



WORLD ORGANISATION FOR ANIMAL HEALTH
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REPORT OF THE MEETING OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 18–22 February 2019

A meeting of the OIE Scientific Commission for Animal Diseases (Scientific Commission) was held at the OIE Headquarters in Paris, France from 18 to 22 February 2019.

1. Welcome and Specialist Commission Performance Management Framework

Dr Matthew Stone, OIE Deputy Director General for International Standards and Science, welcomed the members of the Commission and presented the Commission Performance Management Framework. He explained that the object of the framework is continuous improvement of the work of all four OIE Specialist Commissions and the OIE Secretariats to meet expectations for the benefit of the OIE Member Countries. He noted that the process includes regular meetings between Commission members and the Deputy Director General, the Presidents and the Director General, and a brief review at the end of each Commission meeting. Following the penultimate meeting prior to the next election, feedback on the work of the Commission and individual members will be provided to the Director General and the Council.

Dr Cristóbal Zepeda, President of the Commission, welcomed the Performance Management Framework, which will bring transparency to the processes and improve their efficacy.

2. Adoption of the agenda and appointment of rapporteur

The draft agenda was adopted by the Commission. The meeting was chaired by Dr Cristóbal Zepeda 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 comments received for consideration by the Scientific Commission

a) Chapter 1.4 Animal health surveillance

The Commission discussed the Member comments on the amended chapter that was circulated for the fourth time after the September 2018 Specialist Commission meetings with the intention to be presented for adoption at the 87th General Session in May 2019.

The Commission took note of Member comments and addressed its concerns in the specific articles.

The rationale for the Commission's proposed amendments is attached in Annex 3.

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

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

The Commission addressed the Member comments received on the amended chapter that was circulated for the second time after the Specialist Commission meetings in September 2018.

The Commission noted that at its September 2018 meeting, the Code Commission proposed to consider whether Article 1.1.5. (related to the notification of the absence of diseases) should be moved to Chapter 1.6. The Commission was also informed that the OIE Status Department and World Animal Health Information and Analysis Department (WAHIAD) discussed this issue and agreed on the deletion of Article 1.1.5. from Chapter 1.1. and the incorporation of these provisions, where relevant, under this chapter. OIE Members would declare freedom or regaining of freedom from a disease in their country or zone following the procedures described under Chapter 1.6. and not via the World Animal Health Information System (WAHIS).

The Commission also considered the amendments proposed by the OIE Status Department in support of the harmonisation of the *Terrestrial Code*'s provisions for the official recognition of disease-free status, for the endorsement of official control programmes, and for their maintenance. At its February 2018 meeting, the Commission endorsed the harmonised provisions and forwarded them for the Code Commission's consideration. At its September 2018 meeting, the Code Commission recommended that the horizontal provisions be referenced or addressed in the horizontal Chapters (i.e. Chapters 1.1., 1.4., or 1.6.) of the *Terrestrial Code*. The Commission agreed that the provisions related to the objectives of an OIE endorsed official control programme, the delineation of zone(s), the suspension of an official status, and the withdrawal of the endorsement of an official control programme were horizontal provisions that could be addressed in Chapter 1.6., and therefore concurred with the amendments.

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

c) Draft 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 fifth time after the Specialist Commission meetings in September 2018.

The Commission suggested a modification of the title for clarity and to ensure consistency between the title and the purpose of the chapter, as indicated in the introductory article. The Commission suggested the title: "Official control programme for listed and emerging diseases".

The Commission discussed whether "contagious disease(s)" should be replaced with "transmissible disease(s)". The Commission noted that contagious diseases are a subset of transmissible diseases and that most transmissible diseases are also contagious (with the exception of certain prion diseases).

The Commission was of the opinion that "transmissible disease" should be used throughout the chapter.

In addition, the Commission noted that the "legal framework" should be listed among the components of official control programmes and suggested, when possible, to align the structure of the chapter with the list of components of an official programme. It also suggested to ensure harmonisation of the terminology between the list of general components of an official control programme and the subsequent articles.

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

d) Chapter 8.14. Infection with rabies virus

The Commission discussed the Member comments on the amended chapter that was circulated for the second time after the September 2018 Specialist Commission meetings with the intention to be presented for adoption at the 87th General Session in May 2019.

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

The Commission considered the suggestion of some Members to add recommendations on the control of rabies in wildlife, including oral vaccination. The Commission pointed out that the main purpose of the revision of the chapter was to support the Global Strategic Plan to eliminate dog-mediated human rabies. The Commission suggested considering the inclusion of specific provisions on the control of rabies in wildlife, including oral vaccination in the future modification of the chapter, and suggested seeking guidance on the topic from the Working Group on Wildlife. The Commission also noted that most of the provisions of the articles, including disease freedom, are applicable to both domestic animals and wildlife.

The Commission was informed that the questionnaire to guide Members in the preparation of the dossiers to apply for OIE endorsement of their official national control programmes would be developed and presented for adoption at the General Assembly a year after the adoption of the revised *Terrestrial Code* Chapter 8.14., along with the administrative procedure for the official endorsement.

The Commission took note of Member comments and addressed its concerns in the specific articles.

The 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.

e) Chapter 15.1 Infection with African swine fever virus

The Commission addressed the Member comments received on the revised chapter that was circulated for the second time after the Specialist Commission meetings in September 2018 with the intention to be proposed for adoption at the 87th General Session in May 2019.

Article 15.1.2. General criteria for the determination of the African swine fever (ASF) status of a country, zone or compartment

The Commission noted a Member request to provide technical guidance on how to achieve appropriate biosecurity to effectively separate the domestic pig population from wild pig populations. The Commission noted that some guidelines for the management and surveillance of wild boars are present in the *Handbook on African swine fever in wild boars and biosecurity during hunting*, drafted under the GF-TADs¹ for Europe. It also made reference to the provisions of *Terrestrial Code* Chapter 4.5. on the application of compartmentalisation, that also covers biosecurity requirements. The Commission discussed the possibility of developing dedicated guidelines for compartmentalisation, similar to what was done for avian influenza, and decided that, for the moment it would not be a priority.

Article 15.1.22. Procedures for the inactivation of ASF virus (ASFV) in meat

The Commission took note of the concerns expressed by two Members on the virus inactivation process in dry cured pig meat and thoroughly reviewed the scientific references provided (McKercher *et al.*, 1987², Mebus *et al.*, 1993³, and Mebus *et al.*, 1997⁴). The Commission was not aware of any new scientific evidence since the last adoption of the chapter in May 2017 and requested the OIE Headquarters to conduct a literature review and to contact the OIE ASF Reference Laboratory experts for technical advice on whether or not the article should be amended.

1 GF-TADs: Global Framework for the progressive control of Transboundary Animal Diseases

2 McKERCHER P.D., YEDLOUTSCHNIG R.J., CALLIS J.E., MURPHY R., PANINA G.F., CIVARDI A., BUGNETTI M., FONI E., LADDOMADA A., SCARANO C. & SCATOZZA F. (1987). Survival of viruses in "Prosciutto di Parma" (Parma ham). *Canadian Institute of Food Science and Technology Journal*, **20**, 267–272.

3 MEBUS C.A., HOUSE C., GONZALVO F.R., PINEDA J.M., TAPIADOR J., PIRE J.J., BERGADA J., YEDLOUTSCHNIG R.J., SAHU S., BECERRA V. & SANCHEZ-VIZCAINO J.M. (1993). Survival of foot-and-mouth disease, African swine fever, and hog cholera viruses in Spanish serrano cured hams and Iberian cured hams, shoulders and loins. *Food Microbiology*, **10**, 133–143.

4 MEBUS C., ARIAS M., PINEDA J.M., TAPIADOR J., HOUSE C. & SANCHEZ-VIZCAINO J.M. (1997). Survival of several porcine viruses in different Spanish dry-cured meat products. *Food Chemistry*, **59**, 555–559.

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

f) Chapter 15.2. Infection with classical swine fever (CSF) virus

The Commission addressed the Member comments received on the revised chapter that was last circulated in February 2017.

The Commission took note of Member comments and addressed its concerns in the specific articles.

The rationale for the Commission's proposed amendments is attached in [Annex 5](#).

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

3.2. Other considerations

a) Chapter 8.16. Infection with rinderpest virus

The Commission revised the draft chapter, that had been modified by the OIE HQ with the technical support of the FAO⁵–OIE Rinderpest Joint Advisory Committee (JAC), following a recommendation from the Code Commission in September 2018. The aim of the revision of the chapter was to provide recommendations regarding vaccination-to-live policy in response to rinderpest re-emergence, and to reinstate the requirements for importation in case of a re-emergence of the disease that had been included in the 2010 edition of the *Terrestrial Code*.

The Commission extensively discussed the implementation of zoning in the context of a re-emergence of rinderpest and noted inconsistencies in the use of zoning throughout the chapter. It was of the opinion that the main purpose of the chapter should be to promptly regain global freedom and not to facilitate trade from infected countries in case of re-emergence of rinderpest. The Commission recommended consulting the JAC on this aspect before progressing with the modification of the chapter. The Commission also suggested including an article with provisions for a country free from rinderpest virus (RPV) infection and remarked to indicate that the importation of vaccinated animals should not be recommended under any circumstances.

The Commission proposed a change to the definition of a case to differentiate antibodies due to vaccination from those due to infection in order to avoid discrepancies with Article 8.16.7.

