification of ionophores. The Group noted that ionophores are classified as ‘Polyethers/Ionophores’ by the WHO. The Group noted that not all ionophores are polyethers. Hence, the Group decided to leave the current OIE classification of the antimicrobial class as “ionophores”.

The Group also reviewed the status of the ionophores which are included in the List, but not included in the data collection template, following Resolution 38 of the 85th General Session (May 2017) and acknowledged that there is published information including risk assessments and peer reviewed literature on this topic<sup>2</sup>. The Group will regularly review the classification of ionophores as new information becomes available. The Group suggested that the OIE maintain its current decision not to capture data on consumption of ionophores in the Global Database, but maintain ionophores in the List as they are important antimicrobials in veterinary medicine. The OIE will review this status when more information becomes available.

5. **Macrolides:** The Group considered whether the macrolide category should be sub-categorized by the different chemical structures (i.e., C14, C16); noting that the WHO List does not split the macrolides into different chemical structures. The Group indicated there is a difference in resistance mechanism and use practices between the different chemical structures of macrolides; hence there is potential value to subdivide the macrolides. The Group additionally recommended re-naming these sub-categories as per their ‘Membered ring’. For example the new recommended naming would be ‘13-Membered ring’ instead of C13. The Group noted in particular that C15 is technically inaccurate, and while ‘azalides’ might encompass this sub-class, the Group felt that 15-Membered ring was more consistent with the proposed naming convention for macrolides in the List.
6. **Phosphonic acid:** The Group noted that the OIE List includes this class as ‘Phosphonic acid’; whereas the WHO label these ‘Phosphonic acid derivatives’. The Group noted that fosfomycin is a derivative of phosphonic acid. The Group suggested aligning the terminology with the WHO and label this class ‘Phosphonic acid derivatives’.
7. **Polypeptides:** The Group considered the nomenclature of this class. The Group noted that it was important to include a heading of ‘Polymyxins’ and to have ‘Polymyxin B’ and ‘Polymyxin E (colistin)’ specified under the heading. The Group recommended to remove ‘Cyclic polypeptides’ and just to include ‘Polymyxins’ under the larger heading ‘Polypeptides’. Under the column ‘Specific comments’ the Group suggested the following minor text change for clarity and accuracy: “Polymyxin E (colistin) is used against Gram-negative enteric infections.” The Group discussed whether there should be different categorization of Polymyxin B and Polymyxin E (i.e., VCIA/VHIA/VIA). With this in mind, the Group reviewed the information from the OIE Global database on Antimicrobial Agents Intended for Use in Animals regarding polypeptides and colistin and suggested no change for the categorization of different classes of polypeptides.
8. **Different categorizations of sub-classes of penicillins:** The Group noted that the WHO List has different categorizations for different sub-classes of penicillins. The Group reviewed the current OIE List of penicillins as a class, and considered that the categorisation as VCIA was still appropriate, in the veterinary medical context.
9. The Group considered the potential inclusion of the following specific antimicrobial agents in the List.
  - a. **Cefovecin:** The Group recommended not adding this to the List, as it is only used in companion animals (and the List currently excludes companion animals).
  - b. **Clindamycin:** The Group recommended not adding this to the List, as it is only used in companion animals.

<sup>2</sup> <https://crwad.org/wp-content/uploads/2017/11/CRWAD-2017-Author-Index-and-Abstracts.pdf>

- c. **Ibafloxacin and pradofloxacin:** The Group did not recommend adding these to the List because these products are not used in food-producing animals.
  - d. **Sulfacetamide:** The Group recommended adding this to the List because this product is used in food-producing animals.
  - e. As part of this review of specific classes, the Group noted that **avilamycin** is also used in pigs and recommended adding these to the list of species for avilamycin.
  - f. **Bambermycin:** The Group did not suggest adding phosphoglycolipids to the List because bambermycin is only used as a growth promoter.
10. The Group suggested for ease of use of the List that it be re-ordered alphabetically by antimicrobial class, then by sub-class and then by substances.
  11. The Group discussed the formatting of the text of the List, as there were some words that were underlined, and some words that were underlined and in bold. The Group proposed that antimicrobials only used in animals would be in bold. The Group reviewed the entire list to update this formatting.
  12. The Group noted that it would enhance the clarity of the List if a ‘Scope’ section was included. Using primarily existing text the Group highlighted the scope of the List, as follows:

The OIE List of Antimicrobial Agents of Veterinary Importance:

- i. Addresses antimicrobial agents authorised for use in food-producing animals
- ii. Does not include antimicrobial classes/subclasses only used in human medicine
- iii. Does not include antimicrobial agents only used as growth promoters
- iv. Focuses currently on antibacterials and other important antimicrobials agents used in veterinary medicine

Regarding Growth promoters, the Group confirmed the position adopted for the OIE List not to include antimicrobial agents used only as growth promoters as the List is a positive list highlighting the molecules of importance that need to be used for specific disease purposes.

The Group considered possible future developments of the List and suggested the following:

- **Reformatting existing information by species**
  - Based on existing information contained within the List, the Group proposed presentation of the List in a format that would be useful for each animal species sector. Details regarding the content and format (potentially as an appendix of the List) of such a document would be decided at a later date.
- **Adding a section on companion animals to the List**
  - The Group discussed the benefits to extend the scope of the List, by including non-food animal species such as dogs and cats. The Group noted that this would involve future decisions on what animal species (dogs, cats, pet birds, etc.) could be included and what antimicrobial agents would be included (authorized products, extra label use).
  - The Group was of the opinion that an initial step could be to review the data already provided in the OIE Global Database on Antimicrobial Agents Intended for Use in Animals regarding companion animals to inform next steps to explore what is potentially feasible.

## 5. Presentation of the preliminary results of the third phase of the collection of data on antimicrobial agents intended for use in animals

The preliminary results of the third phase of the collection of data on antimicrobial agents intended for use in animals were presented. The Group congratulated the OIE for these preliminary results, and the continued general improvement of the data collection over the years, and the increased engagement of Member Countries. The target year for the third phase of reporting was 2015. 155 Member Countries (86% of all OIE Member Countries) responded for this third phase, which increased from 130 and 146 in the first and second phase, respectively.

There was also an increase in Member Countries providing quantitative data (118 in the third phase from 89 and 107 in the first and second phase). The sources of data reported were similar to previous phases, where the main sources were sales data (from wholesalers and marketing authorisation) and import data; some 'other' data sources indicated by reporting countries were information from border control points, importer's reports, permits issued by registration authorities, and manufacturer's reports (production data). Member Countries providing only baseline information noted barriers to providing quantitative data, such as lack of regulatory framework (primary reason), lack of cooperation between national authorities and private sector, lack of tools and human resources, and insufficient regulatory enforcement.

Forty-five of reporting countries (29%, out of 155) indicated use of antimicrobials as growth promoters, 15 countries indicated they will create or modify their regulatory framework for growth promotion during 2018. The Group discussed that there may be non-legislative approaches that effectively end the uses of growth promoters and the OIE indicated that the report will reflect this.

The Group discussed that having a section in the report describing data quality would be beneficial from the purpose of drawing the attention of donors for future resources to improve data collection, validation and analysis.

## 6. Presentation of the template for the fourth phase of the collection of data on antimicrobial agents intended for use in animals

Based on challenges identified by the OIE during the analysis of the third phase of data reporting, the Group discussed and agreed on the following changes:

The template and guidance will be updated to reflect the terminology decisions arising from the OIE 86<sup>th</sup> General Session in May 2018, Resolution No. 34 (e.g., definitions for veterinary medical use).

The template will clarify that the questions related to growth promoters apply to the current situation of the country and not to the year of reported quantitative data.

Q14 asks "Please provide a list of antimicrobial agents authorised as growth promoters, if any": A few countries where the use of growth promoters is known to occur but legislation on growth promoters does not exist, did not provide a list of the molecules used. However, in previous years, these countries did provide a list of antimicrobial growth promoters. To address this, the Group agreed to add the word 'used' to this question in the template as follows: "Please provide a list of antimicrobial agents used or authorised as growth promoters, if any."

Some countries consider *Equidae* as companion animals, as food-producing animals or both. There is a need for clarity on how countries are categorising *Equidae* for the reporting of quantitative data (i.e., terrestrial food-producing animal or companion animals). To address this, the Group agreed with a suggestion to add two questions related to companion animals as follows: "Q27. Companion animal species covered by antimicrobial quantities, if any" (options being canines, felines, and other) and "Q28. Clarification of other species considered to be companion animals, if your response to Question 27 is "other" (free text field).

The OIE informed the Group of the timelines for reporting and the next phase of data collection: the data collection template will be distributed in September 2018 to Member Countries for the fourth phase of data collection and the deadline will be the first Friday in December 2018.

## 7. OIE AMU database: conversion from the spreadsheet format to a database system

The OIE presented considerations for moving data collection from spreadsheet format to a semi-automated software. The Group noted that there could be several objectives for the proposed automated database: to help countries to complete the questionnaire (Module 1), to assist with data validation and provide immediate feedback to the data provider (Module 2), to assist in data analysis for quantitative data reported and to link with other databases such as WAHIS (Module 3), to facilitate reporting of the data (Module 4), and to allow countries to better utilise their data (Module 2 and 4) to have a dynamic interface to facilitate use and analysis of the data (similar to the European ESVAC System).

The OIE also identified four additional objectives: (1) to make data submission easier for the Member Countries, (2) to facilitate analysis and data validation and communication with the Member Countries, (3) to have a centralized data repository that could be updated for past years, or submitted for the current phase of data collection; and (4) to have an 'intelligent' software which could facilitate calculations for e.g. conversion of active ingredients in kilograms.

The Group acknowledged that during database development, thought needs to be put into the architecture of the model and future data provision (i.e., will the database be able to accommodate data submissions by animal species or account for other metrics of reporting antimicrobial use, such as DDDvet).

The Group discussed that there needs to be consideration of controls for access to the database. The OIE currently uses TIGER which has all the names of the Delegates and Focal Points for Veterinary Products and suggested that this could be linked with either WAHIS+ or the Global Database on Antimicrobial Agents Intended for use in Animals.

The Group identified (amongst their members) a small working group to assist the OIE regarding database development. The Group suggested inviting the WHO staff member responsible for the data collection on human use.

The Group noted that there may need to be two separate, but linked, activities, focusing on different users: development of a database (data collection, storage, feedback, analysis, and some reporting) which aids submission of the data and development of an interactive data display (data reporting and feedback and visualization) for end-users.

The Group noted that attention needs to be paid to the different versions of spreadsheets (i.e., Excel spreadsheet versions) as this can cause incompatibility issues within the database in the future and to a good traceability of the data submitted.

## 8. Update on annual biomass and analysis planned for third phase

The Group was updated on the animal biomass analysis planned for the third phase of data collection. Following the analysis of 2014 quantitative data adjusted for animal biomass published in last year's report, the report from the third phase will include a similar analysis for 2015 quantitative data.

It was noted that the OIE Regions of Africa and of Asia and the Pacific have significantly increased the number of Member Countries reporting quantitative data for 2015, and accordingly, their biomass coverage increased as well. There were also new contributions from the Middle East for 2015 which will allow for a regional analysis of this quantitative data adjusted for animal biomass in the upcoming report.

There has been continued engagement with OIE Regional/Sub-Regional offices to verify calculated average weights, cycle factors, and carcass conversion factors, where possible.

**9. Update on Second OIE Global Conference on Antimicrobial Resistance, Putting Standards into Practice and poster selection**

The Group reviewed a preliminary draft of the Conference programme and agreed that the programme covered a range of important topics. They provided suggestions for inclusions into the programme, including increased representation of aquaculture and companion animals, reflecting the range of animals addressed in the OIE List and Global Database. The Group similarly emphasised the importance of highlighting public-private partnerships. The significance of anti-parasitological resistance was also discussed.

The Group will act as the Scientific Committee for the Conference. In this capacity, they reviewed abstracts submitted for poster presentations and provided their feedback to the OIE.

**10. Any other business**

The Group proposed that a next meeting could be held from 16-18 January 2019.

**11. Adoption of report**

The Group adopted the report.

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.../Appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON ANTIMICROBIAL RESISTANCE**  
**Paris, 3 – 5 July 2018**

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**Provisional agenda**

1. Opening
  2. Adoption of agenda and appointment of chairperson and rapporteur
  3. Roundtable from the participants on new issues of interest for the Group
  4. Revision of the OIE List of antimicrobial agents of veterinary importance in animals including ionophores
  5. Presentation of the preliminary results of the third phase of the collection of data on antimicrobial agents intended for use animals
  6. Presentation of the template for the fourth phase of the collection of data on antimicrobial agents intended for use animals
  7. OIE AMU database: conversion from the spreadsheet format to a database system
  8. Update on animal biomass and analysis planned for third phase
  9. Update on Second OIE Global Conference on Antimicrobial Resistance, Putting Standards into Practice and poster selection
  10. Any other business
  11. Adoption of the report
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Appendix II**MEETING OF THE OIE AD HOC GROUP ON ANTIMICROBIAL RESISTANCE****Paris, 3 – 5 July 2018****Provisional List of Participants****MEMBERS**

**Professor Peter Borriello**  
(Invited but could not attend)  
Chief Executive Officer  
Veterinary Medicines Directorate  
Woodham Lane, New Haw,  
Addlestone, Surrey KT15 3NB  
UNITED KINGDOM  
[p.borriello@vmd.defra.gsi.gov.uk](mailto:p.borriello@vmd.defra.gsi.gov.uk)

**Dr Carolee Carson**  
Veterinary Epidemiologist / Risk Assessor  
Canadian Integrated Program for Antimicrobial  
Resistance Surveillance  
Centre for Food-borne, Environmental, and  
Zoonotic Infectious Diseases  
Public Health Agency of Canada,  
Guelph, Ontario N1G 5B2 - CANADA  
Tel: (519) 400-3651  
[carolee.carson@phac-aspc.gc.ca](mailto:carolee.carson@phac-aspc.gc.ca)

**Dr Jordi Torren Edo**  
Head of Service of Veterinary Risk and  
Surveillance (V-VM-SUR)  
Veterinary Medicines Department  
European Medicines Agency  
7 Westferry Circus, Canary Wharf  
London E14 4HB - UNITED KINGDOM  
Tel: (44 207) 523 7034  
Fax: (44 207) 418 8447  
[jordi.torren@ema.europa.eu](mailto:jordi.torren@ema.europa.eu)

**Dr Gérard Moulin**  
ANSES - Fougères  
Agence Nationale du Médicament Vétérinaire  
B.P. 90203 - La Haute Marche, Javené  
35302 Fougères Cedex - FRANCE  
Tel: (33) (0) 2 99 94 78 78  
Fax: (33) (0) 2 99 94 78 99  
[gerard.moulin@anses.fr](mailto:gerard.moulin@anses.fr)

**Dr Donald Prater**  
Assistant Commissioner for Food Safety  
Integration  
Office of Foods and Veterinary Medicine  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
UNITED STATES OF AMERICA  
Tel: (1) 301-348-3007  
[Donald.Prater@fda.hhs.gov](mailto:Donald.Prater@fda.hhs.gov)

**Dr Masumi Sato**  
Director  
Pathology and Pathophysiology Research Division  
National Institute of Animal Health  
3-1-5 Kannondai Tsukuba, Ibaraki 305-0856  
JAPAN  
Tel: (81) 29 838 7772  
[masumi@affrc.go.jp](mailto:masumi@affrc.go.jp)

**Dr Herbert Schneider**  
Agrivet International Consultants  
P.O. Box 178  
Windhoek - NAMIBIA  
Tel: (264) 61 22 89 09  
Fax: (264) 61 23 06 19  
[herbert@farmhabis.com](mailto:herbert@farmhabis.com)

**Dr Chris Teale**  
VLA Weybridge, New Haw  
Addlestone, Surrey KT15 3NB  
UNITED KINGDOM  
Tel: (44-1743) 46 76 21  
Fax: (44-1743) 44 10 60  
[Christopher.Teale@apha.gsi.gov.uk](mailto:Christopher.Teale@apha.gsi.gov.uk)

**OTHER PARTICIPANTS**

**Dr Jacques Acar**  
OIE Senior Expert  
22 rue Emeriau, 75015 Paris - FRANCE  
Tel: +33 (0)1 40 59 42 41  
[jfacar7@wanadoo.fr](mailto:jfacar7@wanadoo.fr)

**Dr April Johnson**  
Animal Production and Health Division  
Food and Agriculture Organization of the United  
Nations  
Viale delle Terme di Caracalla  
00153 Rome - ITALY  
[April.Johnson@fao.org](mailto:April.Johnson@fao.org)

**Dr Awa Aidara Kane**  
Coordinator, Foodborne and Zoonotic Diseases  
Department of Food Safety and Zoonoses,  
WHO – World Health Organization  
20 avenue Appia  
1211 Geneva 27 - SWITZERLAND  
Tel: +41 22 791 34 45  
[aidarakanea@who.int](mailto:aidarakanea@who.int)

**Dr Olivier Espeisse**  
HealthforAnimals  
168 Avenue de Tervueren, Box 8  
1150 Brussels, BELGIUM  
Tel: +32 (0)2 541-0111  
[olivier.espeisse@ceva.com](mailto:olivier.espeisse@ceva.com)

**SCAD REPRESENTATIVE**

**Dr Baptiste Dungu**  
Member of the Scientific Commission for Animal  
Diseases  
26 Dalrymple Crescent  
Edinburgh EH9 2NX  
Scotland  
UNITED KINGDOM  
Tel: +212 5 23 30 31 32  
Fax: +212 5 23 30 21 30  
[B.DUNGU@mci-santeanimale.com](mailto:B.DUNGU@mci-santeanimale.com)

**OIE HEADQUARTERS**

**Dr Matthew Stone**  
Deputy Director General  
[m.stone@oie.int](mailto:m.stone@oie.int)

**Dr Elisabeth Erlacher-Vindel**  
Head  
Science and New Technologies Dept  
[e.erlacher-vindel@oie.int](mailto:e.erlacher-vindel@oie.int)

**Dr François Diaz**  
Chargé de mission  
Science and New Technologies Dept  
[f.diaz@oie.int](mailto:f.diaz@oie.int)

**Dr Jorge Pinto Ferreira**  
Chargé de mission  
Science and New Technologies Dept  
[j.p.ferreira@oie.int](mailto:j.p.ferreira@oie.int)

**Dr Delfy Gochez**  
Chargée de mission  
Science and New Technologies Dept  
[d.gochez@oie.int](mailto:d.gochez@oie.int)

**Dr Margot Raicek**  
Chargée de mission  
Science and New Technologies Dept  
[m.raicek@oie.int](mailto:m.raicek@oie.int)

## Appendix III

July 2018

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

The OIE<sup>3</sup> International Committee unanimously adopted the List of Antimicrobial Agents of Veterinary Importance at its 75<sup>th</sup> General Session in May 2007 ([Resolution No. XXVIII](#)).