The Commission acknowledged the recent publication of the Global Rinderpest Action Plan (GRAP) drafted following the adoption of Resolution No. 18 by the OIE Assembly in 2011, updated with Resolution No. 21 adopted by the OIE Assembly in 2017. The Commission acknowledged that the objective of the GRAP is to complement national and regional contingency plans and to lay down the roles and responsibilities of all relevant stakeholders to prepare, prevent, detect, respond and recover from a potential rinderpest outbreak. However, the Commission noted that this document had not been officially endorsed by the OIE Assembly and, therefore, it recommended not to include references to it in the text of the draft chapter.

b) Chapter 12.6. Equine influenza

At its September 2018 meeting, the Commission considered the outcome of the work coordinated by an OIE Reference Laboratory on Equine influenza⁶ on the "Evaluation of current equine influenza vaccination protocols prior to shipment". The Commission acknowledged that the outcome of this study supported the update of the time period recommended in Article 12.6.6. of the *Terrestrial Code* for vaccinating against equine influenza before shipment. However, noting that this study was performed on competition horses, the opinion of an equine influenza expert (OIE Reference Laboratory for equine influenza and member of the OIE Biological Standards Commission) was sought and confirmed that the outcomes of this study were applicable to all horses. The Commission endorsed the expert's recommendation and amended Article 12.6.6. accordingly. The article was forwarded to the Code Commission for its consideration.

⁵ FAO: Food and Agriculture Organization of the United Nations

⁶ Irish Equine Centre, OIE Reference Laboratory for Equine influenza

4. *Ad hoc* and Working Groups

4.1. Meeting reports for endorsement

a) *Ad hoc* Group on Bovine Spongiform Encephalopathy Surveillance: 3–5 October 2018

The Commission reviewed and endorsed the report of the *ad hoc* Group on Bovine Spongiform Encephalopathy (BSE) surveillance, which recommended the revision of the BSE surveillance provisions in support of the categorisation of BSE risk status.

The Commission acknowledged that, historically, intensive active surveillance for BSE has been useful for demonstrating the effectiveness of control measures, such as the ban on feeding ruminants with meat-and-bone meal or greaves. However, now that the effectiveness of the control measures has been clearly established, the purpose of BSE surveillance had to be reconsidered.

The Commission concurred with the *ad hoc* Group that the current points-based surveillance system for BSE can no longer be considered proportionate to the risk or cost-effective. Furthermore, some Members might apply variable definitions for BSE clinical suspects, which could maximise the number of surveillance points and bias the outcome of the points-based surveillance. The Commission also acknowledged that the current surveillance provisions might pose a barrier for less-resourced Members to comply with the requirements for the official recognition of their BSE risk status.

The Commission concurred with the recommendation of the *ad hoc* Group that the primary focus for the official recognition and maintenance of BSE risk status should be based on a comprehensive risk assessment with documented evidence demonstrating effective and continuous BSE risk mitigation. Efforts and resources should be primarily directed towards maintaining and monitoring the rigorous and continual implementation of the various mitigation measures in the field. Passive clinical surveillance for BSE should be maintained, and supported by awareness activities, in order to identify cattle with clinical syndromes consistent with BSE.

The Commission noted that the revision of the provisions for the categorisation of BSE risk status will be finalised by an *ad hoc* Group on BSE Surveillance and Risk Assessment, which will meet in March 2019 and will gather experts from the *ad hoc* Group on BSE Risk Assessment and from the *ad hoc* Group on BSE surveillance.

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

b) *Ad hoc* Group on the evaluation of African horse sickness status: 18 October 2018 (electronic consultation)

The Commission reviewed and endorsed the report of the *ad hoc* Group on the evaluation of the applications from Members for the recognition of their African horse sickness (AHS) free status.

The Commission had considered, via electronic consultation, the recommendation of the *ad hoc* Group regarding an application from a Member for the maintenance of the official recognition of its AHS free country status. Based on its review of the report of the *ad hoc* Group, the AHS status had been suspended with effect from 16 November 2018.

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

c) *Ad hoc* Group on the evaluation of FMD status: 22–25 October 2018

The Commission reviewed the report of the *ad hoc* Group on the evaluation of applications from Members for the recognition of their FMD status.

- *Evaluation of requests from Members for the recognition of FMD free zones where vaccination is not practised*

The Commission agreed with the conclusions of the *ad hoc* Group and recommended that the Assembly recognise a zone of Bolivia consisting of the Department of Pando as an FMD free zone where vaccination is not practised. This zone was previously recognised free from FMD with vaccination. The Commission encouraged Bolivia to take into consideration the recommendations of the *ad hoc* Group and submit documented evidence of their implementation in the annual reconfirmation.

The Commission also agreed with the conclusions of the *ad hoc* Group and recommended that the Assembly recognise Zone 7 of Botswana as a zone free from FMD where vaccination is not practised. In accordance with OIE established procedures, an OIE Headquarters staff member from Botswana withdrew from the meeting during the discussions on Botswana's dossier by the Commission. The Commission encouraged Botswana to take into consideration the recommendations of the *ad hoc* Group and submit documented evidence of their implementation in the annual reconfirmation.

The Commission also considered the recommendation of the *ad hoc* Group regarding the application from Kazakhstan for splitting the officially recognised FMD-free zone without vaccination into five zones: Zone 1 comprising West Kazakhstan, Atyrau, Mangystau and south-western part of Aktobe region; Zone 2 comprising north-eastern part of Aktobe region, southern part of Kostanay region and western part of Karaganda region; Zone 3 comprising northern and central parts of Kostanay region, western parts of North Kazakhstan and Akmola regions; Zone 4 comprising central and eastern parts of North Kazakhstan region and northern parts of Akmola and Pavlodar regions; Zone 5 comprising central and eastern parts of Karaganda region and southern parts of Akmola and Pavlodar regions. The Commission recommended the official recognition of the five separate zones as free from FMD without vaccination.

The Commission highlighted the challenges of maintaining and managing multiple zones in accordance with the requirements of the *Terrestrial Code*. In particular, the Commission emphasised the prerequisites of adequate identification of susceptible animals of each zone as well as the importance of maintaining control of movement of FMD susceptible animals and their products between zones of different status as well as of the same status as long as they remain officially recognised as separate zones. In addition, the Commission recommended that when applying for or maintaining the official status of multiple zones, survey design and sampling should be established for each zone individually or through an overarching protocol stratified by zone. The choice of survey design should be thoroughly justified. Lastly, the Commission reminded Members that annual reconfirmations for the maintenance of official status should be compiled and submitted separately for each zone having an official status.

- *Evaluation of a request from a Member for the recognition of FMD free zones where vaccination is practised*

The Commission considered the recommendations of the *ad hoc* Group regarding the application from a Member regarding two zones and concluded that they did not meet the requirements to be officially recognised as FMD free zones where vaccination is practised. The dossier was referred to the applicant Member along with the rationale for the Commission's position. Suggestions on actions to be taken to comply with the requirements of the *Terrestrial Code* were provided.

- *Evaluation of requests from Members for the endorsement of their national official control programmes for FMD*

The Commission agreed with the conclusion of the *ad hoc* Group on the applications submitted by two Members that did not meet the requirements of the *Terrestrial Code* for the endorsement of their official control programmes for FMD. The dossiers were referred to the applicant Members indicating the main aspects that should be improved in order to comply with the requirements of the *Terrestrial Code* before resubmitting their dossiers.

The Commission emphasised that the official control programmes proposed for OIE endorsement should be applicable to the entire country while focusing on the areas or zones where the Member aims to achieve FMD-free status. The proposed programme should provide a detailed and stepwise timeline of the plan, performance indicators as well as the effectiveness of the programme, which should be documented. The Commission also pointed out the link between the OIE/FAO FMD Progressive Control Pathway (PCP) tool and the OIE procedures for official recognition, and that FMD-PCP Stage 3 should be reached for an official control programme for FMD to be endorsed by the OIE.

- *Review of the updated information provided by a Member with regard to its endorsed official control programme – particularly on the timeline and performance indicators – according to the current FMD situation*

The Commission considered the recommendations and additional questions raised by the *ad hoc* Group with regard to the adjusted timeline and performance indicators for Mongolia's endorsed official control programme for FMD. The Commission noted the questions raised by the *ad hoc* Group and the answers submitted by Mongolia as part of its annual reconfirmation. The Commission acknowledged the efforts made by Mongolia and recommended the endorsement of its official control programme for FMD be maintained. However, the Commission provided detailed recommendations to Mongolia on the actions to be undertaken to further strengthen compliance with the relevant requirements of the *Terrestrial Code*. The Commission requested Mongolia to report on the progress made according to the updated timeline and performance indicators at its next annual reconfirmation in November 2019.

The Commission appreciated the *ad hoc* Group providing written guidelines on how Members could present their serological survey design and results. The Commission endorsed these guidelines and proposed that they be made available to Members wishing to apply for official recognition of FMD status via the OIE website and at OIE workshops providing training on the submission of applications for official status recognition. The Commission advised that such guidelines could also be developed for other diseases as part of the OIE official recognition procedure.

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

d) *Ad hoc* Group on the evaluation of BSE risk status: 29–30 October 2018

The Commission reviewed and endorsed the report of the *ad hoc* Group on the evaluation of the applications from Members for the recognition of their BSE risk status.

The Commission agreed with the conclusions of the *ad hoc* Group and recommended that the Assembly recognise [Ecuador](#) as having a controlled BSE risk and [Serbia](#) as having a negligible BSE risk. The Commission encouraged Ecuador and Serbia to take into consideration the recommendations of the *ad hoc* Group and to submit documented evidence of their implementation in the annual reconfirmation.

The Commission also considered the recommendation of the *ad hoc* Group regarding the application of another Member and concluded that this Member did not meet the requirements of the *Terrestrial Code* for a BSE negligible or controlled risk status. The dossier was referred to the applicant Member indicating the main aspects that should be improved in order to comply with the requirements of the *Terrestrial Code*.

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

e) *Ad hoc* Group on the evaluation of contagious bovine pleuropneumonia status: 13–14 November 2018

The Commission reviewed the report of the *ad hoc* Group on the evaluation of the applications from Members for the recognition of contagious bovine pleuropneumonia (CBPP) status.

The Commission requested additional clarification from Peru and Uruguay during its meeting and concluded by electronic correspondence to recommend that the Assembly recognise [Peru](#) and [Uruguay](#) as CBPP free countries.