**Background**

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

The FAO<sup>4</sup>/OIE/WHO<sup>5</sup> Expert Workshop on Non-Human Antimicrobial Usage and Antimicrobial Resistance held in Geneva, Switzerland, in December 2003 (Scientific Assessment) and in Oslo, Norway, in March 2004 (Management Options) recommended that the OIE should develop a list of critically important antimicrobial agents in veterinary medicine and that WHO should also develop such a list of critically important antimicrobial agents in human medicine.

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

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

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

**Scope****The OIE List of Antimicrobial Agents of Veterinary Importance:**

- Addresses antimicrobial agents authorized for use in food-producing animals
- Does not include antimicrobial classes/sub classes only used in human medicine
- Does not include antimicrobial agents only used as growth-promoters
- Focuses currently on antibacterials and other important antimicrobials agents used in veterinary medicine

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<sup>3</sup> OIE: World Organisation for Animal Health

<sup>4</sup> FAO: Food and Agriculture Organization of the United Nations

<sup>5</sup> WHO: World Health Organization

### **Preparation of the draft list**

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

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

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

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

### **Refinement of the list**

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

### **Adoption of List of antimicrobial agents of Veterinary Importance**

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

This list was further updated and adopted in May 2013, May 2015 and May 2018 by the World Assembly of OIE Delegates.

## CRITERIA USED FOR CATEGORISATION OF VETERINARY IMPORTANT ANTIMICROBIAL AGENTS

In developing the list, the *ad hoc* Group agreed that any antimicrobial agent authorised for use in veterinary medicine according to the criteria of quality, safety and efficacy as defined in the *Terrestrial Animal Health Code* (Chapter 6.9. Responsible and prudent use of antimicrobial agents in veterinary medicine) is important. Therefore, based on OIE Member Country contributions, the Group decided to address all antimicrobial agents used in food-producing animals to provide a comprehensive list, divided into critically important, highly important and important antimicrobial agents.

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

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

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

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

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

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

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

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

### **Revision of the list of antimicrobial agents of Veterinary Importance**

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

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

The OIE *ad hoc* Group on Antimicrobial Resistance met in January 2018 to review and update the OIE List taking into account:

- the Global Action Plan on Antimicrobial Resistance supporting the phasing out of use of antibiotics for animal growth promotion in the absence of risk analysis;
- the Resolution N°38 adopted by the OIE World Assembly of Delegates in May 2017;
- the fifth revision of the WHO list of Critically Important Antimicrobials for Human Medicine (2016) moving Colistin among the Highest Priority Critically Important Antimicrobials; and
- the OIE report on antimicrobial agents intended for use in animals (Second Report), in particular the antimicrobial agents used as growth promoters (english version, page 30, figure 5)

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

## Recommendations

Any use of antimicrobial agents in animals should be in accordance with the OIE Standards on the responsible and prudent use laid down in the Chapter 6.9. of the *Terrestrial Animal Health Code* and in the Chapter 6.3. of the *Aquatic Animal Health Code*.

The responsible and prudent use of antimicrobial agents does not include the use of antimicrobial agents for growth promotion in the absence of risk analysis.

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

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

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

Among the VCIA in the OIE List, some are considered to be critically important both for human and animal health; this is currently the case for Fluoroquinolones and for the third and fourth generation of Cephalosporins. Colistin has been moved in 2016 to the WHO category of Highest Priority Critically Important Antimicrobials. Therefore these two classes and Colistin should be used according to the following recommendations:

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

The classes in the WHO category of Highest Priority Critically Important Antimicrobials should be the highest priorities for countries in phasing out use of antimicrobial agents as growth promoters.

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

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

### Abbreviations:

Animal species in which these antimicrobial agents are used are abbreviated as follows:

AVI:	avian	EQU:	Equine	VCIA:	Veterinary Critically Important Antimicrobial Agents
API:	bee	LEP:	Rabbit	VHIA:	Veterinary Highly Important Antimicrobial Agents
BOV:	bovine	OVI:	Ovine	VIA:	Veterinary Important Antimicrobial Agents
CAP:	caprine	PIS:	Fish		
CAM:	camel	SUI:	Swine		

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

ANTIMICROBIAL AGENTS (CLASS, SUB-CLASS, SUBSTANCE)	SPECIES	Specific comments	VCIA	VHIA	VIA
<b>AMINOCOUMARIN</b> Novobiocin	BOV, CAP, OVI, PIS	Novobiocin is used in the local treatment of mastitis and in septicaemias in fish This class is currently only used in animals			X
<b>AMINOCYCLITOL</b> Spectinomycin	AVI, BOV, CAP, EQU, LEP, OVI, PIS, SUI	Used for respiratory infections in cattle and enteric infections in multiple species	X		
<b>AMINOGLYCOSIDES</b> Dihydrostreptomycin Streptomycin	AVI, BOV, CAP, EQU, LEP, OVI, SUI API, AVI, BOV, CAP, EQU, LEP, OVI, PIS, SUI	The wide range of applications and the nature of the diseases treated make aminoglycosides extremely important for veterinary medicine.			
<b>AMINOGLYCOSIDES + 2 DEOXYSTREPTAMINE</b> Amikacin Apramycin Fortimycin Framycetin Gentamicin Kanamycin Neomycin Paromomycin Tobramycin	EQU AVI, BOV, LEP, OVI, SUI AVI, BOV, LEP, OVI, SUI BOV, CAP, OVI AVI, BOV, CAM, CAP, EQU, LEP, OVI, SUI AVI, BOV, EQU, PIS, SUI API, AVI, BOV, CAP, EQU, LEP, OVI, SUI AVI, BOV, CAP, OVI, LEP, SUI EQU	Aminoglycosides are of importance in septicaemias; digestive, respiratory and urinary diseases.  Gentamicin is indicated for <i>Pseudomonas aeruginosa</i> infections with few alternatives.  <b>Apramycin and Fortimycin are currently only used in animals.</b>  Few economic alternatives are available.	X		
<b>AMPHENICOLS</b> Florphenicol Thiamphenicol	AVI, BOV, CAP, EQU, LEP, OVI, PIS, SUI AVI, BOV, CAP, OVI, PIS, SUI	The wide range of applications and the nature of the diseases treated make phenicols extremely important for veterinary medicine.  This class is of particular importance in treating some fish diseases, in which there are currently no or very few treatment alternatives.  This class also represents a useful alternative in respiratory infections of cattle, swine and poultry.  This class, in particular florfenicol, is used to treat pasteurellosis in cattle and pigs.	X		
<b>ANSAMYCIN – RIFAMYCINS</b> Rifampicin Rifaximin	EQU BOV, CAP, EQU, LEP, OVI, SUI	This antimicrobial class is authorised only in a few countries and with a very limited number of indications (mastitis) and few alternatives.  Rifampicin is essential in the treatment of <i>Rhodococcus equi</i> infections in foals. However it is only available in a few countries, resulting in an overall classification of VHIA.		X	
<b>ARSENICAL</b> Nitarsonne Roxarsone	AVI, SUI AVI, SUI	Arsenicals are used to control intestinal parasitic coccidiosis. ( <i>Eimeria</i> spp.).			X
<b>BICYCLOMYCIN</b> Bicozamycin	AVI, BOV, PIS, SUI	Bicyclomycin is listed for digestive and respiratory diseases in cattle and septicaemias in fish.			X

ANTIMICROBIAL AGENTS (CLASS, SUB-CLASS, SUBSTANCE)	SPECIES	Specific comments	VCIA	VHIA	VIA				
<b>CEPHALOSPORINS</b>									
<b>CEPHALOSPORINS FIRST GENERATION</b>									
Cefacetile	BOV	Cephalosporins are used in the treatment of septicemias, respiratory infections, and mastitis.		X					
Cefalexin	BOV, CAP, EQU, OVI, SUI								
Cefalonium	BOV, CAP, OVI								
Cefalotin	EQU								
Cefapyrin	BOV								
Cefazolin	BOV, CAP, OVI								
<b>CEPHALOSPORINS SECOND GENERATION</b>									
Cefuroxime	BOV	The wide range of applications and the nature of the diseases treated make cephalosporin third and fourth generation extremely important for veterinary medicine.	X						
<b>CEPHALOSPORINS THIRD GENERATION</b>									
Cefoperazone	BOV, CAP, OVI								
Ceftiofur	AVI, BOV, CAP, EQU, LEP, OVI, SUI	Cephalosporins are used in the treatment of septicemias, respiratory infections, and mastitis. Alternatives are limited in efficacy through either inadequate spectrum or presence of antimicrobial resistance.	X						
Ceftriaxone	AVI, BOV, OVI, SUI								
<b>CEPHALOSPORINS FOURTH GENERATION</b>									
Cefquinome	BOV, CAP, EQU, LEP, OVI, SUI								
<b>FUSIDANE</b>									
Fusidic acid	BOV, EQU	Fusidic acid is used in the treatment of ophthalmic diseases in cattle and horses.			X				
<b>IONOPHORES</b>									
Lasalocid	AVI, BOV, LEP, OVI	Ionophores are essential for animal health because they are used to control intestinal parasitic coccidiosis ( <i>Eimeria</i> spp.) where there are few or no alternatives available. Ionophores are critically important in poultry. <b><u>This class is currently only used in animals.</u></b>		X					
Maduramycin	AVI								
Monensin	API, AVI, BOV, CAP								
Narasin	AVI, BOV								
Salinomycin	AVI, LEP, BOV, SUI								
Semduramicin	AVI								
<b>LINCOSAMIDES</b>									
Lincomycin	API, AVI, BOV, CAP, OVI, PIS, SUI	Lincosamides are essential in the treatment of Mycoplasmal pneumonia, infectious arthritis and hemorrhagic enteritis of pigs.		X					
Pirlimycin	BOV, SUI, AVI								
<b>MACROLIDES</b>									
<b>MACROLIDES 14-MEMBERED RING</b>									
Erythromycin	API, AVI, BOV, CAP, EQU, LEP, OVI, PIS, SUI	The wide range of applications and the nature of the diseases treated make macrolides extremely important for veterinary medicine.							
Oleandomycin	BOV								
<b>MACROLIDES 15-MEMBERED RING</b>									
Gamithromycin	BOV	<b>Macrolides are used to treat Mycoplasma infections in pigs and poultry, haemorrhagic digestive disease in pigs (<i>Lawsonia intracellularis</i>) and liver abscesses (<i>Fusobacterium necrophorum</i>) in cattle, where they have very few alternatives.</b>	X						
Tulathromycin	BOV, SUI								
<b>MACROLIDES 16-MEMBERED RING</b>									
Carbomycin	AVI	This class is also used for respiratory infections in cattle							
Josamycin	AVI, PIS, SUI								
Kitasamycin	AVI, SUI, PIS								
Mirosamycin	API, AVI, SUI, PIS								
Spiramycin	AVI, BOV, CAP, EQU, LEP, OVI, PIS, SUI								

ANTIMICROBIAL AGENTS (CLASS, SUB-CLASS, SUBSTANCE)	SPECIES	Specific comments	VCIA	VHIA	VIA
Terdecamycin Tildipirosin Tilmicosin Tylosin Tylvalosin	AVI, SUI BOV, SUI AVI, BOV, CAP, LEP, OVI, SUI API, AVI, BOV, CAP, LEP, OVI, SUI AVI, SUI				
<b>MACROLIDES C17</b> Sedecamycin	SUI				
<b>ORTHOSOMYCINS</b> Avilamycin	AVI, LEP, SUI	Avilamycin is used for enteric diseases of poultry, swine and rabbit. <b>This class is currently only used in animals.</b>			X
<b>PENICILLINS</b>					
<b>NATURAL PENICILLINS (including esters and salts)</b> Benethamine penicillin Benzylpenicillin Benzylpenicillin procaine / Benzathine penicillin Penethamate (hydroiodide)	BOV AVI, BOV, CAM, CAP, EQU, LEP, OVI, SUI BOV, CAM, CAP, EQU, OVI, SUI BOV	<b>Penethamate (hydroiodide) is currently only used in animals</b>			
<b>AMDINOPENICILLINS</b> Mecillinam	BOV, SUI				
<b>AMINOPENICILLINS</b> Amoxicillin Ampicillin Hetacillin	AVI, BOV, CAP, EQU, OVI, PIS, SUI AVI, BOV, CAP, EQU, OVI, PIS, SUI BOV				
<b>AMINOPENICILLIN + BETALACTAMASE INHIBITOR</b> Amoxicillin + Clavulanic Acid Ampicillin + Sulbactam	AVI, BOV, CAP, EQU, OVI, SUI AVI, BOV, SUI	The wide range of applications and the nature of the diseases treated make penicillins extremely important for veterinary medicine.  This class is used in the treatment of septicaemias, respiratory and urinary tract infections.	X		
<b>CARBOXYPENICILLINS</b> Ticarcillin Tobicillin	EQU PIS	This class is very important in the treatment of many diseases in a broad range of animal species.			
<b>UREIDOPENICILLIN</b> Aspoxicillin	BOV, SUI				
<b>PHENOXYPENICILLINS</b>		Few economical alternatives are available.			
Phenethicillin Phenoxyethylpenicillin	EQU AVI, SUI				
<b>ANTISTAPHYLOCOCCAL PENICILLINS</b> Cloxacillin Dicloxacillin Nafcillin Oxacillin	BOV, CAP, EQU, OVI, SUI BOV, CAP, OVI, AVI, SUI BOV, CAP, OVI BOV, CAP, EQU, OVI, AVI, SUI				

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

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



**REPORT OF THE MEETING OF THE OIE AD HOC GROUP  
ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT  
Paris, 3-5 July 2018**

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The OIE *ad hoc* Group on bovine spongiform encephalopathy (BSE) risk assessment (hereafter the Group) met from 3 to 5 July 2018 at the OIE Headquarters to provide independent analysis and advice to the OIE on the risk-based provisions applicable to the categorisation of BSE risk status as well as on the recommendations for international trade.

**1. Opening**

Dr Monique Eloit, Director General of the OIE, welcomed the Group convened to revise the provisions of the *Terrestrial Animal Health Code (Terrestrial Code)* Chapter 11.4. on BSE, in particular the provisions pertaining to the categorisation of official BSE risk status, which may no longer be appropriate to the current BSE risk, and may not reflect the latest scientific evidence. She emphasised that the revision of the BSE standards was considered a priority for the OIE and its Members. She insisted that whilst BSE might be a sensitive and political issue, the Group's proposals should only be scientifically driven.