The Commission concurred with the conclusions of the *ad hoc* Group on another application submitted by a Member that did not meet the requirements of the *Terrestrial Code*. The dossier was referred to the applicant Member.

The Commission agreed with the recommendation of the *ad hoc* Group that the taxonomy of the pathogenic agent causing CBPP should be harmonised with the new nomenclature within the OIE documents.

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

f) *Ad hoc* Group on BSE risk assessment: 20–22 November 2018

The Commission reviewed and endorsed the report of the second meeting of the *ad hoc* Group on BSE risk assessment, which continued the revision of the risk-based provisions in support of the categorisation of BSE risk status initiated at its July 2018 meeting, and started revising the BSE questionnaire (Chapter 1.8. of the *Terrestrial Code*) for alignment with the revised provisions.

The Commission appreciated that the *ad hoc* Group reconsidered the current requirement of having the youngest indigenous case of classical BSE be born more than 11 years ago for a BSE negligible risk status. Indeed, as previously emphasised by the Commission, this requirement might not be proportionate to the risk provided that appropriate investigations have not demonstrated evidence of a breach in the control measures that could have led to an increased risk of exposure (see Annex 18 of the February 2017 report of the Commission “Considerations from the Scientific Commission for Animal Diseases with regard to the OIE official recognition of BSE risk status of Member Countries”).

The Commission therefore agreed with the recommendation of the *ad hoc* Group that for the initial recognition of a negligible BSE risk status, indigenous cases of classical BSE should not be born less than 8 years ago (i.e. at least in 95th percentile of the length of the incubation period for classical BSE), consistent with the time period recommended for surveillance and the implementation of risk mitigation measures.

The Commission also agreed with the recommendation of the *ad hoc* Group that a negligible BSE risk status could be maintained even with the occurrence of indigenous case(s) of classical BSE born less than 8 years ago, provided that documented evidence of investigations confirms the likelihood of the BSE agent being recycled within the cattle population continues to be negligible (i.e. no breach in the implementation of the mitigating measures for the relevant period of time including the effectiveness of the feed ban). Nonetheless, as recommended by the *ad hoc* Group, the BSE negligible risk status would be re-categorised to a controlled risk status pending the outcome of such investigations and provision of documented evidence.

The Commission noted that the revision of the provisions for the categorisation of BSE risk status will be finalised by an *ad hoc* Group on BSE surveillance and risk assessment, which will meet in March 2019. The Commission recommended this *ad hoc* Group clarify, and further justify, the impact of atypical BSE on the recognition and maintenance of official BSE risk status. The Commission emphasised that the proposed provisions for atypical BSE should be (i) risk-based, (ii) pragmatic (especially if the revised surveillance provisions for BSE were to result in a decrease in the likelihood of detection of atypical BSE).

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

g) *Ad hoc* Group on the evaluation of peste des petits ruminants status: 27 November 2018 (electronic consultation)

The Commission reviewed and endorsed the report of the *ad hoc* Group on the evaluation of the applications from one Member.

The Commission agreed with the conclusion of the *ad hoc* Group and recommended that the Assembly recognise Croatia as a peste des petits ruminants (PPR) free country. The Commission encouraged Croatia to take into consideration the recommendations of the *ad hoc* Group and to document their implementation in the annual reconfirmation.

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

h) *Ad hoc* Group on the evaluation of CSF status: 4–6 December 2018

The Commission reviewed the report of the *ad hoc* Group on the evaluation of the applications from Members for the recognition of CSF status.

The Commission agreed with the conclusions of the *ad hoc* Group to recommend that the Assembly recognise Latvia and Uruguay as CSF free countries. The Commission also concurred with the recommendations of the *ad hoc* Group regarding the clarifications and information that should be provided by these Members in support of their annual reconfirmations of their CSF free status.

The Commission also recommended the recognition of a zone of Ecuador comprising the insular territory of the Galapagos, as a CSF free zone. The Commission stressed that strict control of movements between the free and infected zones must remain in place and appropriately documented in the annual reconfirmation.

The Commission concurred with the conclusions of the *ad hoc* Group on two other applications submitted by Members that did not meet the requirements of the *Terrestrial Code*. The dossiers were referred to the applicant Members.

The endorsed report of the *ad hoc* Group is attached as Annex 13.

i) *Ad hoc* Group on animal trypanosomoses of African origin: 15–17 January 2019

The Commission commended the *ad hoc* Group for the work done on the revision of the *Terrestrial Code* chapter and for the thorough evaluation of the most relevant species of trypanosomes of African origin against the criteria of the *Terrestrial Code* Chapter 1.2.

The Commission noted that the main purpose of the chapter was to support affected Members in their efforts to control and eliminate the disease while avoiding unnecessary trade barriers.

The Commission took note of the potential risk of disease introduction via the importation of live animals from infected countries due to the possible reactivation of the parasitaemia at destination induced by stress during transportation. The Commission also considered the *ad hoc* Group recommendations for a free country or zone to implement risk mitigation measures at destination, before releasing the animals imported from an infected country or zone. The Commission agreed that, despite implementing the measures suggested by the *ad hoc* Group, the risk of introducing the disease via the importation of live animals cannot be minimised to an acceptable level. Hence, the Commission reiterated its opinion expressed in September 2018 and recommended amending the draft Article 8.Y.2. that describes the provisions for a country or zone free from infection with animal trypanosomes of African origin. Consequently, it suggested deleting draft Article 8.Y.6. on importation of live animals from infected countries or zones.

The Commission reviewed the *ad hoc* Group assessment of *T. vivax*, *T. congolense*, *T. simiae* and *T. brucei* and the justification provided. It agreed that they matched criteria 1, 2, 3 and 4b (in the case of *T. brucei*, also 4a) of the *Terrestrial Code* Chapter 1.2. The Commission advised that *T. vivax*, *T. congolense*, *T. simiae* and *T. brucei* be added to the OIE list and recommended the Code Commission amend the *Terrestrial Code* Chapter 1.3. accordingly.

The Commission reviewed the *ad hoc* Group assessment of *T. godfreyi* and the justification provided and agreed that it did not match point 4 of Article 1.2.2. of the *Terrestrial Code*, and should not be added to the OIE list.

The Commission reviewed the *ad hoc* Group assessment of *T. evansi* and *T. equiperdum* and the justification provided and agreed that *T. evansi* and *T. equiperdum* matched criteria 1, 2, 3 and 4b (in the case of *T. evansi*, also 4a) of the *Terrestrial Code* Chapter 1.2. The Commission advised *T. evansi* and *T. equiperdum* be retained on the OIE list, and this opinion be provided to the Code Commission accordingly.

The Commission concurred with the recommendation to review the *Terrestrial Manual* Chapter 3.4.16 *Animal trypanosomoses (including tsetse-transmitted, but excluding surra and dourine)* to ensure alignment and to better support Members in the implementation of the draft *Terrestrial Code* chapter.

Finally, the Commission recommended the OIE Director General convene an *ad hoc* Group to finalise the drafting of the *Terrestrial Code* chapters on dourine and on surra.

The amended draft chapter and the endorsed *ad hoc* Group report were forwarded to the Code Commission for its consideration.

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

j) *Ad hoc* Group on antimicrobial resistance: 16–18 January 2019

The Commission reviewed and endorsed the report of the *ad hoc* Group on antimicrobial resistance.

The 2nd Global Conference on Antimicrobial Resistance (AMR) and Prudent Use of Antimicrobials in Animals: Putting Standards into Practice, had been held in Morocco in October 2018. The Conference brought together Ministers, OIE Delegates and National Focal Points for Veterinary Products, as well as experts, professionals, policy makers, international organisations and donors, providing a forum to examine how to best support Members in the continued fulfilment of the objectives of the OIE Strategy on AMR and the Prudent Use of Antimicrobials and the Global Action Plan on AMR. The recommendations of the Conference further encouraged OIE Members to contribute to the OIE annual collection of data on antimicrobial agents, and to publish, whenever possible, their own national reports. Recommendations propose the expansion of the OIE List of antimicrobial agents of veterinary importance to include companion animals, and the subdivision of the List by different animal species, and encourage restrictions on the use of certain antimicrobials (fluoroquinolones, third and fourth generation cephalosporins and colistin) and on the use of antimicrobial growth promoters. These recommendations will guide future activities of the OIE on AMR.

The Commission was informed that both increased participation and detail were noted in submissions to the third round of the OIE data collection. A total of 153 (85%) OIE Members and two non-OIE Members submitted completed questionnaires, with 10 new countries providing data for the first time. Of these, 118 countries (76%) reported quantities of antimicrobial agents intended for use in animals. For the third OIE report, the animal biomass was calculated for 91 countries that provided data for 2015. The preliminary results of this analysis were presented during the 2nd OIE Global Conference on AMR and Prudent Use of Antimicrobial Agents in Animals. The report was published on the OIE website on 14 February 2019 and launched through a press conference. The fourth round of the OIE data collection was sent on 20 September 2018 to all OIE Delegates and Focal Points for Veterinary Products; as of the date of the Commission meeting, 132 Countries had sent their reports to OIE Headquarters.

The Commission was informed that activities on AMR are held in the framework of the Tripartite (FAO, WHO⁷, OIE), based on the specific memorandum of understanding (MoU) signed in 2018 by the Tripartite agencies. As a follow-up, a 2-year collaborative work programme on AMR was developed, and is due to be endorsed in February 2019 at the Tripartite executive meeting.

The Commission was informed that this had been the last meeting of the *ad hoc* Group, as a proposal for the Group to become a Working Group will be presented at the General Session in May 2019. The Commission expressed its interest in keeping the connection with the Working Group, once established.

The Commission was informed that an internal re-structuring has taken place to demonstrate the engagement of the OIE and its work programme and to allow allocation of increased resources to focus on this area and the new OIE AMR and Veterinary Products Department, illustrated this development.

The Commission commended the work done by the *ad hoc* Group and by the OIE on AMR, and suggested the OIE improve visibility of its activities. The Commission pointed out the importance of considering environment in AMR-related activities.