Dr Eloit indicated this Group would probably meet several times to complete its mandate. She also noted that this Group will articulate with another BSE *ad hoc* Group which will focus on BSE surveillance, and some experts might participate in the two Groups.

The World Assembly of OIE Delegates will be updated on the progress of these Groups at the next OIE General Session.

Dr Laure Weber-Vintzel, Head of Status Department, reminded the Group about the confidentiality undertaking that they have signed, and about the importance of properly managing conflicts of interest.

Dr Baptiste Dungu, representative of the Scientific Commission for Animal Diseases, and Dr Masatsugu Okita, representative of the Terrestrial Animal Health Standards Commission, indicated the support of the Commissions they represent to Dr Eloit's point regarding the need to refine the BSE standards based on an adequate risk assessment which would not discriminate against any OIE regions.

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

Dr Noel Murray was appointed Chair and Dr Stephen Cobb acted as rapporteur with the support of the OIE Secretariat. The Group endorsed the proposed agenda for the meeting.

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

**3. Main directions proposed for a revised BSE risk-based approach**

The main directions proposed by the Group regarding a risk-based approach for categorising BSE risk status of a country or *zone* are outlined below with further details provided in section 4 of this report.

Consistent with the recommendations in Chapter 2.1. of the *Terrestrial Code* and the OIE Handbook on Import Risk Analysis for Animals and Animal Products (Volume 1, 2010), the categorisation of BSE risk status should be determined from a comprehensive risk assessment composed of four steps: entry assessment, exposure assessment, consequence assessment, and risk estimation.

The current provisions for the official recognition of BSE risk status primarily place the emphasis on determination of whether or not a country has implemented appropriate measures, particularly through a feed ban, to mitigate against the risk factors associated with the recycling and amplification of the BSE agent. This pathway proved appropriate for countries that have reported indigenous cases of classical BSE in their cattle populations and for those whose import history indicated that there was a non-negligible likelihood that the BSE agent may have been introduced. However, the Group acknowledged that the impact of local husbandry and farming practices on the likelihood of the BSE agent being recycled were insufficiently taken into account. This is particularly relevant for those countries whose cattle populations are reared either predominantly or exclusively under extensive pastoral systems, or where there is practically no animal rendering production. The Group therefore emphasised the need to recognise that there are two pathways whereby the BSE risk status of the cattle population (*Bos taurus* and *Bos indicus*) of a country or *zone* can be considered to pose a negligible risk. One from a negligible likelihood of a cattle population being exposed to the BSE agent due to the local husbandry and farming practices (e.g., extensive pastoral systems), and the other from the implementation of appropriate measures to mitigate risk factors for recycling and amplification of the BSE agent. The Group recommended to explicitly incorporate these two pathways for achieving a BSE negligible risk status, together with the risk-based provisions defining these distinct scenarios, in the *Terrestrial Code*.

The impact of the occurrence of one or more indigenous cases of classical BSE in cattle born after a ruminant-to-ruminant feed ban on the BSE risk status of countries or *zones* recognised as posing a negligible BSE risk should be assessed on the basis of an epidemiological investigation and an updated risk assessment.

Demonstration of compliance with the requirements for negligible BSE risk status, but for an insufficient period of time, would result in a controlled BSE risk status categorisation. This would represent an intermediate step for countries or *zones* to ultimately achieve negligible BSE risk status.

To minimise inconsistencies, duplications should be avoided in the *Terrestrial Code*. Chapter 11.4. should focus on defining the broad requirements applicable to the official recognition of BSE risk status, whereas Chapter 1.8. (the 'BSE questionnaire') should provide a complementary tool for Members to demonstrate that they fulfil the requirements laid out in Chapter 11.4.

Both the BSE questionnaire and the annual reconfirmation form for official recognition of a BSE risk status should be thoroughly reviewed alongside the changes hereby proposed to Chapter 11.4.

The Group emphasised that training by the OIE on the procedures and requirements for the official recognition of the BSE risk status of a country or *zone* would be beneficial for Members once the revised provisions come into force.

#### 4. Revision of Chapter 11.4.

When revising Chapter 11.4., the Group considered the revisions proposed by the OIE *ad hoc* groups on BSE in 2014 and 2016 as well as Members' comments on the 2014 proposals, and gave careful regard to the specific issues listed in the Terms of Reference.

##### 4.1. Article 11.4.1. General provisions, case definition and safe commodities

###### a) *Atypical BSE*

The Group considered how atypical BSE should be addressed in the *Terrestrial Code*. Since atypical BSE is "*believed to occur spontaneously in all cattle populations*", the Group questioned whether BSE would fulfil the second criteria for the inclusion of a disease in the OIE list specified in Article 1.2.2. of the *Terrestrial Code* as it would be implausible for any country with cattle to claim freedom from atypical BSE. Nevertheless, if BSE was to remain a listed disease, then consistent with the approach retained by previous OIE *ad hoc* Groups on BSE and endorsed by the OIE World Assembly in 2015, the occurrence of atypical BSE should not be considered for the purpose of official BSE risk status recognition, and that this should be clearly stated in Article

11.4.2. rather than in Article 11.4.1. Importantly, the Group determined that despite classical BSE is the only BSE strain recognised as being transmitted via feed and considered for the purpose of OIE official BSE risk status recognition, the possible recycling and amplification of all BSE agents, including that of atypical BSE, must be considered in the exposure assessment (Article 11.4.2.b.) when assessing the risk of exposure.

**b) Articles 11.4.1, 11.4.1.bis, and 11.4.1.ter**

The Group reviewed the draft Articles 11.4.1., 11.4.1.bis, and 11.4.1.ter (General provisions, Case definition, and Safe commodities, respectively) proposed by the 2014 and 2016 BSE *ad hoc* Groups. Overall, the Group concurred with the proposed provisions, and edits were suggested to improve clarity.

BSE primarily affects cattle. While natural cases of BSE were reported many years ago in household cats, several ruminant and feline species in zoos, and two goats in commercial herds, these species are not considered to be epidemiologically significant, particularly in the presence of an ongoing ruminant-to-ruminant feed ban<sup>1</sup>. Similarly, although sheep can be experimentally infected by oral challenge and can transmit BSE under usual husbandry conditions, there is no evidence that BSE has become established in the commercial sheep population<sup>2</sup>.

**4.2. Article 11.4.2. The BSE risk status of the cattle population of a country, zone or compartment**

**a) Scope (country, zone, compartment)**

The Group discussed the relevance of defining a BSE risk status at the level of a *zone* or *compartment*.

The official recognition of BSE risk status by the OIE only applies to countries and *zones* (Article 1.6.1. of the *Terrestrial Code*). Regarding *compartments*, their BSE risk status may be claimed by Members on the basis of a self-declaration and their recognition should be based on bilateral negotiations between trading partners.

The Group noted that since legislation supporting a feed ban was likely to be national in scope, monitoring its implementation at the level of a *zone* or *compartment* would likely be challenging. The need for an animal identification and traceability system that underpins the establishment of a *zone* or *compartment* was highlighted. The Group also noted that only a few *zones* have been officially recognised to date, and that some of these were defined “artificially” to exclude portions of the territory of a country where the youngest indigenous BSE case was born less than 11 years ago.

Nevertheless, the Group determined that provisions for the definition of BSE risk status at the level of a *zone* or *compartment* should remain in the *Terrestrial Code* to provide sufficient flexibility to Members in defining a BSE strategy that would best accommodate their specific situation as well as ensuring consistency with the provisions for other diseases in the *Terrestrial Code*.

**b) Risk assessment**

The Group noted that it was specified in the introduction of point 1 of Article 11.4.2. that the risk assessment should be reviewed annually. The Group agreed with this recommendation, but advised that it should be captured in Articles 11.4.3. and 11.4.4. within the provisions for the maintenance of a BSE risk status.

<sup>1</sup> Simmons M, Ru G, Casalone C, et al. DISCONTTOOLS: Identifying gaps in controlling bovine spongiform encephalopathy. *Transbound Emerg Dis.* 2018; 65(Suppl. 1):9–21. DOI: 10.1111/tbed.12671 and Sugurdson CJ and Miller M. Other animal prion diseases. *Br Med Bull* 2003; 66(1):199-212. DOI: 10.1093/bb/dg66.199

<sup>2</sup> Stack M, Jeffrey M, Gubbins S., et al. Monitoring for bovine spongiform encephalopathy in sheep in Great Britain, 1998-2004. *J Gen Virol.* 2006; 87(Pt 7), 2099–2107. DOI: 10.1099/vir.0.81254-0

The Group stressed that factors to be taken into consideration in the entry and the exposure assessments listed in Article 11.4.2. were duplicated -without being fully harmonised- in Articles 11.4.23. to 11.4.29. and in Chapter 1.8. Duplications within the *Terrestrial Code* increase the likelihood of inconsistencies. The Group recommended to delete the details in Article 11.4.2. regarding the factors to be taken into consideration in the entry and the exposure assessments, and to only include them in Chapter 1.8.

Regarding the entry assessment, the Group noted that it included both local factors (points i and ii; i.e., presence/absence of the BSE agent in the indigenous population, and production of MBM or greaves) and factors associated with the introduction of the BSE agent through import (points iii to vii). The Group suggested that, consistent with recommended approaches on risk assessment, including provisions of Chapter 2.1. of the *Terrestrial Code* on Import Risk Analysis and the OIE Handbook on Import Risk Analysis for Animals and Animal Products (Volume 1, 2010), the entry assessment should focus on the likelihood of imported commodities being infected or contaminated with the BSE agent, whilst local factors should be addressed in the exposure assessment. The Group stressed that there are two important outcomes associated with this approach:

- Chapter 1.8. will have to be revised to mirror the proposed changes;
- An exposure assessment will need to be performed regardless of the results of the entry assessment.

With respect to the exposure assessment, the Group clarified that exposure to the atypical BSE agent should be taken into consideration. Indeed, whilst to date there is no evidence that atypical BSE is transmissible, recycling of the atypical BSE agent has not been ruled out and should be avoided as a precautionary measure. The Group noted that this represents another reason why an exposure assessment should be performed regardless of the outcome of the entry assessment.

Consistent with standard OIE methodologies for conducting a risk assessment, the Group proposed that two additional steps (a 'consequence assessment' and a 'risk estimation') should also be undertaken to complete the assessment of the BSE risk.

A consequence assessment estimates the likelihood of cattle becoming infected following exposure to the BSE agent together with the likely extent of any subsequent recycling and amplification of the BSE agent. As an example, in countries where cattle are predominantly reared under an extensive pastoral system, the only plausible exposure pathway to prions would be in those situations where some cattle may be fattened for several months on feed supplements in a so called "terminal feedlot"<sup>3</sup>. Cattle are more likely infected within their first year of life, whereas older animals are likely to be refractory to infection. Even if animals in terminal feedlots were to become infected, considering that they would be slaughtered within months following exposure, they would not have reached a stage in their incubation period when their SRM (those tissues listed in Article 11.4.14) could potentially result in recycling of infectivity if these tissue were then rendered and contaminated ruminant feed. In this example, given the age at the time of exposure and the protracted incubation period of BSE, it would be reasonable to consider negligible the consequences of exposure of yearling or adult cattle to the BSE agent in contaminated feed supplements within one or several months prior to slaughter. As a contrasting example, the consequences of exposure would not be considered negligible for cattle exposed to prion contaminated feed within their first year of life (calves or weaners) when they are more likely to become infected. This is because there is substantial amount of prion infectivity in SRMs of individuals exposed to the BSE agent within their first year of life and that entered the breeding herd and have survived long enough to reach the later stages of a protracted incubation period when the levels of the BSE agent in their SRM would begin to rise dramatically. If these SRMs were rendered and subsequently contaminated ruminant feed, which was then fed to cattle, it is highly likely that some level of recycling of infectivity would occur. It is important to note that while a small amount of contaminated feed may be sufficient to transmit BSE, amplification requires

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<sup>3</sup> A terminal feedlot is a type of feedlot where all cattle leaving it are sent directly to slaughter and do not re-enter the general cattle population.

significant recycling. Unless there is widespread, systemic, ongoing exposure to the BSE agent in a cattle population, an epidemic is unlikely to emerge.

The risk estimation step summarizes the results from the entry, exposure, and consequence assessments. For the official recognition of the BSE risk status of a country or a *zone* by the OIE, the risk estimation would have to be assessed by the OIE *ad hoc* Group on BSE Risk Status Evaluation of Members and endorsed by the Scientific Commission for Animal Diseases.

The Group discussed whether there was a need to outline the different steps of the BSE risk assessment in Chapter 11.4. or if these steps could be covered by a cross-reference to Chapter 2.1. of the *Terrestrial Code*. Considering that Chapter 2.1. focuses on import risk analysis, the Group determined it was appropriate to list and define the steps to be undertaken to perform a comprehensive BSE risk assessment in Article 11.4.2.

The Group noted that points 2 to 4 of Article 11.4.2. (i.e., an ongoing awareness programme for BSE, compulsory notification and investigation, and examination of samples carried out in accordance with the *Terrestrial Manual*) were more related to risk mitigation than to risk assessment. Therefore, to improve clarity, the Group recommended Article 11.4.2. should primarily focus on risk assessment and that the provisions related to risk mitigation should be moved to Article 11.4.3.

### 4.3. Article 11.4.3. Negligible BSE risk

#### a) *Categories of BSE risk status*

The Group discussed the merits of retaining a categorisation system for a country or zone's BSE risk status as a basis for selecting sanitary measures for particular commodities, versus a purely commodity-based approach whereby the same measures would apply to a particular commodity from all countries or zones irrespective of their specific BSE-related risk factors. Overall, the Group agreed that the level of BSE risk could not be considered similar for all Members and therefore determined that a categorisation should be retained to facilitate trade from countries having a lesser risk of BSE.

As highlighted in Section 3 of this report, the current provisions for the official recognition of BSE risk status primarily place the emphasis on determination of whether or not a country has implemented appropriate measures, particularly through a feed ban, to mitigate against the risk factors associated with the recycling and amplification of the BSE agent. This pathway proved appropriate for countries that have reported indigenous cases of classical BSE in their cattle populations and for those whose import history indicated that there was a non-negligible likelihood that the BSE agent may have been introduced. However, the Group acknowledged that the impact of local husbandry and farming practices on the likelihood of the BSE agent being recycled were insufficiently taken into account. This is particularly relevant for those countries whose cattle populations are reared either predominantly or exclusively under extensive pastoral systems, or where there is practically no animal rendering production.

The Group determined that a negligible BSE risk status could result from either:

- a negligible likelihood of a cattle population being exposed to BSE agent due to the local husbandry and farming practices (e.g., extensive pastoral systems) for more than the 95th percentile of the incubation period (i.e., for at least 8 years);
- the appropriate mitigation of risk factors for recycling and amplification of the BSE agent for the same duration as defined above (i.e., at least 8 years).

The Group recommended that these two pathways for achieving a negligible BSE risk status should be recognised in the *Terrestrial Code* and that provisions adequate to these distinct scenarios should be proposed.

**b) Prerequisites for the detection of BSE cases**

The Group agreed that regardless of which pathway leads to a categorisation as negligible BSE risk status (i.e., on the basis of husbandry and farming practices, or as a result of the effective application of measures to prevent recycling), requirements for an ongoing awareness programme, compulsory notification and investigation of clinical suspects, as well as a laboratory examination of appropriate samples performed in accordance with the *Terrestrial Manual*, continue to be relevant as they support the identification of BSE cases. The Group recommended that the *ad hoc* Group on BSE surveillance should determine how long these requirements need to have been in place before a BSE risk status can be officially recognised by the OIE (currently 7 years based on the provisions of Articles 11.4.3. and 11.4.4.).

The Group also recommended that the *ad hoc* Group on BSE surveillance should define the surveillance provisions for countries posing a negligible BSE risk as well as the duration for which these provisions should have been applied before an official BSE risk status can be recognised by the OIE.

**c) Ruminants not fed with meat-and-bone meal or greaves derived from ruminants**

The Group emphasised that, depending on traditional husbandry and farming practices, particularly in countries with extensive pastoral systems, a legislated feed ban enforced by national regulations may not always be necessary to provide assurance that ruminants are not fed with meat-and-bone meal nor greaves derived from ruminants. However, it remains reasonable that, under such circumstances, these countries would be required to demonstrate that neither meat-and-bone meal nor greaves derived from ruminants have been fed to ruminants for at least eight years. In addition, they would need to demonstrate that the consequences of cross contamination, that might occur in a terminal feedlot, would be negligible. Rather than official control and audits, the Group recommended that documented evidence be provided to substantiate any claims made concerning the impact of husbandry and farming practices on mitigating against BSE related risks. This would include a detailed explanation of husbandry and farming practices for both ruminant and non-ruminant species, the demographics of the cattle population and other farmed animal species, the activities to deal with cattle mortalities and slaughterhouse waste, and the existence or lack of rendering facilities and feed mills. Such an approach would allow for more flexibility to accommodate different situations and practices particularly in lower and middle income countries.