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

⁷ WHO: World Health Organization

k) *Ad hoc* Group on Middle East Respiratory Syndrome Coronavirus: 22–24 January 2019

The Commission reviewed and endorsed the report of the *ad hoc* Group on Middle East Respiratory Syndrome Coronavirus (MERS-CoV).

The *ad hoc* Group was convened with the purpose of drafting a *Terrestrial Manual* Chapter on MERS-CoV, to review the current case definition for reporting MERS-CoV in dromedary camels and to assess the disease against listing criteria of *Terrestrial Code* Chapter 1.2.

The Commission reviewed the *ad hoc* Group assessment and the justification provided, and agreed that MERS-CoV in dromedary camels matched criteria 1, 2, 3 and 4a of the *Terrestrial Code* Chapter 1.2. The Commission advised MERS-CoV be added to the OIE list and recommended the Code Commission to amend the *Terrestrial Code* Chapter 1.3. accordingly.

The Commission noted the need to better understand the transmission dynamics in animal populations and mechanisms of zoonotic transmission to humans before recommending risk mitigation measures in the *Terrestrial Code*, so as to avoid unjustified trade barriers.

The Commission reviewed the updated the Questions & Answers (Q&A) document on MERS-CoV and took note of the information provided by the *ad hoc* Group for joint animal–human investigations and the recommendations to avoid animal–human transmissions. The Commission recommended including a section in the Q&A document with information on the precautionary measures to avoid human exposure and spread of the disease.

The Commission was also updated on a document that provided best practices and recommendations for managing MERS-CoV at the human–animal interface, which had been commented on by the *ad hoc* Group.

The Commission endorsed the case definition for reporting MERS-CoV in dromedary camels proposed by the *ad hoc* Group. However, for clarity, it suggested deleting the last paragraph of the introductory section regarding trade of dromedary camels.

The Commissions advised to publish the updated Questions & Answers document and the amended MERS-CoV case definition in the OIE website⁸.

The endorsed report of the *ad hoc* Group is attached to the Biological Standard Commission report of February 2019, Annex 3.

l) Working Group on Wildlife: 4–7 December 2018

The Commission reviewed the draft report of the Working Group on Wildlife.

The Commission took note in particular of the information on the emerging and noteworthy wildlife disease occurrences worldwide during the past year as well as the work programme and priorities set for the Working Group for 2019.

The report of the Working Group was endorsed (87 SG/13 GT).

4.2. Planned *ad hoc* Groups

- a) *Ad hoc* Group on BSE risk assessment and surveillance: 18–21 March 2019
- b) *Ad hoc* Group on veterinary emergencies (2019–2020)
- c) *Ad hoc* Group on the evaluation of AHS status: 24–26 September 2019 (to be confirmed)
- d) *Ad hoc* Group on the evaluation of BSE risk status: 1–3 October 2019 (to be confirmed)
- e) *Ad hoc* Group on the evaluation of CSF status: 22–24 October 2019 (to be confirmed)
- f) *Ad hoc* Group on the evaluation of FMD status: 5–7 November 2019 (to be confirmed)
- g) *Ad hoc* Group on the evaluation of CBPP status: 19–21 November 2019 (to be confirmed)
- h) Working Group on Wildlife: 3–6 December 2019
- i) *Ad hoc* Group on the evaluation of PPR status: 9–11 December 2019 (to be confirmed)

⁸ <http://www.oie.int/en/animal-health-in-the-world/information-on-aquatic-and-terrestrial-animal-diseases/>

5. Official disease status

5.1. Annual reconfirmations for maintenance of official status

a) Comprehensive review of annual reconfirmations (for pre-selected status and all OIE endorsed national official control programmes)

The Commission comprehensively reviewed the annual reconfirmations of the Members that were pre-selected at its last meeting in September 2018.

The Commission underlined the importance of timely submission (by the end of November of each year) of the annual reconfirmations for maintenance of official status and of endorsement of official control programme. The Commission reiterated that lack of submission or finalisation of the annual reconfirmation by the end of January of the following year could lead to the suspension of the official status or to the withdrawal of the endorsement of an official control programme of Members.

b) Report of the annual reconfirmation assessments by the Status Department

The Commission reviewed and endorsed the report prepared by the OIE Status Department on the remaining annual reconfirmations (those that were not selected for comprehensive review). The Commission also reviewed the annual reconfirmations for which the Status Department required the Commission's scientific advice.

The Commission concluded that the annual reconfirmations were compliant with the relevant requirements of the relevant chapter of the *Terrestrial Code* for the maintenance of the officially recognised status and made recommendations to some Members regarding their annual reconfirmations for maintenance of official disease status.

The report of all annual reconfirmations, including those comprehensively reviewed by the Commission and those reviewed by the OIE Status Department and reported to the Commission, is attached as [Annex 16](#).

5.2. Expert missions to Members requested by the Commission

a) Follow-up of past missions: action plans and progress reports

- *Kazakhstan (zones free from FMD where vaccination is practised)*

An OIE mission took place to Kazakhstan in May 2017 prior to the granting of the official recognition of five zones free from FMD where vaccination is practised. The Commission reviewed the report provided by Kazakhstan on the progress made regarding the implementation of the recommendations of this OIE mission and encouraged Kazakhstan to continue its efforts for the maintenance of the officially recognised free status, particularly in managing the integrity of the different zones with strict movement control of susceptible animals and their products in accordance with the provisions of the *Terrestrial Code*.

- *Madagascar (FMD free status where vaccination is not practised)*

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 continual compliance of Madagascar with the requirements of the *Terrestrial Code*. The Commission reviewed the report provided by Madagascar informing it of the progress made regarding the implementation of the recommendations of this OIE mission, together with the annual reconfirmation of the FMD free status of Madagascar. The assessment of the Commission is detailed in [Annex 16](#) (report of the annual reconfirmation assessments).

- *Romania (CSF)*

An OIE mission took place to Romania in May 2017 prior to the granting of the official recognition of the CSF free country status. A follow up OIE mission will be conducted in Romania in 2019 to assess the progress made regarding the implementation of the recommendations of this OIE mission, as well as to assess the issues previously raised by the Commission on implementation of appropriate biosecurity at the field level, particularly in backyard holdings.

b) 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 undertaken, in light of the priority issues identified by the Commission when reviewing the annual reconfirmations submitted in November 2018. The prioritised list of missions would be confirmed following consultation with the Director General of the OIE.

5.3. Specific update on official disease status

a) Update on situation of countries/zone with suspended or re-instated disease status

- *Myanmar (AHS)*

Based on the assessment by the *ad hoc* Group on the evaluation of AHS status of Myanmar's dossier to document compliance with the OIE *Terrestrial Code* provisions for the maintenance of its AHS free country status, and following the endorsement of the recommendations of the *ad hoc* Group by the Commission by electronic consultation, this status was suspended with effect from 16 November 2018.

- *Colombia (FMD)*

The Commission was informed that following an outbreak of FMD in Cesar, the approval of the containment zone had been withdrawn and the "FMD free zone where vaccination is practised" status of Colombia was suspended with effect from 10 August 2018.

- *United Kingdom – Scotland (BSE)*

Following the notification of a domestic case of classical BSE in a 5-year-old cow in Scotland, the negligible BSE risk status of the zone of Scotland was suspended on 2 October 2018. The Commission assessed by electronic consultation the dossier provided by the United Kingdom for the re-instatement of a controlled BSE risk status for the zone of Scotland. The Commission concluded that the zone of Scotland fulfils the requirements of the *Terrestrial Code* and the controlled BSE risk status of the zone of Scotland was regained with effect from 26 December 2018. As a result, three zones of the United Kingdom have an official BSE risk status: Scotland (controlled BSE risk status), England and Wales (controlled BSE risk status), and Northern Ireland (negligible BSE risk status).

- *South Africa (FMD)*

The Commission was informed that following the notification of an outbreak of FMD in Makhado Municipality (Limpopo Province), the status of FMD free zone where vaccination is not practised for this zone of South Africa was suspended with effect from 2 January 2019. Based on the report submitted by South Africa to the WAHIS, the FMDV had been introduced from the infected zone into the free zone through wildlife.

5.4. Standards related to official status recognition

a) Proposed plan for the harmonisation of requirements for disease free status recognition and maintenance in disease-specific chapters (Chapter 1.6. and Chapter 14.7. Infection with peste des petits ruminants virus, as a model)

As presented in Section 3.1.b of this report, the Code Commission considered the harmonised provisions for the official recognition of disease status, for the endorsement of official control programmes, and for their maintenance at its September 2018 meeting and recommended that provisions that would apply to all five diseases for official recognition of disease-free status be referenced or addressed in the horizontal chapters. After the September 2018 meeting, it was agreed that the harmonisation work be first presented to Members using Chapter 14.7. as a model because it was most recently adopted and there are no ongoing or pending issues since its adoption. The Commission endorsed the harmonised provisions for the official recognition of a PPR free status, for the endorsement of an official control programme for PPR, and for their maintenance. Regarding Article 14.7.34. on the OIE endorsed official control programme for PPR, the Commission stressed that the requirements remain the same and modifications had been made to improve structure and clarity.

The two amended articles of Chapter 14.7. on PPR were forwarded to the Code Commission for its consideration.

During the joint meeting, the Scientific Commission and the Code Commission discussed the proposed work programme for the harmonisation of the provisions for the official recognition of disease-free status and their maintenance for AHS, CSF, CBPP and FMD, and for the harmonisation of the provisions for the endorsement of official control programmes for CBPP and FMD (See discussion under agenda item 8.1.a).

b) BSE test methods and maintenance of official BSE risk status

In 2017, the *ad hoc* Group on evaluation of BSE status pointed out that some Members officially recognised as having a BSE risk status may use BSE diagnostic methods that are no longer recommended in Chapter 3.4.5. of the *Terrestrial Manual*.

The BSE diagnostic methods used by Members having an official BSE risk status was documented via the submitted 2018 annual reconfirmations. BSE diagnostic methods used by three Members were not in compliance with the current recommendations of the *Terrestrial Manual*. The Commission emphasised that, in accordance with Chapter 3.4.5 of the *Terrestrial Manual*, histopathology is not appropriate for defining a sample as negative for BSE and that rapid tests (other than a rapid Western Blot) are not appropriate as confirmatory tests for BSE. The Commission provided detailed recommendations to these Members for revising their testing protocols for BSE. The Commission recommended that the BSE diagnostic methods used by those Members should be followed up through the annual reconfirmations to be submitted in November 2019.

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 previous meeting in September 2018 in the framework of the Global FMD Control Strategy.

The Commission was informed that one of the members of the FMD Working Group from the FAO has retired and his replacement was still to be officially communicated.

The first FMD roadmap meeting for Central Africa took place in Cameroon from 25 to 27 September 2018. The eight invited countries attended and were represented by their Chief Veterinary Officers/OIE Delegates. The participant countries were trained in preparing mid- and long-term national action plans for FMD control. The roadmap for the region based on the second edition of the PCP guidelines was agreed during the meeting.

The next West Eurasia roadmap meeting would take place in Iran from 4 to 6 March 2019. It would present an opportunity to commemorate the 10th anniversary of the first roadmap in the region.

The Commission was informed that the GF-TADs FMD Working Group met from 29 to 30 January 2019 and adopted the 2-year Action Plan (2019–2020). It had also been decided to explore the possible synergies between the two Global Strategies (FMD and PPR) and improve coordination of activities as recommended by the Global Steering Committee of the GF-TADs.

The GF-TADs FMD Working Group continued to review and to provide feedback to Members regarding their national control plans and risk-based strategic plans for advancement of the Progressive Control Pathway for FMD. The Commission acknowledged with appreciation the strong involvement of EuFMD⁹ in the implementation of the FMD Global Control Strategy.

Finally, the Commission acknowledged the advancements on the country self-assessment questionnaires that are used by countries prior to the roadmap meetings, the translation of the guidelines on post-vaccination monitoring and the intention to make both available online to assist Members and facilitate the work of the GF-TADs FMD Working Group.

⁹ EuFMD: European Commission for the control of Foot-and-Mouth disease

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

The Commission was updated on the development of the PPR Global Control and Eradication Strategy.

The Commission was informed that in October 2018, the 2nd meeting of the PPR Advisory Committee took place at the FAO Headquarters in Rome, Italy. In addition, in December 2018, the OIE Working Group on Wildlife, during its meeting in Paris, discussed PPR issues related to wildlife and agreed to undertake the task of developing guidelines for outbreak management in wildlife specifically for PPR, in collaboration with the PPR Global Research and Expertise Network (GREN), for countries to consider when developing their PPR national strategic plans.

The main actions planned for 2019 would be the continuation of the second round of regional roadmap meetings with the organisation of the meetings for West Africa, SADC¹⁰ and AMU¹¹ as well as the organisation of a Workshop on “Controlling PPR at the livestock/wildlife Interface”, the 3rd meeting of the PPR Advisory Committee and the 2nd meeting of the PPR GREN in March, July and October 2019, respectively. Moreover, following the successful pilot of the PVS¹² Evaluation missions with a PPR-specific component in Afghanistan and Turkey in 2017, the methodology has now been finalised and several PVS-PPR missions had been either conducted or scheduled, e.g. for Burundi, Chad, Iran and Nigeria.

Finally, the Commission was informed that two workshops on the OIE procedure for the official recognition of PPR free status and endorsement of official PPR national control programmes would be held in Central Asia in April and in Africa in June 2019. These Workshops would target countries that have implemented control and eradication programmes and thus can indicate some progress along the step-wise approach of the PPR Global Strategy, as well as countries that had never reported the disease, to encourage them to enter the OIE pathway towards official recognition of freedom from PPR.

The Commission commended the numerous activities both already performed and planned for the future, and urged the OIE to continue raising awareness among countries of the need to report and promote success stories on PPR control and eradication, and the eventual recognition of PPR free status that can be achieved by following the OIE procedures for official recognition.

6.3. Zero by 30: the Global Strategic Plan to End Human Deaths from Dog-Mediated Rabies

The Commission was updated on the progress with the implementation of the Global Strategic Plan to end human deaths from dog-mediated rabies by 2030.

The OIE Director General, on behalf of FAO, WHO and GARC¹³, formally invited the Ministers of Agriculture/Livestock and Health from the Phase 1 targeted countries to sign a statement to reaffirm their commitment to prioritising rabies prevention in their national plans, and to work with human and animal health stakeholders to eliminate human deaths from rabies nationally by 2030. The Commission commended those countries that had submitted the statement duly signed and invited the OIE Delegates to advocate to their Ministers to sign the statement.

The Commission was informed that the OIE, FAO, WHO and GARC (United Against Rabies [UAR]) collaboration were finalising an operational plan that would lead to the implementation of Phase 1 of the Global Strategic Plan, which would target 29 countries. Key stakeholders would be invited to participate in the operational plan aimed at finding synergies and ensuring coordination of rabies activities at the global level. During 2019, UAR would make an effort to support and guide the target countries in the development of national rabies elimination strategies following the One Health approach.

10 SADC: Southern African Development Community

11 AMU: Arab Magreb Union

12 PVS: Performance of Veterinary Services

13 GARC: Global Alliance for Rabies Control

The Commission was also informed on the OIE initiative to develop a specific methodology to conduct a PVS evaluation with rabies-specific content, following a similar approach applied for PPR. The PVS evaluation mission would include specific content and a dedicated focus on national Veterinary Services capacity to control and eliminate rabies. The rabies-specific aspects would not be the main focus of the mission but a supplement or addition to the generic mission and report, which will be completed in full.

7. OIE Collaborating Centres

7.1. Traditional veterinary medicine

The Commission was asked its view on an application received for an OIE Collaborating Centre for Traditional Veterinary Medicine. The Commission, in agreement with the Biological Standard Commission, recommended additional supporting information be provided in regard to the definition of traditional veterinary medicine and the activities any future OIE Collaborating Centre on the subject would undertake before considering the request.

7.2. Application for the designation of an OIE Collaborating Centre for Risk Analysis and Modelling

The Commission took note of the 5-year workplan provided by the future OIE Collaborating Centre for Risk Analysis and Modelling in response to a request made by the Commission.

8. Liaison with other Specialist Commissions

8.1. Terrestrial Animal Health Standard Commission

a) Joint meeting

The Code Commission and the Scientific Commission held a Joint meeting on 21 February 2019 chaired by the Director General, Dr Monique Eloit. The meeting provided an opportunity for members of the two Commissions to meet and discuss items of common interest, notably: relevant chapters to be proposed for adoption at the upcoming General Session, the establishment of a formal written Standard Operating Procedure (SOP) guiding decisions to list pathogenic agents, a proposed work programme for the harmonisation of requirements for the official recognition and maintenance of disease-free status and endorsement of official control programmes in disease-specific chapters, and the presentations by the Presidents of the Specialist Commissions at the General Session.

All members agreed that this meeting provided an excellent mechanism to strengthen collaboration between the two Commissions. It was agreed to hold this meeting annually during the February Commission meetings.

b) Temporary protection zone: Chapter 4.3. on Zoning and compartmentalisation

Following on from the initiative started in September 2018, the Presidents and First Vice-Presidents of the Scientific and Code Commissions held a technical working group meeting in the margins of the two Commission meetings. 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 further develop existing zoning provisions for the *Terrestrial Code* and the OIE procedure for official recognition of disease status, in order to allow and encourage Members to implement enhanced preventive measures to protect their sanitary status in response to an increased risk of disease incursion, while minimising the impact on their status and consequently on trade. The working group considered the application and impact of the concept for different diseases, and for diseases for which the official status recognition procedure applies and those for which it does not.

The two Commissions agreed on an approach to be followed, and requested OIE Headquarters to draft a discussion paper describing the link and transition process between a temporary protection zone and containment zone and to present the draft amendments to *Terrestrial Code* Chapter 4.3. and disease-specific chapters, where relevant, for consideration by the Scientific Commission at its September 2019 meeting.

8.2. Biological Standards Commission

None at this meeting.

9. Conferences, workshops, meetings

The Commission was updated on the main conclusions of the following meetings in which the OIE was involved since the September 2018 meeting:

- 3rd Regional Workshop on Swine Disease Control and African Swine Fever, Cebu, Philippines, 2–5 October 2018
- 7th meeting of the GF-TADs Standing Group of Experts for Lumpy Skin Disease, Ohrid, the Former Yugoslav Republic of Macedonia, 18–19 October 2018
- 11th meeting of the GF-TADs Standing Group of Experts on African Swine Fever in Europe, Warsaw, Poland, 24–25 September 2018

10. Disease control specific issues

10.1. Evaluation of diseases against listing criteria

a) State of play of the development of a Standard Operating Procedure guiding listing decisions

The Commission was informed of the progress made by the OIE Headquarters to improve rigor, transparency and consistency of the process to list and delist pathogenic agents. The Commission endorsed the amended discussion document on the establishment of a formal written SOP to guide the listing and delisting decisions. The Commission advised that the decision to initiate the procedure for assessing the need for listing or delisting a pathogenic agent should take into consideration its possible implications for international trade.

The Commission reviewed and amended the guidance on the application of the criteria for listing terrestrial animal diseases drafted by the OIE Headquarters. The Commission emphasised that experts need to base their evaluations on scientific evidence (e.g. peer-reviewed papers, official reports, factual evidence provided by experts). Appropriate references should be clearly mentioned in the evaluation.