**d) Occurrence of indigenous cases of classical of BSE**

The Group discussed the impact of the occurrence of one or a few indigenous cases of classical BSE on the BSE risk status. In particular, the Group assessed the current requirement that “*if there has been an indigenous case, every indigenous case was born more than 11 years ago*”.

This 11-year period was defined based on unpublished data at the time the corresponding provision in Chapter 11.4. was adopted in May 2006. The Group pointed out the lack of any robust scientific evidence supporting this time period, and recommended that the occurrence of a BSE case (without any specification of a time window) and its potential impact on the overall level of risk should be addressed in the consequence assessment.

The Group agreed that the occurrence of one or a few indigenous cases of classical BSE in animals born after the implementation of a feed ban did not necessarily raise concerns over the ongoing effectiveness of the feed ban. The Group noted the outcome of a detailed investigation described in a recent opinion from the European Food Safety Authority<sup>4</sup> of 60 classical BSE cases in the European Union (EU) born after the “total<sup>5</sup>” feed ban was enforced from January 2001 (such cases are referred to as BARBs).

<sup>4</sup> EFSA, Bovine spongiform encephalopathy (BSE) cases born after the total feed ban, EFSA Journal (2017) ;15(7):4885 (2017) <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4885>

<sup>5</sup> Under the total feed ban the feeding of all processed animal proteins (PAPs) was banned from feeding to all farmed animals.

In the context of considerable uncertainty resulting from the timespan between the confirmation of any BSE cases and their potential exposure to the BSE agent within their first year of life, it is extremely unlikely that a specific source of infection can ever be ascertained. In this investigation, feeding material contaminated with the BSE agent could not be excluded as the origin for any of the BARBs, with the apparent exception of one. At the same time, while it was not possible to definitively attribute feed as the cause of any of these cases, it was considered unlikely that they were spontaneous. Considering that it is well known that the BSE agent can remain biologically active for many years, isolated pockets of residual infectivity in a complex network of rendering, feed production, distribution and storage may account for rare, sporadic opportunities of exposure. In fact, it is worth noting that the rate of occurrence of the BARBs in the 11 Member States of the EU from which they were reported has been extremely rare. Collectively, testing over 97 million cattle between 2001 and 2015 led to the detection of just 60 BARBs. Since the year of birth of a BSE case is accepted to be a surrogate indicator of the year when the exposure to the BSE agent occurred, it is informative to consider that the vast majority (90%) of the BARBs were born within the first four years<sup>6</sup> following the implementation of the reinforced (total) feed ban in the EU in January 2001. The remaining 10% (6) cases were born between 2005 and 2011, with single cases reported from each of these years, except for 2008 when no case arose. Taken together, the results from the EU's ongoing surveillance program confirm that the occurrence of a limited number of BARBs is not indicative of gaps or failures in a feed ban. Rather, they are more than likely to be indicative of isolated, residual pockets of infectivity with extremely limited opportunities of exposure involving one or a few animals that ultimately have negligible consequences in terms of recycling of infectivity, particularly considering the ongoing implementation of a feed ban. Overall, the Group could not conclude that the occurrence of one or a few cases of classical BSE in animals born after a feed ban systematically reveals a breach in the effective enforcement of the feed ban.

The Group stressed that, currently, the occurrence of a single indigenous case of classical BSE born less than 11 years ago automatically leads to the downgrading of a BSE risk status of a country or *zone* from negligible to controlled. The Group emphasised that, based on the rationale outlined in the preceding paragraph, withdrawal of negligible BSE risk status in such circumstances is likely to be disproportionate to the risk associated with the occurrence of one or a few indigenous cases of classical BSE in animals born after a feed ban, particularly where effective mitigating measures have been continuously implemented.

Overall, the Group reaffirmed that the provisions applicable to BSE in the *Terrestrial Code* should be based on a risk assessment. Therefore:

- For the initial recognition of a negligible BSE risk status of a country or a *zone*, the age of the youngest indigenous case of classical BSE should be taken into consideration in the BSE risk assessment (consequence assessment);
- For countries or *zones* recognised as posing a negligible BSE risk status, the occurrence of indigenous case(s) should trigger an investigation and an update of the BSE risk assessment by the Member. The impact on the BSE risk status of the country or the *zone* should then be assessed by the Scientific Commission for Animal Diseases, with the support of the OIE *ad hoc* Group on BSE Risk Status Evaluation of Members, based on the outcome of the corresponding investigation and updated risk assessment. This may lead to resetting the date from which the feed ban can be considered effectively enforced, with possible consequences for the age of animals from which commodities can be traded.

The Group discussed the provisions applicable to birth cohort animals when an indigenous case of classical BSE is identified. The Group acknowledged that tracing birth cohorts can be challenging in practice. In addition, the potential gain in risk reduction following the complete destruction of all cohort animals was assessed. The Group reviewed the surveillance data from the EU from 2001 to 2017, which include a total of 13,037 cases of classical BSE identified through various surveillance streams. The surveillance stream "eradication measures" includes tested animals from birth cohorts, feed cohorts, live offspring, and sire and dams. Overall, 48 cases were identified through this surveillance stream, accounting for 0.4% of all BSE cases identified over the last 16 years. Surveillance data from Great Britain from 1996 to 2008 also showed the occurrence of BSE cases

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<sup>6</sup> A total of 25 cases (41.6%) were born in 2001; 14 cases (23.3%) born in 2002; 8 cases born in 2003; 7 cases (11.6%) born in 2004.

amongst cohorts to be much lower than in other surveillance streams<sup>7</sup>. Based on these findings, together with a consideration of the ongoing application of various sanitary measures to protect public health, principally through the hygienic removal of SRM (those tissues listed in Article 11.4.14) at slaughter, as well as animal health through the ongoing implementation of a feed ban, the Group determined that the complete destruction of all cohort animals would not provide a significant gain in risk reduction. Overall, the Group concluded that as long as measures including a feed ban and the removal and destruction of tissues listed in Article 11.4.14. had been continuously and effectively implemented, and an effective surveillance system for the detection and investigation of cases is in place, any risks associated with cohort animals would be effectively eliminated.

#### 4.4. Article 11.4.4. Controlled BSE risk

If a country or *zone* can demonstrate compliance with the requirements listed in Article 11.4.3., but not yet for the relevant period of time, it would qualify to be recognised as having a controlled BSE risk. As such, controlled BSE risk status provides an intermediate step for Members as they work towards achieving negligible BSE risk status as well as ensuring the sanitary safety of exported commodities.

#### 4.5. Article 11.4.5. Undetermined BSE risk

By default, the cattle population of a country, *zone* or *compartment* not recognised as fulfilling the requirements of negligible or controlled BSE risk would be considered as posing an undetermined BSE risk.

#### 4.6. Articles 11.4.6. to 11.4.19. Requirements for trade

The Group undertook a preliminary evaluation of the requirements for trade listed in Articles 11.4.6. to 11.4.19 and determined that a detailed review of these requirements would be undertaken at its next meeting.

#### 4.7. Articles 11.4.23. to 11.4.29. BSE risk assessment

The Group noted that while Articles 11.4.23 to 11.4.29 set out the requirements for an entry and exposure assessment together with the assumptions, the broad questions to be answered, and the supporting rationale and evidence required for key steps in the risk assessment, these are not fully harmonised with Chapter 1.8. (the 'BSE questionnaire') of the *Terrestrial Code*. As a result, there are a number of inconsistencies that potentially create confusion for Members requesting official recognition by the OIE. To address this issue, the Group recommended that Articles 11.4.23 to 11.4.29 be deleted from Chapter 11.4. In this way, and to be consistent with the structure of other Chapters of diseases that have official recognition, Chapter 11.4. would focus on defining the requirements applicable to the official recognition of BSE risk status, whereas Chapter 1.8. would provide a tool in the form of a questionnaire for Members to provide the relevant information and demonstrate how they fulfil the requirements set in Chapter 11.4.

The Group emphasised that Chapter 1.8. will need to be thoroughly reviewed to ensure that it fully reflects the proposed revisions to Chapter 11.4.

### 5. Preliminary considerations for Chapter 1.8.

The Group undertook a preliminary evaluation of the BSE questionnaire (Chapter 1.8.) and determined that its detailed revision would be undertaken at the next *ad hoc* group meeting.

<sup>7</sup> Wilesmith JM, Ryan JBM, Arnold ME, et al. Descriptive epidemiological features of cases of bovine spongiform encephalopathy born after July 31, 1996 in Great Britain. *Vet Record* 2010; 167:279-286. DOI: 10.1136/vr.c4552

### 5.1. Article 1.8.1.

The Group noted that a general description of bovine husbandry and slaughtering practices is requested in the introduction (Article 1.8.1.1.). However, in accordance with the proposed revisions to Articles 11.4.2. and 11.4.3., and as husbandry and farming practices may be a key pillar to support the recognition of a negligible or controlled BSE risk status of a country or *zone*, rather than a general description of these practices, comprehensive details would need to be provided by the applicant Member. The most appropriate place in the questionnaire to request this information would be in the exposure assessment.

### 5.2. Article 1.8.2. BSE risk status

#### a) *Entry assessment*

Detailed quantitative information (e.g., volume, statistics, etc.) is currently requested on importations of various imported commodities regardless of whether or not the relevant measures within Chapter 11.4. that ensure their sanitary safety are applied. The Group considered that requesting detailed quantitative information for commodities imported under conditions consistent with the recommendations in the Chapter 11.4 cannot be justified. Rather, the emphasis should be on documenting the details of the measures applied to imported commodities depending on the BSE risk status of the country or *zone* of origin and whether or not they are consistent with or provide an equivalent level of assurance with the recommendations laid out in Chapter 11.4. The rationale and supporting evidence upon which a claim of consistence with Chapter 11.4 or equivalence is being made should be provided. In addition to describing the measures, details would need to be provided on how the Competent Authority verifies compliance with them through supporting legislation, certification, etc. In situations where the measures are not consistent and cannot be considered to provide an equivalent level of assurance, it would be reasonable to request that detailed quantitative information continue to be provided.

#### b) *Exposure assessment*

Depending on which pathway is relevant for a Member seeking status recognition as having a negligible or controlled BSE risk (husbandry and farming practices, or appropriate risk mitigating measures), the information that needs to be provided for the exposure assessment would differ. Specific details of the amounts and types of information required for each pathway will be developed at the next meeting of the *ad hoc* group.

The Group emphasized that only official inspections (i.e., those undertaken by the Competent Authority) should be considered in the exposure assessment. The Group recommended to review the tables in the questionnaire where audit findings in rendering plants and feed mills are recorded. In particular, clarification is needed on the meaning of the term “supervision” in relation to the number of rendering plants and feed mills inspected under Competent Authority supervision. Also, when referring to infractions in feed mills and rendering plants, the term 'corrective action' should be used instead of 'method of resolution'. Also, inconsistent use of the terms “cattle”, “bovine”, “ruminants” and “by-products” throughout the BSE questionnaire needs to be reviewed.

#### c) *Consequence assessment and risk estimation*

Consistent with draft Article 11.4.2, explicit sections on consequence assessment and risk estimation will need to be developed and included in the BSE questionnaire.

**5.3. Articles 1.8.3 and 1.8.4. Other requirements and BSE surveillance and monitoring systems**

The sections on other requirements and BSE surveillance and monitoring systems will be reviewed by the *ad hoc* Group on BSE surveillance.

**5.4. Article 1.8.5. BSE history**

Evidence regarding the historic presence (or absence) of the BSE agent addressed in Article 1.8.5. of the BSE questionnaire should be included in the exposure assessment (however, the information on cohorts would no longer be relevant in the assessment in light of the revised provisions of Article 11.4.3.).

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

The Group reviewed and amended the draft report. The Group agreed that the report reflected the discussions.

**7. Way forward**

The Group suggested the *ad hoc* Group on BSE surveillance be convened before this Group meets again to complete its terms of reference.

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.../Appendices

Appendix I**MEETING OF THE OIE AD HOC GROUP ON BSE RISK ASSESSMENT****Paris, 3 to 5 July 2018****Terms of Reference****Purpose**

The purpose of this *ad hoc* Group is to provide independent analysis and advice to OIE on the risk-based provisions applicable to the categorisation of BSE risk status as well as on the subsequent recommendations applicable for international trade.

**Functions**

This *ad hoc* Group will report to the Director General of the OIE, and approved reports will be considered by the relevant Specialist Commissions (the Scientific Commission or the Terrestrial Animal Health Standards Commissions) when necessary, in accordance with the OIE Basic Texts.

The responsibilities of this *ad hoc* Group will be to review current scientific evidence, provide guidance and draft recommendations on:

1. The assessment of the risk with regard to the BSE agent:
  - i. Assess the need for revising Article 11.4.1. of the *Terrestrial Code*, especially the list of susceptible species of significance for the purpose of the *Terrestrial Code*;
  - ii. Revise Article 11.4.2 of the *Terrestrial Code*;
  - iii. Revise Articles 11.4.23. to 11.4.29. of the *Terrestrial Code*. In addition, considering that BSE risk assessment is addressed in Article 1.6.5 (now Chapter 1.8., Article 1.8.2. points 2 and 3) as well as in Articles 11.4.2. point 1 and 11.4.23. to 11.4.29. of the *Terrestrial Code*, advise as to the best structure to be retained in the *Terrestrial Code* to avoid duplications.
  - iv. Revise and clarify the relationship between the entry and the exposure assessments. In particular, the necessity of performing an exposure assessment if the likelihood of entry of the BSE agent is negligible should be further assessed;
  - v. Re-assess the requirement that no indigenous case of classical BSE should be born less than 11 years ago and whether this should be encompassed in the overall risk assessment.
2. The provisions applicable to the categorisation of BSE risk status (revision of Articles 11.4.3. and 11.4.4. of the *Terrestrial Code*)
  - i. assess the relevance of the current categorisation of BSE risk status (negligible, controlled and undetermined categories of risk). This assessment should encompass the following as well as any additional factors identified as relevant by the Group:
    - the different requirements applicable to the recognition and maintenance of controlled and negligible BSE risks;
    - the prevailing epidemiological situation (countries currently having a controlled risk status and expected application in the future);
    - the impact on risk associated with the duration of the implementation of an effective feed ban and the time elapsed since the birth of the youngest indigenous case of classical BSE;

- relevance of the high level of continuous active surveillance required for maintenance of BSE risk status (N.B. this is common to both *ad hoc* Groups, and therefore interaction between the groups on this aspect is expected);
  - the relevance of a zoning or compartmentalisation approach for the categorisation of BSE risk status, and the corresponding requirements- if considered appropriate.
- ii. If appropriate based on the assessment described in i), the requirements applicable to the current categories of BSE risk status or new categories of BSE risk status and corresponding requirements for risk-based categorisation, with particular attention to:
- Whether the timelines should be reassessed based on current scientific evidence on the epidemiology of the disease;
  - Clarifying the information required to demonstrate the effectiveness of the feed ban;
  - The potential impact of the new requirements/categorisation on the status of countries or *zones* already having an officially recognised BSE risk status.
3. The relevance of the requirements for trade applicable to the different categories BSE risk status (revision of Articles 11.4.6 to 11.4.19 of the *Terrestrial Code*).
  4. The relevance of providing requirements for trade applicable to atypical BSE.
  5. The list of safe commodities if appropriate in light of the recent scientific knowledge (revision of Article 11.4.1. of the *Terrestrial Code*) taking into consideration the recommendations made by the *ad hoc* Group on BSE which met in 2016.
  6. The list of specified risk materials (SRMs) if appropriate in light of the recent scientific knowledge (revision of Article 11.4.14. on recommendations on commodities that should not be traded).
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Appendix II

**MEETING OF THE OIE AD HOC GROUP ON BSE RISK ASSESSMENT**  
**Paris, 3 to 5 July 2018**

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**Agenda**

1. Opening.
2. Adoption of the agenda and appointment of chairperson and rapporteur.
3. Main directions proposed for a revised BSE risk-based approach
4. Revision of Chapter 11.4.
5. Preliminary considerations on Chapter 1.8.
6. Finalisation and adoption of the draft report
7. Way forward