Concerning criterion 1), the Commission highlighted that the fact that a disease being present in different countries is not sufficient to prove that international spread of the pathogenic agent happens via live animals or their products, vectors or fomites. Hence, experts should provide a sound description of the mechanisms of disease transmission to correctly evaluate pathogenic agents against this criterion. The Commission agreed that the presence of disease or infection in imported animals in a quarantine station, while not affecting the animal health status of the country or zone, does provide evidence of international spread as it shows the potential for spread caused by animals moving undetected.

The Commission noted the difficulties the experts were having in assessing criterion 2 of the *Terrestrial Code* Chapter 1.2., and invited the OIE to improve guidance on this point so as to improve consistency in the expert assessment.

Concerning criterion 4), the Commission pointed out that the one-off occurrence of disease in humans is not sufficient to prove natural transmission to humans, as the public health impact should be taken into consideration.

The Commission revised the guidelines accordingly and sent them to the Code Commission for its consideration.

b) Evaluation of a pathogenic agent against the listing criteria of *Terrestrial Code* Chapter 1.2.:

i) MERS CoV

See discussion under agenda item 4.1.k).

ii) Animal trypanosomes of African origin

See discussion under agenda item 4.1.i).

iii) Porcine epidemic diarrhoea

The Commission reviewed the expert assessment of porcine epidemic diarrhoea and the justification provided, and agreed that it does not fulfil point 2 of Article 1.2.2. of the *Terrestrial Code*, and should not be added to the OIE list.

The expert assessment of porcine epidemic diarrhoea against the listing criteria of Article 1.2.2. of the *Terrestrial Code* is attached as [Annex 17](#).

iv) Chronic wasting disease

The Commission reviewed the expert assessment of chronic wasting disease and the justification provided, noting that the experts did not have a consensus agreement, namely for point 2 and 4c of Article 1.2.2. of the *Terrestrial Code*. However, based on the information provided and considering the opinions of the *ad hoc* Group on BSE and the Working Group on Wildlife, the Commission considered that it does not fulfil point 4 of Article 1.2.2. of the *Terrestrial Code*, and should not be added to the OIE list.

The expert assessment of chronic wasting disease against the listing criteria of Article 1.2.2. of the *Terrestrial Code* is attached as [Annex 18](#).

v) *Theileria lestoquardi*, *T. luwenshuni*, *T. uilenbergi* and *T. orientalis*

The Commission reviewed the expert assessment of *Theileria lestoquardi*, *T. luwenshuni*, *T. uilenbergi* and *T. orientalis* (Ikeda and Chitose) and the justification provided, and agreed that they fulfil criteria 1, 2, 3 and 4b of the *Terrestrial Code* Chapter 1.2. The Commission advised that they should be added to the OIE list and recommended the Code Commission amend *Terrestrial Code* Chapter 1.3. accordingly.

The expert assessment of *Theileria lestoquardi*, *T. luwenshuni*, *T. uilenbergi* and *T. orientalis* (Ikeda and Chitose) against the listing criteria of Article 1.2.2. of the *Terrestrial Code* is attached as [Annex 19](#).

10.2. Update on the foot and mouth disease reference laboratory network and disease global situation

The Commission was updated by Dr Donald King (the Pirbright Institute, United Kingdom) on the activities of the OIE/FAO FMD reference laboratory network and on significant events related to FMD that occurred globally in the past 12 months, which are included in the 2018 annual report.

In the past 12 months, the 15 members of the OIE/FMD Laboratory Network signed an MoU to share, in real-time, unpublished data; detailed procedures will soon be developed. The Commission commended the network for being very active and highlighted the importance of sharing laboratory results. The Commission encouraged Members to regularly submit good quality samples to the FMD reference laboratories and to share test results.

The Commission acknowledged the importance of regularly testing the quality of FMD vaccines and welcomed the ongoing OIE twinning project between Pirbright and AU-PANVAC¹⁴ aimed at establishing an independent FMD vaccine quality control system at PANVAC, including a stakeholder agreement that will involve vaccine manufactures in the East Africa region.

¹⁴ AU-PANVAC: Pan African Veterinary Vaccine Centre of African Union

10.3. Prion disease in dromedary camels in Algeria

The Commission took note of the opinion of the *ad hoc* Group on BSE risk status evaluation and of the *ad hoc* Group on diseases of camelids – consulted electronically – on whether or not prion disease in dromedary camels should be considered as an emerging disease according to the definition in the *Terrestrial Code*.

The Commission emphasised that camel prion disease should be considered as a new disease and should not be overlooked. However, it was noted that the scientific literature available described the event in only one country and that the evidence was not sufficient to measure the impact of the disease on animal or public health.

The Commission recommended Members to pursue further surveillance and research on this disease to monitor its presence in countries with dromedary camel populations as well as to determine its likely origin, routes of transmission, impact on animal health, and zoonotic potential. Members and the scientific community were encouraged to communicate any significant finding to the OIE in a timely manner.

The Commission encouraged the Camel Middle East Network (CAMENET) to lead the investigation into this disease with the support of the OIE Regional Representation for the Middle East and Sub-Regional Representation for North Africa.

The Commission would reassess whether this disease should be considered as an emerging disease based on the criteria listed in the *Terrestrial Code* when new scientific evidence becomes available.

10.4. Zoonotic potential of hepatitis B in gibbons

The Commission was informed of concerns expressed on the inclusion of gibbon hepatitis B virus (GiHBV) in Article 6.12.4. of the OIE *Terrestrial Code*. The Commission recommended consulting the Working Group on Wildlife for any existing scientific evidence to demonstrate the transmission of hepatitis B from gibbons to humans.

10.5. Risk of transmission of lumpy skin disease vaccine-like strain

The Commission discussed the possible risk of transmission of lumpy skin disease (LSD) vaccine-like strain and emphasised the importance of the use of preventive vaccination with high quality live attenuated strains of capripoxvirus manufactured according to the recommendations of the *Terrestrial Manual*.

The Commission highlighted the experience shared by some Members affected by the disease – mainly from the Middle East and Europe – demonstrating that using homologous live attenuated Neethling strain LSD virus vaccines in conjunction with other strategies, such as biosecurity and movement control, proved to be successful in preventing, controlling and eliminating the disease. The Commission also noted that the scientific literature indicated that the risk of transmission of the Neethling vaccine strain to non-vaccinated cattle was considered very low provided the vaccine used is of high quality.

The Commission was not aware of any change in the transmission route of virus in countries using live attenuated Neethling strain vaccines and invited Members to share with the OIE and relevant scientific fora the technical information that may be relevant for a better understanding of the transmission mechanism.

11. For the Commission's information

11.1. Update on rinderpest activities

The Global Rinderpest Action Plan (GRAP) was published in November 2018 and is available on the FAO and OIE websites. The FAO-OIE Joint Advisory Committee (JAC) for rinderpest met at the OIE Headquarters from 11 to 12 December 2018. The pending applications for rinderpest holding facilities (RHF) were discussed. It is expected that CIRAD¹⁵, France, and the China Institute for Veterinary Drug

¹⁵ CIRAD: Centre international en recherche agronomique pour le développement (agricultural research and international cooperation organization)

Control be proposed for designation as RHF's Category A and B by Resolution presented by the OIE Scientific Commission at the next General Session in May 2019. The Sequence and Destroy project being undertaken by two OIE Reference Laboratories for Rinderpest (CIRAD, France, and The Pirbright Institute, United Kingdom) will be concluded in March 2019, when all the sequenced materials will have been destroyed. The OIE "Never Turn Back" communications and awareness campaign, including the Rinderpest Game, had been a success. More than two thousand players from over 80 countries played the game.

The Commission was informed that the annual survey on RPV-containing materials (RVCM) held by countries was underway. The results would be shared with the President of the Commission in due time, so they can be presented during the next General Session in May 2019.

The Commission noted that only 10 Members are known to have or suspected of having RVCM outside of RHF's. The Commission concurred with JAC's recommendation to stop asking all OIE Members for annual reports on RVCM and instead focus advocacy efforts on those 10 countries.

The Commission emphasised the importance of destroying RVCM and strongly recommended the Members that still report having RVCM out of the RHF's to destroy it or to send it to RHF's.

11.2. Update on biological threat reduction activities

The activities related to biological threat reduction (BTR) are cross-cutting within the OIE and at the same time often involve stakeholders from other sectors, e.g. law enforcement, forensics experts or public health professionals. BTR activities include cooperation with the WHO Health Security Interface (HSI), the United Nations Office of Counterterrorism, the United Nations Interregional Crime and Justice Research Institute, the Biological Weapons Convention (BWC) and the BWC Implementation Support Unit, the United Nations Security Council Committee established under Resolution 1540 (2004), the African Union and non-governmental organisations such as the Nuclear Threat Initiative. In addition, OIE representatives participated in international workshops and meetings related to BTR. Furthermore, the OIE *ad hoc* group on BTR developed guidelines for responsible conduct in veterinary research. The guidelines are currently being translated into French and Spanish and will be made available on the OIE website.

The Commission was informed that the activities related to BTR were also described in the OIE Annual Report.

11.3. Update on emergency management activities

The Commission was informed of the OIE and FAO initiative to develop a joint strategy to support Member capacity building in emergency management and for international response to animal health emergencies.

The strategy will be partially supported by a 3-year project (signed in October 2018), which will be jointly implemented by the OIE, FAO and INTERPOL¹⁶ with financial support from the Weapons Threat Reduction Programme of Global Affairs Canada. The objective is to strengthen multi-sectoral capacity to manage animal health emergencies by fostering cooperation at the regional and international levels, and building capacity through training and exercising. The project will focus on emergencies that result from agro-terror or agro-crime, whilst aiming to build resilience against all types of animal health emergencies. The project will be run in three phases: 1) An assessment phase, to develop an information base for capacity building activities; 2) A training and exercising phase, which will include training in contingency planning and running simulation exercises, and implementation of three regional exercises; 3) A coordination phase involving a governance framework, a large international exercise, and an OIE Global Conference on emergency management.

¹⁶ INTERPOL: International Criminal Police Organization

During 2018 the OIE initiated preliminary scoping work on assessing global capacity for emergency management. This involved actively collecting and analysing information about national contingency plans and also analysing PVS data. A preliminary report is available on the OIE website http://www.oie.int/fileadmin/database/report/Final_Report-OIE_project_NCPs_PVS_442018.pdf

The OIE also invited Members to share their national contingency plans on a web-based platform to support capacity building through transparency (the plans may be used as a template by other countries) <http://www.oie.int/solidarity/emergency-management/planning-for-emergencies/>

In terms of response, the OIE has been working closely with FAO and WHO (in the context of the Emergency Management Center–Animal Health and the Global Outbreak Alert and Response Network [GOARN], respectively) to improve synergy and efficiency of joint operations.

In addition, three OIE Collaborating Centres had submitted a proposal to the OIE to form a collaborating centre network on ‘Veterinary Emergencies’.

11.4. Project update: replacement International Standard Bovine Tuberculin

The Commission was updated on an ongoing project to prepare and calibrate a replacement for the International Standard Bovine Tuberculin (ISBT). In a preliminary laboratory evaluation, the potency and specificity of two candidate tuberculin were evaluated in comparison with the current ISBT, and the results were satisfactory. A larger scale international collaborative study is currently underway to further evaluate and calibrate the candidates in guinea-pigs, and to evaluate fitness for purpose in cattle. This second phase of testing is scheduled to be completed by August 2019.

10.5. 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) and by its Secretariat (SIRCAH), which is co-hosted by the OIE.

Working groups of experts delivered draft research roadmaps for vaccine development for bovine tuberculosis, brucellosis and porcine reproductive and respiratory syndrome, and for vaccine and diagnostic development for ASF and FMD. These were published on the consortium’s website and would be presented at the next STAR-IDAZ IRC Executive Committee meeting, which would be held in Beijing, China (People’s Rep. of) in March 2019. The meeting would be organised back-to-back with a workshop aimed at increasing collaboration on international research on pig diseases, with a focus on ASF, and with a meeting of the STAR-IDAZ regional network for Asia and Australasia, so as to collect information on research activities and priorities and increase research coordination in the region.

In December 2018, a workshop was organised in Washington DC, United States of America, to bring together research programme owners and associated stakeholders from the public and private sectors in the USA to discuss how they can engage with the STAR-IDAZ IRC research roadmaps and move forward collectively to shorten the innovation pipeline to tackle animal disease in the livestock sectors. The workshop was held back-to-back with a reception for key political leaders with an interest in agriculture and other stakeholders from the livestock sectors, aimed at galvanising international political support for a global research initiative on the development of new and improved animal disease control strategies, including vaccines.

10.5. Project on “Capacity building and surveillance for Ebola Virus Disease (EVD)” (EBO-SURSY) between the European Union and the OIE

The Commission was updated on the progress of the 5-year project launched in 2017, with the financial support of the European Union and the technical support from CIRAD, the Institut de Recherche pour le Développement (IRD) and the Institut Pasteur and its International Network (IP).

The aim of the project is to strengthen national and regional early detection systems in wildlife in ten countries in West and Central Africa using a One Health approach to better detect, differentiate and prevent future EVD outbreaks or outbreaks of other emerging zoonotic pathogens.

The activities of the project are being implemented as planned. One of the main achievements in 2018 was the creation of a database to store all project field sample information and the development of an agreement that outlines the conditions of data access by partners and external stakeholders.

12. Resolutions for the General Session

The Commission identified the Resolutions that would be presented to the Member Countries during the 87th General Session.

12.1. Resolutions related to disease status recognition

The Commission took note of the draft Resolutions on disease status recognition that would be presented at the forthcoming General Session in May 2019 and that, for the first time, the clarified situation regarding non-contiguous territories that are part of Members' already recognised official status would be included in the Resolutions proposed for adoption.

13. Any other issues

None at this meeting.

14. Programme and priorities

14.1. 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 20](#).

15. Adoption of the report

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

16. Date of next meeting

The next meeting of the Scientific Commission is scheduled for 9–13 September 2019.

17. Meeting review

In the context of the Commission Performance Management Framework, a meeting review was conducted.

.../Annexes

MEETING OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 18-22 February 2019

Provisional agenda

Opening

- 1. Induction Session and Specialist Commission Performance Management Framework**
- 2. Adoption of the agenda**
- 3. Terrestrial Animal Health Code**
 - 3.1. Member Country comments received for SCAD consideration**
 - a) Chapter 1.4. Animal health surveillance
 - b) Chapter 1.6. Procedures for self-declaration and for official recognition by the OIE
 - c) Chapter 4.Y. Official control of listed and emerging diseases
 - d) Chapter 8.14. Infection with rabies virus
 - e) Chapter 15.1. Infection with African swine fever virus
 - f) Chapter 15.2. Infection with classical swine fever virus
 - 3.2. Other considerations**
 - a) Chapter 8.16. Infection with rinderpest virus
 - b) Chapter 12.6. Equine influenza
- 4. Ad hoc and Working Groups**
 - 4.1. Meeting reports for endorsement**
 - a) *Ad hoc* Group on BSE surveillance: 3-5 October 2018
 - b) *Ad hoc* Group on the evaluation of AHS status: 18 October 2018 (electronic consultation)
 - c) *Ad hoc* Group on the evaluation of FMD status: 22-25 October 2018
 - d) *Ad hoc* Group on the evaluation of BSE risk status: 29-30 October 2018
 - e) *Ad hoc* Group on the evaluation of CBPP status: 13-14 November 2018
 - f) *Ad hoc* Group on BSE risk assessment: 20-22 November 2018
 - g) *Ad hoc* Group on the evaluation of PPR status: 27 November 2018 (electronic consultation)
 - h) *Ad hoc* Group on the evaluation of CSF status: 4-6 December 2018
 - i) *Ad hoc* Group on animal trypanosomoses of African origin: 15-17 January 2019
 - j) *Ad hoc* Group on antimicrobial resistance: 16-18 January 2019
 - k) *Ad hoc* Group on MERS CoV: 22-24 January 2019
 - l) Working Group on Wildlife: 4-7 December 2018
 - 4.2. Planned *ad hoc* Groups and confirmation of proposed agendas**
- 5. Official disease status**
 - 5.1. Annual reconfirmations for maintenance of official status**
 - a) Comprehensive review of annual reconfirmations (for pre-selected status and all OIE endorsed national official control programmes)
 - b) Report of the annual reconfirmation assessments by the Status Department
 - 5.2. Expert missions to Member Countries requested by the Commission**
 - a) Follow-up of past missions: action plans and progress reports
 - b) State of play and prioritisation

- 5.3. Specific update on official disease status
 - a) Update on situation of countries/zone with suspended or re-instated disease status
 - a. Myanmar (AHS), Colombia (FMD), United Kingdom – Scotland (BSE), South Africa (FMD)
- 5.4. Standards related to official status recognition
 - a) Proposed plan for the harmonisation of requirements for disease free status recognition and maintenance in disease-specific chapters (Chapter 1.6. + Chapter 14.7. Infection with PPR virus as a model)
 - 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. OIE Collaborating Centres
 - 7.1. OIE Collaborating Centre for Health of Marine Mammals
 - 7.2. Risk analysis and modelling Collaborating Centre application
8. Liaison with other Commissions and Departments
 - 8.1. Terrestrial Animal Health Standard Commission
 - a) Procedure for the evaluation of disease against the listing criteria of *Terrestrial Code* chapter 1.2.
 - b) Temporary protection zone. Chapter 4.3. on Zoning and compartmentalisation
 - 8.2. Biological Standards Commission
 - a) n.a.
9. Conferences, workshops, meetings, missions
 - 9.1. 3rd Regional Workshop on Swine Disease Control and African Swine Fever workshop, Cebu, Philippines, 2-5 October
 - 9.2. 7th meeting of the GF-TAD Standing Group of Experts for LSD, Ohrid, the Former Yugoslav Republic of Macedonia, 18-19 October
 - 9.3. OIE Second Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents: Putting Standards into practice, Marrakesh, Morocco, 29-31 October
 - 9.4. 11th meeting of the GF-TADs Standing Group of Experts on African swine fever in Europe. Warsaw, Poland, 24-25 September 2018
10. Disease control specific issues
 - 10.1. Evaluation of diseases against listing criteria
 - a) State of play of the development for an SOP guiding listing decision
 - b) Evaluation of pathogenic agent against listing criteria of *Terrestrial Code* Chapter 1.2.:
 - a. MERS CoV
 - b. Animal trypanosomes of African origin
 - c. Porcine Epidemic Diarrhoea
 - d. Chronic Wasting Disease
 - e. *Theileria lestoquardi*, *T. luwenshuni*, *T. uilenbergi* and *T. orientalis*

- 10.2. Update on the foot-and-mouth disease reference laboratory network and disease global situation
 - 10.3. Prion disease in dromedary camels in Algeria
 - 10.4. Zoonotic potential of hepatitis B in gibbons
 - 10.5. Heat treatment to inactivate CSF, ASF and FMD viruses in swill
 - 10.6. Risk of LSD vaccine-like strain transmission
 - 11. For the Commission information**
 - 11.1. Update on rinderpest activities
 - 11.2. Update on biological threat reduction activities
 - 11.3. Update on emergency management activities
 - 11.4. Project update: replacement International Standard Bovine Tuberculin
 - 11.5. Update on the SIRCAH STAR-IDAZ International Research Consortium
 - 11.6. Project “Capacity building and surveillance for Ebola Virus Disease (EVD)” (EBO-SURSY) between the European Union and the OIE
 - 11.7. Update on the ongoing revision of the bovine spongiform encephalopathy (BSE) standards
 - 12. Resolutions for the General Session**
 - 12.1. Resolutions related to disease status recognition
 - 13. Any other issues**
 - 14. Programme and priorities**
 - 14.1. Update and prioritisation of the work plan
 - 15. Adoption of the report**
 - 16. Date of next meeting**
 - 17. Meeting review**
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MEETING OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 18 – 22 February 2019

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Rationale for the amendments to:

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

Article 1.4.2. Definitions

The Commission disagreed with a Member proposal to add a definition for “surveillance system sensitivity” and amend the current definition of “confidence”. The Commission considered that the current definition of “confidence” already captured the concept of surveillance system sensitivity, and it was adequate for the purpose of the chapter.