Appendix III**MEETING OF THE OIE AD HOC GROUP ON BSE RISK ASSESSMENT**

Paris, 3 to 5 July 2018

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

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**Dr Stephen Cobb**  
 Manager (New Organisms)  
 Environmental Protection Agency,  
 NEW ZEALAND  
 Tel: +64 474 55 22  
[stephen.cobb@epa.govt.nz](mailto:stephen.cobb@epa.govt.nz)

**Dr Hae-Eun Kang**  
 Director of the Foreign Animal Disease  
 Division, Animal and Plant Quarantine Agency  
 QIA  
 Mafra  
 KOREA  
 Tel: +82 54 912 0884  
[kanghe@korea.kr](mailto:kanghe@korea.kr)

**Dr Ximena Melón**  
 Servicio Nacional de Sanidad y Calidad  
 Agroalimentaria (SENASA)  
 Paseo Colón 367, CABA (1063)  
 ARGENTINA  
 Tel: +54 11 41 21 5425  
[xmelson@senasa.gob.ar](mailto:xmelson@senasa.gob.ar)

**Dr Letlhogile Modisa**  
 (invited, but could not attend)  
 Director Veterinary Services  
 Private Bag 0032  
 Gaborone  
 BOTSWANA  
 Tel: +267 318 15 71  
[lmodisa@gov.bw](mailto:lmodisa@gov.bw)

**Dr Noel Murray**  
 Canadian Food Inspection Agency  
 1400 Merivale Road, Ottawa, K1A0Y9,  
 Ontario  
 CANADA  
 Tel: +1 613 773 5904  
[noel.murray@canada.ca](mailto:noel.murray@canada.ca)

**Dr Ángel Ortiz-Pelaez**  
 European Food Safety Authority (EFSA)  
 Via Carlo Magno 1A,  
 43126 Parma  
 ITALY  
 Tel: +39 0521 036 640  
[angel.ortizpelaez@efsa.europa.eu](mailto:angel.ortizpelaez@efsa.europa.eu)

**Dr Eric Thévenard**  
 European Commission  
 B-1049 Brussel  
 BELGIUM  
 Tel: +32 2 296 99 66  
[Eric.thevenard@ec.europa.eu](mailto:Eric.thevenard@ec.europa.eu)

**Representatives from the Specialist Commissions**

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**Dr Baptiste Dungu**  
 Member of the Scientific Commission for Animal Diseases  
 26 Dalrymple Crescent  
 Edinburgh EH9 2NX  
 Scotland  
 UNITED KINGDOM  
 Tel.: +212 523 30 31 32  
 Fax: +212 523 30 21 30  
 Fax: (49-38351) 7-151  
[b.dungu@mci-santeanimale.co](mailto:b.dungu@mci-santeanimale.co)

**Dr Masatsugu Okita**  
 Member of the Terrestrial Animal Health Standards Commission  
 Ministry of Agriculture, Forestry and Fisheries (MAFF)  
 Director of the International Animal Health Affairs Office, Animal  
 Health Division, Food Safety and Consumer Affairs Bureau  
 1-2-1 Kasumigaseki, Chiyoda-ku  
 Tokyo, 100-8950  
 JAPAN  
 Tel.: +81 3 3502 8295  
 Fax.: +81 3 3502 3385  
[masatsugu\\_okita130@maff.go.jp](mailto:masatsugu_okita130@maff.go.jp)

**OIE HEADQUARTERS**

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**Dr Monique Eloit**  
 Director General  
[m.eloit@oie.int](mailto:m.eloit@oie.int)

**Dr Laure Weber-Vintzel**  
 Head  
 Status Department  
[l.weber-vintzel@oie.int](mailto:l.weber-vintzel@oie.int)

**Dr Morgane Dominguez**  
 Project officer  
 Status Department  
[m.dominguez@oie.int](mailto:m.dominguez@oie.int)

**Dr Fernanda Mejía-Salazar**  
 Chargée de mission  
 Status Department  
[f.mejia-salazar@oie.int](mailto:f.mejia-salazar@oie.int)

**MEETING OF THE OIE AD HOC GROUP ON  
ALTERNATIVES FOR SURVEILLANCE FOR DEMONSTRATION OF FREEDOM  
FROM FOOT AND MOUTH DISEASE (FMD) AND RECOVERY PERIODS**

**Paris, 28-30 August 2018**

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A meeting of the OIE *ad hoc* Group on alternatives for surveillance for demonstration of freedom from foot and mouth disease (FMD) and recovery periods (hereafter the Group) was held at the OIE Headquarters from 28-30 August 2018.

**1. Opening**

Dr Monique Eloit, Director General of the OIE, welcomed and thanked the Group for its commitment and its extensive support towards the OIE in fulfilling the mandates given by Members.

She thanked the experts for having signed the form for undertaking of confidentiality, as well as for having declared any potential conflict of interest. She mentioned that should any members of the Group feel a possible conflict of interest that could influence their opinion, they should state so and withdraw from discussions on that subject matter. She also encouraged the Group to capture the detailed rationale supporting its proposals and recommendations in its meeting report for the consideration of Members. She recommended that when consensus was not reached within the Group, minority opinions should be duly recorded in the meeting report.

Dr Eloit highlighted one of the core missions of the OIE as a standard-setting organisation for the safe international trade in animals and animal products, and that decisions made should be science-based. In relation to this core mission, she informed the Group that the OIE Council will meet at the end of September to initiate the preparation of the OIE 7th Strategic Plan which will address the role of the OIE in science. She indicated that OIE experts and Collaborating Centres might be consulted at a later stage in this regard.

Lastly, she informed the Group that Dr Neo Mapitse has replaced Dr Laure Weber-Vintzel as Head of the Status Department, and of the nomination of Dr Min-Kyung Park as Deputy Head of the Status Department. She also congratulated Dr Kris de Clercq on his re-election as first Vice President of the Scientific Commission for Animal Diseases (Scientific Commission).

The OIE and the Group welcomed Drs Sam Hamilton and Eoin Ryan as new members participating in an OIE *ad hoc* Group for the first time.

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

The Group was chaired by Dr David Paton. Dr Tom Smylie acted as rapporteur, with the support of the OIE Secretariat. The Group adopted the proposed agenda.

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

### 3. Background

Following requests received from some Members to reduce the recovery period after FMD outbreaks, an *ad hoc* Group was convened in June 2017 to explore the alternatives for surveillance for demonstration of freedom from FMD and their possible impact on the duration of recovery periods. This Group explored and discussed the pros and cons of different options and indicated its preference: to maintain the current timing requirements of Article 8.8.7. of the *Terrestrial Animal Health Code (Terrestrial Code)*, but to add a sentence at the end of the article, clarifying that the waiting period should be respected unless there is evidence that the appropriate level of confidence has been reached earlier by implementing additional surveillance or other measures. The Group also indicated the need to provide guidance on the qualitative methods that would be used in the evaluation of the additional surveillance and other measure of reaching the appropriate level of confidence. After consideration by the Scientific Commission of: i) the report of the *ad hoc* Group, ii) an option document linking the conclusion and its impact on the FMD Chapter of the *Terrestrial Code*, and iii) opinion of the *ad hoc* Group on the evaluation of FMD status, the Scientific Commission was informed that the two *ad hoc* Groups were in agreement with the preferred options related to the provisions on waiting time requirements, on level of confidence and the method to be used for the assessment of the level of confidence.

The two aforementioned *ad hoc* Groups (*cf.* Reports of the Scientific Commission: Annex 13 of the September 2017 meeting and Annex 11 of the February 2018 meeting) recommended that the surveillance objectives, for recovery of FMD status in a country or zone should be modified to demonstrate the absence of infection in the non-vaccinated population and the absence of transmission of FMDV in the vaccinated population. Furthermore, the current minimal waiting period (i.e. six months) set in Article 8.8.7. point 1.c). of the *Terrestrial Code* for the recovery of FMD free status (where vaccination is not practised) where emergency vaccination not followed by the slaughtering of all vaccinated animals was conducted should apply, unless evidence demonstrating freedom, with an appropriate level of confidence, could be provided earlier by implementing additional surveillance or other measures.

Elaborating on this recommendation, the main goals of the Group were to: (i) review and propose relevant amendments, clearly describing the additional surveillance or other measures required in shortening the waiting period of six months under Chapter 8.8. of the *Terrestrial Code*, (ii) develop additional questions in the recovery section of the questionnaire that Members should answer and compile appropriate information justifying and demonstrating high level of confidence to claim freedom from FMD earlier than six months. Accordingly, the Group focused on additional surveillance measures for early recovery and not on additional control measures.

The Group also considered the applicability of a similar strategy for shortening the waiting period set in Article 8.8.7. point 3.a) of the *Terrestrial Code* for the recovery of a FMD free status where vaccination is practised.

### 4. Revision of Article 8.8.7. point 1.c) - Recovery of free status without vaccination where emergency vaccination not followed by the slaughtering of all vaccinated animals is applied

The Group was in agreement with the recommendation of the previous *ad hoc* Groups<sup>1</sup> that the surveillance objectives in Article 8.8.7. point 1.c), should be to demonstrate the absence of infection in the non-vaccinated population and the absence of transmission of FMDV in the vaccinated population.

The Group emphasised that the main risk of transmission amongst vaccinated animals is associated with subclinical infection which may result from flaws in the vaccination programme (i.e. the vaccine itself was not effective or vaccination was not performed properly). Therefore, where census surveillance of vaccinated ruminants is not undertaken, to qualify for an early recovery of a free status, it would be critical for countries to demonstrate the efficacy of the emergency vaccine used and of its effective deployment when demonstrating absence of transmission in the vaccinated population, in addition to absence of infection in the non-vaccinated population.

With regard to the timing requirement, the Group also agreed that the waiting period in Article 8.8.7. point 1.c) could be shortened to less than six months if a country can submit sufficient evidence demonstrating absence of infection in the non-vaccinated population and absence of transmission in the vaccinated population based on proposed provisions. However, the Group suggested specifying that the period for recovery can only be reduced to a minimum of three months consistent with the minimal timeframe for the recovery of a free status where a stamping out policy is applied without emergency vaccination (Article 8.8.7. point 1.a) or where emergency vaccination and a stamping-out policy with the slaughter of all vaccinated animals is applied (Article 8.8.7. point 1.b).

The Group therefore recommended the following sentence be added at the end of Article 8.8.7. point 1.c):  
“*This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of infection in the non-vaccinated population and absence of transmission in the vaccinated population based on the provisions of Article 8.8.40. point 7.*”

The Group recommended the additional requirements for shortening the waiting period for recovery of a FMD free status be listed in draft Article 8.8.40. point 7, and compliance with these requirements be documented based on draft Section 8 of Articles 1.11.1. for recovery of a free country status and 1.11.3. for recovery of a free zone status.

The Group emphasised that countries should consider the different options for the recovery of a free status when control measures are first implemented at the onset of the outbreak in order to plan for the applicable requirements to be met.

#### **5. Additional requirements for shortening the waiting period for recovery of a FMD free status without vaccination where stamping-out policy and emergency vaccination are not followed by the slaughtering of all vaccinated animals**

The Group carefully considered the additional measures listed by the previous *ad hoc* Groups<sup>1</sup>, including their respective objective, benefits and performance.

Building on these recommendations, the Group recommended the effective implementation of the additional requirements in draft Article 8.8.40. point 7 should be well-documented and justified in order to demonstrate the absence of infection in the non-vaccinated population and the absence of transmission in the vaccinated population with a high level of confidence, and to eventually qualify for an early recovery of a free status.

Importantly, the Group stressed that these requirements for an earlier recovery of a FMD free status, were indeed additional to the other requirements applicable for the recovery of a free status as defined in Article 8.8.7. point 1.c) of the *Terrestrial Code*.

The Group proposed two options for early recovery of free status:

- “Option 1” (as detailed in draft Article 8.8.40 point 7.a) involved undertaking census surveillance of vaccinated ruminants, random sampling of pigs in all vaccinated epidemiological units, and multistage random sampling of non-vaccinated susceptible species that do not show reliable clinical signs.
- “Option 2” (as detailed in draft Article 8.8.40 points 7.b and 7.c) involved using a combination of risk-based surveillance and random serological surveillance in vaccinated herds, intensified abattoir and clinical surveillance, and multistage random sampling of non-vaccinated susceptible species that do not show reliable clinical signs, and possibly virological surveillance, as well as the demonstration of vaccine efficacy and vaccination effectiveness.

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<sup>1</sup> *Ad hoc* Group on Alternatives for surveillance for demonstration of freedom from FMD and recovery periods – June 2017 and *Ad hoc* Group on the Evaluation of FMD Status of Members – November 2017.

With regard to option 1, the Group advised that for vaccinated ruminants, a census NSP serological survey should be conducted to identify any subclinical infection. However, this requirement for a census survey was established based on current scientific knowledge; the Group took note that if all vaccinated epidemiological units are sampled, a less stringent within herd design prevalence might be acceptable if it could be supported by further scientific evidence on the frequency of subclinical infection in herds of vaccinated ruminants. For pigs, the Group pointed out that census serological surveys may not be practical due to the potential size of the herds (i.e. potential number of animals to be sampled). Furthermore, pigs do not become carriers and the occurrence of subclinical infections in pigs, even in vaccinated individuals is rare<sup>2</sup>. For vaccinated pigs, the Group therefore recommended that NSP serological surveillance should be conducted in all vaccinated epidemiological units with 5% maximum design prevalence within epidemiological unit (95% confidence level).

The Group carefully considered the definition of epidemiological unit of the Glossary of the *Terrestrial Code*, as well as the definition of sampling unit and the recommendations for survey design provided in current Chapter 1.4. and draft revised Chapter 1.4. on Animal health surveillance. The Group pointed out that terms such as herd, establishment and epidemiological unit may be open to differing interpretations based on the specific context in which they are applied. The Group agreed that for the purposes of the design of the NSP serological surveys under discussion, it was important that the highest level of resolution was achieved. For example, if an intensively reared pig herd was kept in three discretely managed buildings on one establishment, each of the three buildings should be regarded as individual epidemiological units for the purposes of NSP serological sampling, and the random selection of sufficient pigs for sampling to provide 95% confidence that disease was not present at a level above 5% prevalence would need to take place independently in the populations in each of these three buildings. The term “herd” is generally understood to mean “epidemiological unit” in many contexts, but perhaps not all. The Group considered it important that Members applying for shorter recovery periods understand this point, and therefore settled on the use of the term “epidemiological unit” as being the most appropriate and least ambiguous in relation to design prevalence. The Group therefore advised that the design prevalence for NSP serological surveys should be applied in each epidemiological unit in order to achieve the highest level of resolution and allow for a high level of confidence in demonstrating the absence of transmission in vaccinated animals.

The Group noted that neither the Glossary of the *Terrestrial Code*, the current Chapter 1.4. nor the draft revised Chapter 1.4. on Animal health surveillance provided a definition of ‘design prevalence’. The Group recommended such a definition could be useful to be included in the *Terrestrial Code*.

Maximum design prevalence and confidence level were set for some surveillance components as well as minimum values for vaccination coverage in the targeted and eligible population. The Group reiterated that this was more prescriptive than the usual recommendations of the *Terrestrial Code* for surveillance and vaccination. However, the Group was of the opinion that defining these parameters provided important guidance to Members to ensure that a high level of confidence can be reached.

Regarding surveillance components to be implemented in support of option 2, the Group recommended that random surveillance be performed throughout the area of emergency vaccination to provide baseline data and be strengthened by additional risk-based surveillance. The design of any risk-based surveillance, in particular the rationale for the applied stratification, should be clearly justified when answering the questionnaire.

The Group noted that ongoing virological surveillance through technologies like bulk milk testing, rope sampling and other methods may provide further information on the status of vaccinated herds; negative results would add to confidence in the free status of these herds.

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<sup>2</sup> D.J. Paton, A.E. Füssel, W. Vosloo, A. Dekker, K. De Clercq, 2014, The use of serosurveys following emergency vaccination, to recover the status of "foot-and-mouth disease free where vaccination is not practiced", *Vaccine*, 32, 7050-7056

In conjunction with the NSP serological surveys for option 1 and the serological surveillance for option 2, both aiming at demonstrating the absence of transmission in the vaccinated population, the Group recommended that serological surveys be conducted in non-vaccinated susceptible species kept in the control area that do not show reliable clinical signs in order to demonstrate the absence of infection in the non-vaccinated population. In addition, the Group recommended that applicant Members for an early recovery of their free status should justify the rationale for not vaccinating certain susceptible species, and conversely, the rationale for selecting target species and herds to be vaccinated.

Vaccine efficacy and vaccination effectiveness are key to prevent infection and transmission, including subclinical infections in vaccinated animals, and should therefore be duly documented in support of any application for an early recovery of a free status. As well as evidence of high potency ( $\geq 6$  PD50 or equivalent) and a good match between the vaccine strain and the field virus, protection should also be documented for relevant target animals immunised with the specific vaccine batch and dose used in the emergency vaccination programme. Protection in these animals, against the relevant field virus, can be measured preferably by challenge, or else by serology.

#### **6. Questionnaire for earlier recovery of FMD free status where vaccination is not practised - addendum to Section 8 of Articles 1.11.1. and 1.11.3.**

The Group noted that the questionnaire for recovery of FMD free status stated, “*Member Countries applying for recognition of recovery of free status for a country/zone should [...] provide detailed information as specified in Sections 1-7 (inclusive) of this questionnaire.*” The Group noted that Sections 1 to 7 were primarily designed for initial applications for the recognition of a FMD free status and recommended that when filling in the questionnaire in support of the application for the recovery of a free status, applicant Members should place emphasis on the recent situation in the context of the outbreak(s) as being of most relevance. The Group noted that a questionnaire specifically targeted to applications for the recovery of free status could be developed in the future.

As Sections 1 to 7 of the questionnaire already contains baseline questions, the Group drafted questions under ‘Section 8. Recovery of free status’ of the relevant FMD questionnaires (i.e. Articles 1.11.1 and 1.11.3 of the *Terrestrial Code*) focusing on the additional requirements that should be documented by Members when applying for an earlier recovery according to Article 8.8.7. point 1.c) and draft Article 8.8.40. point 7. Therefore, Members seeking for an earlier recovery<sup>3</sup> of their free status based on the implementation of additional requirements should answer these questions, in addition to those already requested under Section 8 of the questionnaires.

#### **7. Considerations on Article 8.8.7. point 2. - Recovery of a free status with vaccination after the suspension of a free status without vaccination**

The Group explored the applicability of a similar strategy to the waiting period (i.e. 6 months after the disposal of the last animal killed) defined in Article 8.8.7 point 2: country or zone previously free from FMD without vaccination, where a stamping-out policy has been applied and a continued vaccination policy has been adopted. In other words, a country/zone previously free without vaccination seeking to recover as free country/zone status with vaccination. The Group emphasised that this represents not only a recovery of status but also a change in the initially recognised official status. Considering that a country requesting a change of status from FMD free without vaccination to FMD free with vaccination after an outbreak, usually does so due to ongoing risks, the Group considered that it would not be appropriate to shorten this waiting period.

#### **8. Revision of Article 8.8.7. point 3.a) - Recovery of a free status with vaccination where a stamping-out policy and emergency vaccination are applied**

The Group considered whether the additional requirements (cf Section 5) for shortening the waiting period would be also applicable for recovery of free status with vaccination with reference to Article 8.8.7. point 3.a) of the *Terrestrial Code*.

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<sup>3</sup> More than three months but less than six months after the disposal of the last animal killed or the last vaccination whichever occurred last, where a stamping-out policy, emergency vaccination not followed by the slaughtering of all vaccinated animals

The Group extensively discussed this issue and concluded that, similar to the proposal made for an earlier recovery of a free status without vaccination, the waiting period for the recovery of a free status with vaccination may be reduced to a minimum of three months if the absence of infection in the non-vaccinated population and absence of transmission in the vaccinated population could be demonstrated earlier with a high level of confidence. However, since animals would already have been routinely vaccinated prior to the outbreak and emergency vaccination, the Group noted that additional factors (i.e. relationship between the routine vaccine, emergency vaccine, and the virus that caused the outbreak) would need to be taken into account in the additional requirements for shortening the waiting period for recovery. Prior vaccination might mask clinical expression of disease and the Group considered that this also gave rise to some different requirements to provide reassurance of absence of virus transmission outside of the emergency vaccination area (compared to the use of emergency vaccination within previously FMD-free country or zones).

The Group recommended the following sentence be added at the end of Article 8.8.7. point 3.a):

*“This period can be reduced to a minimum of three months if a country can submit sufficient evidence demonstrating absence of infection in the non-vaccinated population and absence of transmission in the vaccinated population based on the provisions of Articles 8.8.40. point 7. or 8.8.40. point 8. as appropriate”.*

## **9. Additional requirements for shortening the waiting period for recovery of a free status with vaccination where a stamping-out policy and emergency vaccination is applied**

The Group recommended that an early recovery of the free status with vaccination would be supported by distinct provisions for: (i) the area(s) where emergency vaccination has been applied; (ii) the area of the country/zone where emergency vaccination has not been applied.

- Area(s) of the country/zone where emergency vaccination has been applied

Regarding the early recovery of the free status of the area(s) where emergency vaccination has been applied, the Group recommended that measures similar to those described in draft Article 8.8.40. point 7 (*cf* Section 5) would provide a high level of confidence in the absence of transmission in vaccinated animals. However, the Group noted that, in practice, it might be difficult to apply census NSP serological surveillance in a population which has been routinely vaccinated due to anticipated high numbers of false positive reactors.

- Area of the country/zone where emergency vaccination has not been applied

The Group considered Article 4.3.7. on containment zones, together with the provisions for the establishment of a containment zone for FMD defined in Article 8.8.6. The Group noted that the establishment of a containment zone, based on the provisions of Article 8.8.6. that included all emergency vaccination area(s), could be one way of providing assurance that FMD has not occurred in the area outside of the emergency vaccination area(s).

An alternative option for an early recovery of the free status of the area where emergency vaccination has not been applied would be based on the demonstration of the absence of infection in non-vaccinated animals and absence of transmission in vaccinated animals with a high level of confidence. However, in that regard, the Group noted that different situations should be considered: (i) routine vaccination ensures protection against the outbreak strain; (ii) routine vaccination does not ensure protection against the outbreak strain (e.g. incursion of new serotype); (iii) routine vaccination ensures partial protection against the outbreak strain. These different situations would impact the likelihood of infection of animals routinely vaccinated and the likelihood of showing clinical signs if infected. In addition, the Group noted that other factors including vaccination coverage and timing of vaccination could also influence the rate of transmission and expression of clinical signs. The Group pointed out that information on the effectiveness of vaccination would only be relevant in support of the recovery of the free status if the routine vaccine was protective against the virus that caused the outbreak(s). Considering the above, the Group recommended that applicant Members should document the protective value of the routine vaccination but did not prescribe any minimum requirements.

Draft requirements for an early recovery of the free status of the area outside of the area(s) where emergency vaccination has been applied were listed in draft Article 8.8.40. point 8.

## 10. Questionnaire for earlier recovery of FMD free status where vaccination is practised - addendum to Section 8 of Articles 1.11.2. and 1.11.4.

The Group drafted questions to be included in Section 8 of Articles 1.11.2. and 1.11.4. of the *Terrestrial Code* focusing on the additional requirements to be documented by applicant Members when applying for earlier recovery of their FMD free status with vaccination in accordance with draft Article 8.8.40. points 7 and 8.

## 11. Further considerations

The Group suggested that after adoption in the *Terrestrial Code*, the paths for early recoveries of FMD free status with or without vaccination could be further presented to Members through the OIE workshops on official status recognition.

As indicated in Section 6 of this report, in reviewing relevant sections in Articles 1.11.1. to 1.11.4, the Group noted that the phrasing of the questionnaire was primarily designed for initial applications for the recognition of a FMD free status and may not necessarily be suitable for Members applying for the recovery of a free status. The Group mentioned that there may be benefits in further reviews of this material.

As indicated in Section 4 of this report, the Group recommended changing the requirement in Article 8.8.7. point 1.c). to require surveillance to substantiate freedom from transmission rather than freedom from infection in vaccinated animals. Indeed, the Group considered that evidence of freedom based on the demonstration of absence of infection in a non-vaccinated population and demonstration of absence of transmission of FMDV in a vaccinated population is adequate to regain a FMD free status without vaccination. However, once freedom is regained, vaccinated animals can mix with non-vaccinated animals at a national level and, if this occurs within three months, then carriers may be present if not eliminated by an appropriate surveillance approach. The Group acknowledged that with the exception of African buffalo, carriers do not play an epidemiologically significant role in FMDV transmission (as specified in Article 8.8.1. point 6 of the *Terrestrial Code*). Therefore, considering that carrier animals present negligible risk to others, even if non-vaccinated, then this could imply that the current requirements for surveillance to detect infection could be changed elsewhere in Chapter 8.8. to a requirement for detecting transmission, regardless of vaccination status.

## 12. Adoption of the report

The Group reviewed the draft report provided by the rapporteur and agreed to circulate the draft report electronically for comments before the final adoption. Upon circulation, the Group agreed that the report captured the discussions.

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.../Appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP ON  
ALTERNATIVES FOR SURVEILLANCE FOR DEMONSTRATION OF FREEDOM  
FROM FOOT AND MOUTH DISEASE (FMD) AND RECOVERY PERIODS  
Paris, 28-30 August 2018**

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**Agenda**

- 1) Opening
  - 2) Adoption of the agenda and appointment of chairperson and rapporteur
  - 3) Background
  - 4) Revision of Article 8.8.7. point 1.c) - Recovery of free status without vaccination where emergency vaccination not followed by the slaughtering of all vaccinated animals is applied
  - 5) Additional requirements for shortening the waiting period for recovery of a FMD free status without vaccination where stamping-out policy and emergency vaccination are not followed by the slaughtering of all vaccinated animals
  - 6) Questionnaire for earlier recovery of FMD free status where vaccination is not practised -addendum to Section 8 of Articles 1.11.1. and 1.11.3.
  - 7) Considerations on Article 8.8.7. point 2. - Recovery of a free status with vaccination after the suspension of a free status without vaccination
  - 8) Revision of Article 8.8.7. point 3.a) - Recovery of a free status with vaccination where a stamping-out policy and emergency vaccination are applied
  - 9) Additional requirements for shortening the waiting period for recovery of a free status with vaccination where a stamping-out policy and emergency vaccination is applied
  - 10) Questionnaire for earlier recovery of FMD free status where vaccination is practised - addendum to Section 8 of Articles 1.11.2. and 1.11.4.
  - 11) Further considerations
  - 12) Adoption of the report
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## Appendix II

**MEETING OF THE OIE AD HOC GROUP ON  
ALTERNATIVES FOR SURVEILLANCE FOR DEMONSTRATION OF FREEDOM  
FROM FOOT AND MOUTH DISEASE (FMD) AND RECOVERY PERIODS  
Paris, 28-30 August 2018**

**List of participants**

**MEMBERS**

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**Dr Gideon Brückner**

30 Schoongezicht  
1 Scholtz Street  
Somerset West 7130  
SOUTH AFRICA  
[gkbruckner@gmail.com](mailto:gkbruckner@gmail.com)

**Dr Sergio Duffy**

Centro de Estudios Cuantitativos en  
Sanidad Animal  
Facultad de Ciencias Veterinarias  
Universidad Nacional de Rosario (UNR)  
Arenales 2303 - 5 piso  
1124 Ciudad Autónoma de Buenos Aires  
ARGENTINA  
[sergio.duffy@yahoo.com](mailto:sergio.duffy@yahoo.com)

**Dr Sam Hamilton**

Department of Agriculture and Water  
Resources  
Director, Animal Disease Preparedness  
and Response  
GPO Box 858  
Canberra, ACT 2601  
AUSTRALIA  
[Sam.Hamilton@agriculture.gov.au](mailto:Sam.Hamilton@agriculture.gov.au)

**Dr David Paton**

The Pirbright Institute  
Ash Road, Woking  
Surrey GU20 0NF  
UNITED KINGDOM  
[david.paton@pirbright.ac.uk](mailto:david.paton@pirbright.ac.uk)  
[dajapaton@gmail.com](mailto:dajapaton@gmail.com)

**Dr Eoin Ryan**

Department of Agriculture, Food and the  
Marine  
IRELAND  
[Eoin.Ryan@agriculture.gov.ie](mailto:Eoin.Ryan@agriculture.gov.ie)

**Dr Tom Smylie**

Senior Staff Veterinarian  
Office of the Chief Veterinary Officer of  
Canada  
Policy and Programs Branch  
Canadian Food Inspection Agency  
Government of Canada  
CANADA  
[tom.smylie@canada.ca](mailto:tom.smylie@canada.ca)

**REPRESENTATIVE OF THE SPECIALIST COMMISSIONS**

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**Dr Kris de Clercq**

Sciensano  
Department of Virology  
Section Epizootic Diseases  
Groeselenberg 99  
B-1180 Ukkel  
BELGIUM  
[kris.declercq@sciensano.be](mailto:kris.declercq@sciensano.be)

**OIE HEADQUARTERS**

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**Dr Monique Eloit**

Director General  
12 rue de Prony  
75017 Paris, FRANCE  
Tel: (33) 1 44 15 18 88  
Fax: (33) 1 42 67 09 87  
[oi@oie.int](mailto:oi@oie.int)

**Dr Min Kyung Park**

Deputy Head  
Status Department  
[m.park@oie.int](mailto:m.park@oie.int)

**Dr Morgane Dominguez**

Project Officer  
Status Department  
[m.dominguez@oie.int](mailto:m.dominguez@oie.int)



### Summary of the comments on the OIE *Terrestrial Code*

Do *M. caprae* and *M. tuberculosis* fit the criteria for listing in the OIE *Terrestrial Animal Health Code* ?

Three experts participated in this consultation:

- Dr Lucía de Juan (Bovine Tuberculosis EURL, Spain)
- Dr Bernardo Alonso (OIE Bovine Tuberculosis Reference Laboratory, Argentina)
- Dr María Laura Boschioli (OIE Bovine Tuberculosis Reference Laboratory, France)

The table below presents the answers for the 6 questions included in in Chapter 1.2 “Criteria for the inclusion of diseases, infections and infestations in the OIE list”

<i>M. caprae</i>			
Criteria	Response 1	Response 2	Response 3
Question 1.	YES	YES	YES
Question 2.	YES	YES	YES
Question 3.	YES	YES	YES
Question 4a.	YES	YES	YES
Question 4b.	YES	YES	YES
Question 4c.	YES	YES	YES
Conclusion	YES	YES	YES
<i>M. tuberculosis</i>			
Criteria	Response 1	Response 2	Response 3
Question 1.	NO	NO	NO
Question 2.	YES	YES	YES
Question 3.	YES	YES	YES
Question 4a.	YES	YES	YES
Question 4b.	NO	NO	NO
Question 4c.	NO	NO	YES
Conclusion	NO	NO	Other

Hereby the merge of the scientific rationale on each question:

#### ***Mycobacterium caprae***

**Question 1:** International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.

*M. caprae* and *M. bovis* are the main aetiological agents of TB in animals and produce clinically indistinguishable infections. *M. caprae* infection was initially attributed to goats (e.g. main agent causing TB in goats in Spain) but infection has been reported not only in this species but also in cattle and other domestic and wildlife species and humans (see reference in next sections).

Therefore, *M. caprae* infected animals can spread the disease in the same way to *M. bovis* infected ones.

In 2005 our laboratory has contributed to a European wide-study which objective was to characterise *Mycobacterium caprae* by means of a very discriminant genotyping method (Miru-VNTR) in combination with spoligotyping. This study demonstrate the existence of several *M. caprae* clusters, that in the big majority are shared by 2 or more member states (mainly Germany, Austria, Hungary, Italy and France) albeit some other strains are exclusively found in some countries such as Spain and France. The first observation by itself would per se mean that

animal trading between these countries could have given rise to this genotype sharing. But most importantly, while I was making the selection of *M. caprae* strains from our strain collection to be included in the study I discovered the presence of many *M. caprae* strains from foreign born animals (neighbouring UE member states) that were introduced and found infected in France.

Moreover, in 2013 France imported live red-deer from another eastern EU member state which were found infected by *Mycobacterium caprae* in France.

On the other hand, *M. caprae* cattle TB cases found detected in Northern African countries have been explained by the introduction of European animals to these countries (Algeria, Tunisia, and Morocco).

**Question 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 provisions of Chapter 1.4.

Only TB in cattle is subjected to a compulsory eradication programme in Europe. According to the Working Documents SANCO/10067/2013 and SANCO/7059/2013 Bovine TB is the infection in cattle with any of the disease-causing mycobacterial species within the *M. tuberculosis* complex. *M. caprae* infects and is maintained in cattle and therefore this species together with *M. bovis* should be included as members of the *M. tuberculosis* complex causing bovine TB, not least due to its zoonotic potential. In fact, *M. caprae* infection in cattle should be reported in the same conditions as that caused by *M. bovis*. Therefore, to reach the OTF-status according to the 64/432/CEE and to be in compliance with that Directive, the conditions should be accomplished regardless the species of the *M. tuberculosis* complex affecting cattle. This means that OTF-status for bovine TB in Europe is not only related to *M. bovis* but also to *M. caprae* infection or by any of the other members of the *M. tuberculosis* complex in cattle.

E.g. According to EFSA scientific report [EFSA Journal 2016; 14 (12):4634], Austria only reported 4 herds infected by *M. caprae*. During 2015, Austria was an OTF MS for all its regions and also covered by an EU co-financed eradication programme for some single regions.

*Mycobacterium caprae* leads to the same type of infection as *Mycobacterium bovis*. Infection in susceptible animals in the UE context is notifiable in the same way. Infection with *Mycobacterium caprae* is also taken into consideration as a bovine tuberculosis cause in Northern African countries where this bacterium has also been isolated.

**Question 3:** Reliable means of detection and diagnosis exist and a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections or infestations.

Accurate molecular tools (PCR, spoligotyping, WGS...) are available to define the species of the *M. tuberculosis* complex causing the infection.

Ante-mortem detection in animals infected with this bacterium as the same tools used for detecting *Mycobacterium bovis* are useful for infection. With respects direct diagnosis, the lesions provoked by *M. caprae* are that those caused by *M. bovis*: detection by this means at the abattoir is possible. The histological lesions are the same as those of caused by *M. bovis* so TB detection by this means is also possible. *Mycobacterium caprae* can be distinguished from *Mycobacterium bovis* by molecular biology means upon direct detection but it is hardly distinguished by classical bacteriological and biochemical methods. Nowadays these molecular based methods are applied in the EU and whichever the bacillus -*M. bovis* or *M. caprae*- causing the infection, TB is notified in the UE.

*Mycobacterium caprae* or any other mycobacterium complex infection in domestic animal –including *M. bovis*- are clearly distinguished from other diseases, infections or infestations

**Question 4a:** Natural transmission to humans has been proven, and human infection is associated with severe consequences.

*M. caprae* infection is a zoonotic agent and infection in humans has been reported although is a rare disease and mainly restricted to Europe. Infection in humans by *M. bovis* or *M. caprae* can be as severe as that caused by *M. tuberculosis*.

E.g. references:

Nebreda T. et al., 2016. IDCases, 4: 50-52.

De la Fuente J. et al., 2015. PLoS Neglected Tropical Diseases, 19; 9 (11): e0004232

Prodinger WM. et al., 2014. Expert Rev Anti Infect Ther, 12 (12): 1501-1513.

Müller B. et al., 2013. Emerg Infect Dis, 19 (6): 899-908.

Several articles prove this, hereby some of them:

Prodinger WM, Indra A, Koksalan OK, Kilicaslan Z, Richter E. *Mycobacterium caprae* infection in humans. *Expert Rev Anti Infect Ther.* 2014 Dec;12(12):1501-13. doi: 10.1586/14787210.2014.974560. Epub 2014 Oct 27. Review. PubMed PMID: 25345680.

Aimé B, Lequen L, Balageas A, Haddad N, Maugein J. [*M. bovis* and *M. caprae* infections in Aquitaine: A clinico-epidemiologic study of 15 patients]. *Pathol Biol (Paris).* 2012 Jun;60(3):156-9. doi: 10.1016/j.patbio.2011.05.001. Epub 2011 Jun 30. French. PubMed PMID: 21723048.

Álvarez-Prida E, Blanco B, Remacha MA, Samper S, Jiménez MS. Peritoneal tuberculosis due to *Mycobacterium caprae*. *Nebreda T, IDCases.* 2016 Apr 5;4:50-2. doi: 10.1016/j.idcr.2016.02.010. eCollection 2016.

**Question 4b:** The disease has been shown to have a significant impact on the health of domestic animals at the level of a country or a zone taking into account the occurrence and severity of the clinical signs, including direct production losses and mortality

As it has been mentioned in previous sections, *M. caprae* infection causes a similar infection to *M. bovis* and the consequences are similar regarding severity of clinical signs, mortality, production losses and movement restrictions.

E.g. references:

Bezoz J. et al., 2015. *Vet Immunol Immunopathol.* 167 (3-4): 185-189.

Djemal SE. et al., 2017. *BMC Vet Res.* 13 (1): 393.

Ghielmetti G. et al., 2017. *Plos One.* 12(2): e0172474.

The number of articles dealing with *Mycobacterium caprae* infection in domestic animals is nowadays very profuse. Some remarkable examples are the following:

de la Fuente J, Díez-Delgado I, Contreras M, Vicente J, Cabezas-Cruz A, Tobes R, Manrique M, López V, Romero B, Bezoz J, Dominguez L, Sevilla IA, Garrido JM, Juste R, Madico G, Jones-López E, Gortazar C. Comparative Genomics of Field Isolates of *Mycobacterium bovis* and *M. caprae* Provides Evidence for Possible Correlates with Bacterial Viability and Virulence. *PLoS Negl Trop Dis.* 2015 Nov 19;9(11):e0004232. doi: 10.1371/journal.pntd.0004232. eCollection 2015 Nov. PubMed PMID: 26583774; PubMed Central PMCID: PMC4652870.

Bezoz J, Casal C, Díez-Delgado I, Romero B, Liandris E, Álvarez J, Sevilla IA, Juan Ld, Domínguez L, Gortázar C. Goats challenged with different members of the *Mycobacterium tuberculosis* complex display different clinical pictures. *Vet Immunol Immunopathol.* 2015 Oct 15; 167(3-4):185-9. doi: 10.1016/j.vetimm.2015.07.009. Epub 2015 Jul 26. PubMed PMID: 26235598.

Pesciaroli M, Alvarez J, Boniotti MB, Cagiola M, Di Marco V, Marianelli C, Pacciarini M, Pasquali P. Tuberculosis in domestic animal species. *Res Vet Sci.* 2014 Oct; 97 Suppl:S78-85. doi: 10.1016/j.rvsc.2014.05.015. Epub 2014 Jun 12. Review. PubMed PMID: 25151859.

Bezoz J, Marqués S, Álvarez J, Casal C, Romero B, Grau A, Mínguez O, Domínguez L, de Juan L. Evaluation of single and comparative intradermal tuberculin tests for tuberculosis eradication in caprine flocks in Castilla y León (Spain). *Res Vet Sci.* 2014 Feb; 96(1):39-46. doi: 10.1016/j.rvsc.2013.10.007. Epub 2013 Oct 31. PubMed PMID: 24239314.

de Val Pérez B, López-Soria S, Nofrarías M, Martín M, Vordermeier HM, Villarreal-Ramos B, Romera N, Escobar M, Solanes D, Cardona PJ, Domingo M. Experimental model of tuberculosis in the domestic goat after endobronchial infection with *Mycobacterium caprae*. *Clin Vaccine Immunol.* 2011 Nov; 18(11):1872-81. doi: 10.1128/CI.05323-11. Epub 2011 Aug 31. PubMed PMID: 21880849; PubMed Central PMCID: PMC3209027.

Aranaz A, Liébana E, Gómez-Mampaso E, Galán JC, Cousins D, Ortega A, Blázquez J, Baquero F, Mateos A, Suárez G, Domínguez L. *Mycobacterium tuberculosis* subsp. *caprae* subsp. nov.: a taxonomic study of a new member of the *Mycobacterium tuberculosis* complex isolated from goats in Spain. *Int J Syst Bacteriol.* 1999 Jul; 49 Pt 3:1263-73. PubMed PMID: 10425790.

**Question 4c:** The disease has been shown to, or scientific evidence indicates that it would, have a significant impact on the health of wildlife taking into account the occurrence and severity of the clinical signs, including direct economic losses and mortality, and any threat to the viability of a wildlife population

Different wildlife species (and animals from zoos) have been described as reservoirs of *M. caprae*. Tuberculosis by *M. caprae* in wildlife has the same impact than that caused by *M. bovis*.

E.g. references:

Fink M. et al., 2015. *Emerg Infect Dis*, 21 (3): 464-467.

Chiari M. et al., 2014. *J Wildl Dis*, 50 (2): 330-333.

García-Jiménez WL. et al., 2013. *Transbound Emerg Dis*, 60 (2): 102-109.

Rodríguez S. et al., 2011. *Emerg Infect Dis*, 17 (3): 532-535.

Pate M. et al., 2006. *J Vet Med B Infect Dis Vet Public Health*. 53 (8): 387-392.

As for question 4b, there are nowadays a great number of articles sustaining that *Mycobacterium caprae* is a TB infectious agents for several wild life hosts. Some examples are the following:

Krzysiak MK, Jabłoński A, Iwaniak W, Krajewska M, Kęsik-Maliszewska J, Larska M. Seroprevalence and risk factors for selected respiratory and reproductive tract pathogen exposure in European bison (*Bison bonasus*) in Poland. *Vet Microbiol*. 2018 Feb; 215:57-65. doi: 10.1016/j.vetmic.2018.01.005. Epub 2018 Jan 27. PubMed PMID: 29426407.

Malone KM, Gordon SV. *Mycobacterium tuberculosis* Complex Members Adapted to Wild and Domestic Animals. *Adv Exp Med Biol*. 2017; 1019:135-154. doi: 10.1007/978-3-319-64371-7\_7. PubMed PMID: 29116633.

Ghielmetti G, Scherrer S, Friedel U, Frei D, Suter D, Perler L, Wittenbrink MM. Epidemiological tracing of bovine tuberculosis in Switzerland, multilocus variable number of tandem repeat analysis of *Mycobacterium bovis* and *Mycobacterium caprae*. *PLoS One*. 2017 Feb 21; 12(2):e0172474. doi: 10.1371/journal.pone.0172474. eCollection 2017. PubMed PMID: 28222182; PubMed Central PMCID: PMC5319696.

García-Jiménez WL, Cortés M, Benítez-Medina JM, Hurtado I, Martínez R, García-Sánchez A, Risco D, Cerrato R, Sanz C, Hermoso-de-Mendoza M, Fernández-Llario P, Hermoso-de-Mendoza J. Spoligotype diversity and 5-year trends of bovine tuberculosis in Extremadura, southern Spain. *Trop Anim Health Prod*. 2016 Dec; 48(8):1533-1540. Epub 2016 Aug 14. PubMed PMID: 27524741.

Santos N, Santos C, Valente T, Gortázar C, Almeida V, Correia-Neves M Widespread Environmental Contamination with *Mycobacterium tuberculosis* Complex Revealed by a Molecular Detection Protocol. *PLoS One*. 2015 Nov 11; 10(11):e0142079. doi: 10.1371/journal.pone.0142079. eCollection 2015. PubMed PMID: 26561038; PubMed Central PMCID: PMC4641585.

Fink M, Schleicher C, Gonano M, Prodinge WM, Pacciarini M, Glawischnig W, Ryser-Degiorgis MP, Walzer C, Stalder GL, Lombardo D, Schobesberger H, Winter P, Büttner M. Red deer as maintenance host for bovine tuberculosis, Alpine region. *Emerg Infect Dis*. 2015 Mar; 21(3):464-7. doi: 10.3201/eid2103.141119. PubMed PMID: 25695273; PubMed Central PMCID: PMC4344270.

Chiari M, Zanoni M, Alborali LG, Zanardi G, Avisani D, Tagliabue S, Gaffuri A, Pacciarini ML, Boniotti MB. Isolation of *Mycobacterium caprae* (Lechtal genotype) from red deer (*Cervus elaphus*) in Italy. *J Wildl Dis*. 2014 Apr; 50(2):330-3. doi: 10.7589/2013-06-135. Epub 2014 Feb 5. PubMed PMID: 24499334.

Domogalla J, Prodinge WM, Blum H, Krebs S, Gellert S, Müller M, Neuendorf E, Sedlmaier F, Büttner M. Region of difference 4 in alpine *Mycobacterium caprae* isolates indicates three variants. *J Clin Microbiol*. 2013 May; 51(5):1381-8. doi: 10.1128/JCM.02966-12. Epub 2013 Feb 13. PubMed PMID: 23408688; PubMed Central PMCID: PMC3647898.

García-Jiménez WL, Benítez-Medina JM, Fernández-Llario P, Abecia JA, García-Sánchez A, Martínez R, Risco D, Ortiz-Peláez A, Salguero FJ, Smith NH Gómez L, Hermoso de Mendoza J. Comparative pathology of the natural infections by *Mycobacterium bovis* and by *Mycobacterium caprae* in wild boar (*Sus scrofa*). *Transbound Emerg Dis*. 2013 Apr; 60(2):102-9. doi: 10.1111/j.1865-1682.2012.01321.x. Epub 2012 Apr 2. PubMed PMID: 22469036.

Cunha MV, Matos F, Canto A, Albuquerque T, Alberto JR, Aranha JM, Vieira-Pinto M, Botelho A. Implications and challenges of tuberculosis in wildlife ungulates in Portugal: a molecular epidemiology perspective. *Res Vet Sci*. 2012 Apr; 92(2):225-35. doi: 10.1016/j.rvsc.2011.03.009. Epub 2011 Apr 2. PubMed PMID: 21459394.

Duarte EL, Domingos M, Amado A, Botelho A. Spoligotype diversity of *Mycobacterium bovis* and *Mycobacterium caprae* animal isolates. *Vet Microbiol.* 2008 Aug 25; 130(3-4):415-21. doi: 10.1016/j.vetmic.2008.02.012. Epub 2008 Feb 26. PubMed PMID: 18417301.

#### Summary Conclusion:

*M. caprae* was included as a new member of the *M. tuberculosis* complex in 2003 and previously was considered a subspecies of *M. tuberculosis* and *M. bovis*. *M. caprae* infection is rare and mainly restricted to Europe but in terms of severity of clinical signs, epidemiology/transmission, and zoonotic potential is similar to that caused by *M. bovis*. In fact, current co-financed eradication programmes considered that the cattle herds infected by *M. caprae* or other members of the *M. tuberculosis* complex different have to be subjected to the same controls and restriction than those infected by *M. bovis*. Due to these similarities and attending to the Chapter 1.2 of the Manual of Terrestrial Animal Health Code, *M. caprae* match the listing criteria to be listed in the OIE List.

#### *Mycobacterium caprae* definitely meets these criteria

### *Mycobacterium tuberculosis*

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**Question 1:** International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.

*M. tuberculosis* infection has been reported in domestic and wildlife species but it is not well adapted to infect animals and they usually show mild lesions without clinical signs. In fact, it is widely accepted that animals are probably dead-end reservoirs of *M. tuberculosis* since only few studies reported *M. tuberculosis* transmission between animals or from animals to humans (in the latter case it is only suggested or mainly based on the intradermal tuberculin test conversion). Regarding domestic animals, no *M. tuberculosis* transmission between individuals or to from animals to humans have been reported but there are few cases in wild animals (mainly elephants).

E.g. references:

Villarreal-Ramos B. et al., 2018. *Sci Rep.* 8 (1): 894  
 Ghielmetti G. et al., 2017. *Sci Rep.* 2017 Nov 7;7(1):14647.  
 Bezos J. et al., 2015. *Vet Immunol Immunopathol.* 167 (3-4): 185-189.  
 Romero B. et al., 2011. *Emerg Infect Dis.* 17 (12): 2393-1395.  
 Mikota SK, Maslow JN. 2011. *Tuberculosis (Edinb).* 91(3):208-11.  
 Murphree R. et al., 2011. *Emerg Infect Dis.* 17(3):366-71.  
 Oh P. et al., 2002. *Emerg Infect Dis* 8 (11): 1290-1293.

As far as I am concerned there is no scientific prove for this spread at an international scale. Besides, in general terms, *Mycobacterium tuberculosis* does not seem to be transmissible within animal populations; its spread in livestock, even at a local level, has not been proven. Livestock ruminants, infected by the true reservoir of the bacterium, i.e. human beings, are considered dead end host of this pathogen.

**Question 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 provisions of Chapter 1.4.

As it was mentioned for *M. caprae* infection, up to now only bovine TB is subjected to compulsory eradication programmes but infection in cattle by any member of *M. tuberculosis* in cattle is considered a case of Bovine TB. In this sense, OTF status is also related to *M. tuberculosis* infection in cattle.

Infection of *Mycobacterium tuberculosis* in cattle can lead to a less important although detectable immunological response that can lead to TB notification -as for *M. caprae* and *M. bovis* infections- in susceptible animals. As for *M. bovis* (or *M. caprae*) countries can thus demonstrate freedom or impending freedom from the disease or infestation in populations of susceptible animals

**Question 3:** Reliable means of detection and diagnosis exist and a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections or infestations.

Accurate molecular tools (PCR, spoligotyping, WGS...) are available to define the species of the *M. tuberculosis* complex causing the infection.

Regarding the official in vivo diagnosis (that cannot differentiate between species of mycobacteria), *M. tuberculosis* is less adapted to infect animals (excluding perhaps primates) and this matter may affect in some way to the performance of the tests (e.g. intradermal tuberculin tests and IFN-g assay) in comparison to *M. bovis*/*M. caprae*.

E.g. references:

Bezoz J. et al., 2015. Vet Immunol Immunopathol. 167 (3-4): 185-189.

Romero B. et al., 2011. Emerg Infect Dis. 17 (12): 2393-1395.

As mentioned before, ante-mortem detection is possible if animals are infected with this bacterium as the same tools used for detecting *Mycobacterium bovis* (or *M. caprae*) apply for *M. tuberculosis* infection. The only caveat is that *M. tuberculosis* infection leads to a weaker immunological response and the sensitivity of these methods are then less important. With respects direct diagnosis, the lesions provoked by *M. tuberculosis* are similar (albeit less important) that the lesions caused by *M. bovis* (or *M. caprae*) infection, thus leading to detection by this means at the abattoir possible. Histology permits TB confirmation with this bacterium. Bacteriology or molecular diagnosis used for *M. bovis* (or *M. caprae*) is also transposable. *M. tuberculosis* can be distinguished from *M. bovis* (or *M. caprae*) with molecular diagnosis tools but also with bacteriological or biochemical methods.

*Mycobacterium tuberculosis* or any other mycobacterium complex infection in domestic animal –including *M. bovis* or *M. caprae*- are clearly distinguished from other diseases, infections or infestations

**Question 4a:** Natural transmission to humans has been proven, and human infection is associated with severe consequences.

*M. tuberculosis* transmission from humans to animals has been demonstrated in most of the reported cases. Nevertheless, transmission from animals to humans has been rarely demonstrated. More studies are required to elucidate this matter although the low adaptation, in general, of *M. tuberculosis* to infect animals and the low severity of lesions showed in infected animals suggest that the potential transmission is minimized. Cases suggesting/demonstrating transmission to humans had as main species the elephants and the infection in humans was in most of the cases suggested by a reactivity to the intradermal tests of the people in contact with the animals (no clinical infection was reported).

E.g. references:

Ghielmetti G. et al.. Sci Rep. 2017 Nov 7; 7(1):14647.

Mikota SK, Maslow JN. 2011. Tuberculosis (Edinb). 91(3):208-11.

Murphree R. et al., 2011. Emerg Infect Dis. 17(3):366-71

As far as I know, natural transmission of *Mycobacterium tuberculosis* from animals to humans has been proven although not yet from cattle or any other livestock animal. One article reviewing this is the following:

Ghodbane R, Drancourt M. Non-human sources of *Mycobacterium tuberculosis*. Tuberculosis (Edinb). 2013 Nov;93(6):589-95. doi: 10.1016/j.tube.2013.09.005. Epub 2013 Sep 22.

However, a spillback infection from cattle to human beings might have been under detected. Indeed, articles confirming the presence of *M. tuberculosis* in milk are available that therefore demonstrate that the zoonotic risk is far from being negligible, in particular given that this human bacillus that even low doses are sufficiently infectious for men. Unfortunately, as cattle or goats infected with *Mycobacterium tuberculosis* are mostly found in very endemic human TB countries, the source of infection in rural communities is difficult to discern.

Villarreal-Ramos B, Berg S, Whelan A, Holbert S, Carreras F, Salguero FJ, Khatri BL, Malone K, Rue-Albrecht K, Shaughnessy R, Smyth A, Ameni G, Aseffa A, Sarradin P, Winter N, Vordermeier M, Gordon SV. Experimental infection of cattle with *Mycobacterium tuberculosis* isolates shows the attenuation of the human tubercle bacillus for cattle. Sci Rep. 2018 Jan 17; 8(1):894. doi: 10.1038/s41598-017-18575-5. PubMed PMID: 29343690; PubMed Central PMCID: PMC5772528.

**Question 4b:** The disease has been shown to have a significant impact on the health of domestic animals at the level of a country or a zone taking into account the occurrence and severity of the clinical signs, including direct production losses and mortality.

The impact on Public Health is unquestionable: according WHO, *M. tuberculosis* infected 10.4 million people and 1.8 million died from TB in 2016. For this reason, the isolation of *M. tuberculosis* from animals concerns in a great manner to the public and animal health authorities. However, the infection by *M. tuberculosis* in domestic animals is very rare and when present, it shows a lower severity in comparison to *M. bovis*/*M. caprae* infection as it has been demonstrated in naturally and experimentally infected animals. A significant impact can arise from the infection of animals in zoo with a high economic value.

*M. tuberculosis* is less infectious for cattle than for human beings, the morbidity of this infection is lower than that of *M. bovis* (or *M. caprae*). This has been proven by experimental infections:

Villarreal-Ramos B, Berg S, Whelan A, Holbert S, Carreras F, Salguero FJ, Khatri BL, Malone K, Rue-Albrecht K, Shaughnessy R, Smyth A, Ameni G, Aseffa A, Sarradin P, Winter N, Vordermeier M, Gordon SV. Experimental infection of cattle with *Mycobacterium tuberculosis* isolates shows the attenuation of the human tubercle bacillus for cattle. *Sci Rep.* 2018 Jan 17;8(1):894. doi: 10.1038/s41598-017-18575-5. PubMed PMID: 29343690; PubMed Central PMCID: PMC5772528.

Whelan AO, Coad M, Cockle PJ, Hewinson G, Vordermeier M, Gordon SV. Revisiting host preference in the *Mycobacterium tuberculosis* complex: experimental infection shows *M. tuberculosis* H37Rv to be avirulent in cattle. *PLoS One.* 2010 Jan 1;5(1):e8527. doi: 10.1371/journal.pone.0008527. PubMed PMID: 20049086; PubMed Central PMCID: PMC2795854.

Nonetheless, retrospectively but also more recently several articles describe the presence of important TB clinical stages due to *M. tuberculosis* on livestock animals. The frequency of these cases is incomparably low with respect to those provoked by *M. bovis*/*M. caprae*. One very good example is the following article:

Sweetline Anne N, Ronald BS, Kumar TM, Kannan P, Thangavelu A. Molecular identification of *Mycobacterium tuberculosis* in cattle. *Vet Microbiol.* 2017 Jan;198:81-87.

**Question 4c:** The disease has been shown to, or scientific evidence indicates that it would, have a significant impact on the health of wildlife taking into account the occurrence and severity of the clinical signs, including direct economic losses and mortality, and any threat to the viability of a wildlife population.

As far as I know, no cases of *M. tuberculosis* infection have been reported in wildlife living in their habitat (without contact with humans) although several cases in domesticated wild animals, close-contact with humans or from sanctuaries or zoos has been described. The infection is very rare and is not considered a threat to the viability of the populations.

E.g. references:

Zachariah A. et al., 2017. *Emerg Infect Dis.* 23 (3): 504-506.

Seo MG. et al., 2017. *J Food Prot.* 80 (6): 1009-1014.

Gong et al., 2017. *Exp Anim.* 66 (4): 357-365.

Evidence exists for semi-free wildlife (rhinos or elephants) and many others on captive wildlife (principally elephants), mainly from zoological parks or circus:

Chandranaik BM, Shivashankar BP, Umashankar KS, Nandini P, Giridhar P, Byregowda SM, Shrinivasa BM. *Mycobacterium tuberculosis* Infection in Free-Roaming Wild Asian Elephant. *Emerg Infect Dis.* 2017 Mar;23(3):555-557. doi:10.3201/eid2303.161439. PubMed PMID: 28221114; PubMed Central PMCID: PMC5382756.

Zachariah A, Pandiyan J, Madhavalatha GK, Mundayoor S, Chandramohan B, Sajesh PK, Santhosh S, Mikota SK. *Mycobacterium tuberculosis* in Wild Asian Elephants, Southern India. *Emerg Infect Dis.* 2017 Mar;23(3):504-506. Doi: 10.3201/eid2303.161741. PubMed PMID: 28221104; PubMed Central PMCID: PMC5382741.

Michel AL, Hlokwe TM, Espie IW, van Zijll Langhout M, Koeppel K, Lane E. *Mycobacterium tuberculosis* at the human/wildlife interface in a high TB burden country. *Transbound Emerg Dis.* 2013 Nov;60 Suppl 1:46-52. doi: 10.1111/tbed.12099. PubMed PMID: 24171848.

However other free ranging wildlife species usually affected by *M. bovis* (or *M. caprae*), that interact actively with livestock (deer, wild boar, badgers, possums, etc.), and which have been pointed out as being spillback species of the disease to cattle, have never been found infected by *Mycobacterium tuberculosis* (at least in the wild).

**Summary Conclusion:**

Making a strict interpretation, *M. tuberculosis* do not match the listing criteria to be included in the OIE list but the main drawback is that there is scarce information (due to the low cases of *M. tuberculosis* infection reported in animals) regarding some of the criteria. In this sense, we believe that the absence of available data regarding some of the matters does not discard the possibility of a positive response in some of the points. Perhaps other experts have additional information that can elucidate some of the questions and therefore, it should be further discussed within the OIE expert panel before accepting or discarding the inclusion of *M. tuberculosis* in the list.

*M. tuberculosis* does not exactly not match the listing criteria to be included in the OIE list. Other than in captive elephants or other primates, infection due to it seems not to be a real animal health problem. On the contrary *Mycobacterium tuberculosis* infection is still one of the major causes of mortality for human beings. The zoonotic implication that an animal infection could have *per se* has historically been the reason why it is included as a causative agent of notifiable animal TB. Nowadays that livestock infection reports due to this bacillus are increasing, most probably due to more sensitive and specific detection methods, and of the rise of cattle rearing in very endemic human disease developing countries, it seem sensible to keep it as a causative agent of bovine tuberculosis.

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**WORK PROGRAMME FOR  
THE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES (SEP 2018)**

Issue and priority order (1-3; 1 being highest priority)		Status and action
<b>Update of OIE standards</b>		
1	Glossary	Revised a new and amended definitions and sent to TAHSC.
2	Ch. 1.1. Notification of diseases, infections and infestations, and provision of epidemiological information	Proposed to provide specific guidance about what is intended as “new strain” in the relevant disease specific chapters to support immediate notification. Proposal from BSC considered. SCAD comments sent to TAHSC.
1	Ch. 1.4. Animal Health Surveillance	Proposed amendments and sent to TAHSC.
1	Ch. 1.6. Procedures for self-declaration and official recognition by the OIE	Proposed amendments and sent to TAHSC.
2	Ch. 4.3. Zoning and compartmentalisation (TPZ)	Meeting held between SCAD and TAHSC to discuss the concept of temporary protection/preventive zone. Discussion paper to be drafted by OIE HQ for review by both Commissions in February 2019.
2	Ch. 4.X. Vaccination	Considered one comment on the definition of population immunity and proposal not to amend the chapter.
3	Ch 4.Y. Official control of listed and emerging diseases	Proposed amendments and sent to TAHSC.
2	Ch.8.8. Infection with foot and mouth disease	Reviewed and endorsed <i>ad hoc</i> Group on alternative for surveillance for demonstration of freedom from FMD and recovery periods and the draft surveillance articles prescribing requirements for earlier recovery of free status when emergency vaccination not followed by slaughtering of animals is applied.
1	Ch. 8.14. Infection with rabies virus	Addressed Member comments after consultation with the Reference Laboratories experts. Proposed amendments and sent to TAHSC.
3	Ch. 8.16. Infection with rinderpest virus (recovery status)	Received update on current advancement. Draft provisions on recovery of status to be delivered to the Commission for the February 2019 meeting.
3	Ch 8.X. <i>Trypanosoma evansi</i> (not equine surra)	Considered the opinion of the <i>ad hoc</i> Group on animal African trypanosomoses. Proposed assessment against the criteria described in Chapter 1.2. of the <i>Terrestrial Code</i> .
1	Ch. 8.Y. Animal African Trypanosomoses	<i>Ad hoc</i> Group report and draft chapter reviewed, and comments sent back to the <i>ad hoc</i> Group on animal African trypanosomoses. Suggested assessing the different species included in the case definition against the criteria described in Chapter 1.2. of the <i>Terrestrial Code</i> .
1	Ch.10.4. Infection with avian influenza virus	<i>Ad hoc</i> Group report and draft chapter considered. Comments sent to TAHSC.
1	Ch. 11.4. Bovine spongiform encephalopathy	<i>Ad hoc</i> Group report on BSE risk assessment and draft chapter considered. Work ongoing by <i>ad hoc</i> Groups on BSE risk assessment and BSE surveillance.
3	Ch. 11.9. Infection with lumpy skin disease virus (Country or zone free where vaccination is implemented)	Not applicable.
3	Ch. 11.12. infection with <i>T. anulata</i> , <i>T. orientalis</i> , <i>T. parva</i>	Not applicable.
2	Ch. 12.2 Contagious equine metritis	Proposed amendments and sent to TAHSC.

3	Ch. 12.3. Infections with Trypanozoon in equids	Considered the opinion of the <i>ad hoc</i> Group on animal African trypanosomoses. Proposed assessment against the criteria described in Chapter 1.2. of the <i>Terrestrial Code</i> .
2	Ch. 12.6. Infection with equine influenza virus	Proposed amendments and sent to TAHSC.
2	Ch. 12.7. Equine piroplasmiasis	Proposed amendments and sent to TAHSC.
3	Ch. 14.X. infection with <i>T. lestoquardi</i> , <i>T. luwenshuni</i> , <i>T. uilenbergi</i>	Not applicable.
1	Ch 15.1. African Swine Fever	Considered some Member comments and proposed not to amend the chapter.
<b>Official disease status recognition</b>		
1	Evaluation of Member dossiers	[Each February meeting] SCAD will consider the report of the ad hoc Groups for evaluation of Members' status, analysis of the dossiers and other findings and recommend the final outcome for adoption by the World Assembly in May 2019.
2	Experts missions to Member Countries	[Continuous process] SCAD prioritised in-country missions to be deployed to monitor continuous compliance with the <i>Terrestrial Code</i> requirements for maintenance of official status.
2	Follow up of Member Countries with official disease status or with suspended status	[Continuous process] Situation in the listed countries reviewed and follow-up on recommendation of SCAD for certain countries; on-going process.
1	Review of annual reconfirmations	[Each September meeting] SCAD selected 10% of countries' disease status for comprehensive review at its meeting in February 2019.
1	Harmonisation the requirements in the <i>Terrestrial Code</i> Chapters for official disease freedom (OIE HQ)	Ongoing/Not applicable.
2	Review of the procedures on official status of non-contiguous territories	Recommended that current provisions of the <i>Terrestrial Code</i> ( <i>i.e.</i> containment zone) should apply for recovery of status.
2	Procedures on self-declaration	Invited Members to send comments to OIE ( <a href="mailto:disease.status@oie.int">disease.status@oie.int</a> ).
<b>Disease control issues</b>		
2	Advise on Global Control and eradication strategies (FMD, PPR, rabies)	Update on the progress made.
1	Assess and endorse non-disease-Status and non-standard-setting <i>ad hoc</i> Groups reports falling into the SCAD remit	Endorsement of AHG report on prioritisation of diseases for which vaccines could reduce antimicrobial use in cattle, sheep and goats.
1	Assess recent developments in the practical problems of control and eradication of infectious diseases and the impact of these developments	Consideration and proposed recommendations on the following: <ul style="list-style-type: none"> <li>- Rapid screening of bovine carcasses to determine the absence of FMDv (PCR test on lymph nodes);</li> <li>- Evaluation if <i>M. caprae</i> and <i>M. tuberculosis</i> match the OIE listing criteria of <i>Terrestrial Code</i> Chapter 1.2.;</li> <li>- Prion disease in dromedary camels in Algeria;</li> <li>- Resistance to antiparasitics;</li> <li>- Definition of a seasonally vector free period;</li> <li>- Update on rinderpest activities;</li> <li>- Update on the project on replacement of International Standard Bovine Tuberculin.</li> </ul>
1	Define a procedure for the evaluation of diseases against the listing criteria of Chapter 1.2.	Draft SOP agreed with minor revisions and proposed amendments. Sent to TAHSC for consideration and inputs.
2	Advise on the composition and activities of the Working Group on Wildlife Diseases and coordinate its work	Recommendation on the agenda of the next meeting sent to the Working Group.

AMR		
1	Assess and endorse AMR related <i>ad hoc</i> Groups reports	Report endorsed and forwarded to TAHSC.
Other activities that could impact SCAD work programme		
1	Evaluation of applications for OIE Collaborating Centre status	Not applicable.
	Any other business	

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