Article 1.4.3. Surveillance systems

The Commission considered a Member proposal to introduce four types of case definitions (i.e. suspicious case, probable case, confirmed case, and rejected case). While acknowledging the need for such information in some disease control programmes, the Commission disagreed with the proposal, as the purpose of the chapter is to define a confirmed case. The Commission pointed out that, when needed, the definition of suspected case was included in specific-disease chapters (e.g. draft *Terrestrial Animal Health Code (Terrestrial Code)* Chapter 8.14. on rabies). The Commission also pointed out that the proposed definition of wildlife infection or infestation surveillance was appropriate.

The Commission agreed with some Members that indicated that the performance of a test is described by its sensitivity and specificity, and noted that predictive values would also depend on disease prevalence.

The Commission disagreed with a Member request to provide practical guidance for applying sophisticated mathematical or statistical analyses in surveillance, including collection of appropriate field data. The Commission pointed out that the quality of data is critical for ensuring consistent interpretation of the results of the models and of any other statistical analysis. The Commission pointed out that the OIE had already published guidelines on surveillance that cover the importance of quality of data and modelling (e.g. *Guide to Terrestrial Animal Health Surveillance*, 2014), and references on how to manage uncertainty (e.g. *Handbook on Import Risk Analysis for Animals and Animal Products*, Vol I and II). The Commission emphasised that point 2.b. of the same article (i.e. Data collection and management) described different factors affecting data quality.

The Commission agreed with a Member proposal to specify test sensitivity and specificity in target species but pointed out that, in case a test had not been validated in a particular species, Members should refer to *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* Chapter 1.1.6. or to appropriate available data.

Article 1.4.4. Surveillance methods

The Commission agreed that timeline is an important aspect to be considered for the design of a survey. However, it would have welcomed a proposal of text from Members to properly address the raised issue. The Commission decided not to add any further information at this point and invited Members to submit a text proposal to be considered in future revisions of the chapter.

The Commission agreed with the Member comments on the fact that in some cases sampling techniques are deliberately non-representative (e.g. risk-based) and this type of sampling can be more appropriate if the aim is to maximise disease detection. In this case, representativeness would not be necessarily required. The Commission noted that, in order to extrapolate results of non-representative sampling to the study population, risk factors need to be weighted and underpinned by scientific evidence. The Commission recommended to amend the text accordingly.

The Commission disagreed with some Members proposal to always consider cluster sampling as part of risk-based sampling, as it can also be used in non-risk-based sampling.

In response to several Members request for explanatory definitions regarding the different sampling methods, the Commission pointed out that these could be found in different epidemiological texts and did not consider it appropriate to add explanatory text.

In response to a Member comment, the Commission reiterated that risk-based methods could be used both in probability and non-probability-based sampling and that a definition of “risk” was already provided in the *Terrestrial Code* Glossary.

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

The Commission agreed with a proposal from the OIE Status Department to add information on measures to prevent the introduction of the infection or infestation, as was present in some disease-specific chapters.

The Commission considered a Member request for the scientific rationale to support the provision of Article 1.4.6.2.(b).i) and iii) especially for the period of “10 years of no vaccination” and “25 years of absence of infection and infestation”. The Commission reiterated its position that the timelines were adopted by the Members in the first version of the Chapter in 2005 and the Commission was not aware of any new scientific evidence supporting modification of the adopted timeframe. The Commission invited the Member to submit the scientific rationale to support the modification of the timelines.

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 concurred with a Member on the importance of taking into account the antigenic variants of the rabies virus to determine if it should be considered dog-mediated rabies. However, as the definition should be applicable globally, the Commission considered it not necessary to mention in the chapter specific variants, lineages, subtypes etc., that may only apply in certain regions. In addition, the Commission reiterated that, if the rabies virus is not independently circulating in dogs, it does not match the definition of dog-mediated rabies. Likewise, if the rabies virus strain evolves and is adapted to the dog population, even if the variant was originally associated with other species (e.g. bat-associated variants), then the new evolved strain should also be considered dog-mediated.

The Commission agreed to refer to dogs as *Canis lupus familiaris*, so as to distinguish them from the grey wolf.

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

The Commission agreed with some Members proposal to add one point concerning the Member's history of disease reporting. The Commission noted this proposal is in line with the current work on harmonisation for Chapter 1.6. The same modification was proposed throughout the chapter.

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

In response to a Member request for clarification, the Commission emphasised that cases of rabies in cattle transmitted by haematophagous bats or other antigenic variants that are not demonstrated to be maintained in dogs should not be considered dog-mediated rabies.

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

The Commission considered several comments from some Members concerning the proposed reduction of the minimum interval between vaccination and shipment of dogs. The Commission made references to its opinion provided at the September 2018 meeting when it was pointed out that the previously adopted chapter also required a minimum of 4 months before shipment (i.e. 3 months after the titration test, which implies testing at least 1 month after vaccination). The Commission suggested that the Members consider the wording proposed in September 2018.

The Commission took note of some experts' opinion on the feasibility of reducing the period between vaccination and shipment without increasing the risk of importing infected animals during the incubation period. The Commission invited rabies experts to submit a position paper to scientifically justify the reduction of the time between vaccination and shipping. Their opinion could be considered in future revisions of the chapter.

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

In response to a Member request to provide examples of what would be considered "significant problems" with the performance of the Veterinary Services, the Commission noted that the term was used in several other chapters for which an OIE endorsement of an official control programme exists. The Commission suggested referring to Section 3 (Chapter 3.1. and 3.2.) of the *Terrestrial Code* for more clarity. The Commission noted that, should the chapter be adopted, this article should be included in the ongoing harmonisation work of the disease-specific chapters relevant for official disease status recognition.

The Commission suggested deleting the reference to Article 1.Xbis, as a specific questionnaire had not yet been developed.

Rationale for the amendments to:

**CHAPTER 15.2. INFECTION WITH CLASSICAL SWINE FEVER (CSF) VIRUS
provided by the Scientific Commission**

Article 15.2.3. Country or zone free from CSF

The Commission agreed with several comments from some Members pointing out that information in points 1) to 5) of this same article is to be re-submitted annually, as these are all relevant considerations when deciding whether a country or zone should be retained on the list of CSF free countries or zones. The Commission also noted that this chapter will be affected by the harmonisation work and thus might be further modified for this purpose.

Article 15.2.6. Recovery of free status

The Commission agreed with a Member that a country could recover its CSF free status 3 months after the completion of the stamping-out policy, which includes cleaning and disinfection. When a stamping-out policy is enacted, the same principle should apply regardless of whether it is with or without implementation of emergency vaccination. The Commission recommended that the recovery articles of other chapters on diseases that are part of the OIE procedure for official recognition of disease status take this change into account.

Article 15.2.6bis. Direct transfer of pigs within a country from an infected zone to a free zone for slaughter

In response to a Member request to consider biocontainment conditions during the transportation of pigs, the Commission pointed out that requirements in this same article ensure that the transported animals are not infected with CSF virus (CSFV), and thus considered current provisions under points 4 and 6 of the article to already be sufficient. The Commission noted that adequate measures to handle pig meat so as to avoid cross-contamination are already present under point 5 and in the last paragraphs of the article. The Commission suggested adding a reference to Article 15.2.25. to the last paragraph so as to consider all pig products.

Article 15. 2.14bis. Recommendations for importation from countries or zones not free from CSF, where an official control programme exists

The Commission considered a Member request for clarification of whether or not “official control programme” refers to an OIE recognised official control programme. The Commission noted that the OIE does not endorse official control programmes for CSF, and that the term official control programme in the chapter is referring to the definition in the Glossary.

Article 15.2.15. Recommendations for the importation of fresh meat of wild and feral pigs

The Commission agreed with a Member that the fact that a wild or feral pig is killed in a free country or zone does not represent an adequate mitigation measure for the importation of its fresh meat. The chapter on CSF has provisions for granting free status for domestic and captive wild pigs, but not for wild and feral pigs, which is different from the chapter on ASF, which has provisions to recognise free status for wild and feral pigs. Therefore, point 1) (i.e. that were killed in a country or zone free from CSF in accordance with point 1) or point 2) of Article 15.2.3.) does not provide the necessary assurances for the trade of fresh meat of wild pigs. The Commission noted that, even with comprehensive testing of carcasses, a negative result does not provide the necessary assurances for safe trade of fresh meat of wild and feral pigs based on samples taken on carcasses. The Commission reiterated its proposal from September 2017 to delete this article.

Article 15.2.22. Procedures for the inactivation of CSFV in swill

In response to a Member comment, the Commission pointed out that swill and meat cannot be compared directly and that, for the treatment of meat, specific references are provided based on the scientific literature (Cowan *et al.*, 2015¹). Given the diversity of materials that could be present in swill, some of which could potentially protect the virus, the thermal inactivation requirements should be more stringent than for meat. The Commission noted that, while requirements for ASF and CSF are equivalent, there is no article on procedure for virus inactivation in the foot and mouth disease (FMD) chapter. Taking into consideration the risk that swill feeding could pose for this disease, the Commission suggested the inclusion of such an article in Chapter 8.8.

Article 15.2.23. Procedures for the inactivation of CSFV in meat

In response to a Member comment on the discrepancy between inactivation parameters for meat versus swill, the Commission referred to its reply under Article 15.2.22.

Article 15.2.24. Procedures for the inactivation of CSFV in casings of pigs

In response to a Member comment concerning the use of saturated brine or phosphate-supplemented dry salt for inactivating CSFV in casing, the Commission agreed the text needed clarification, and proposed to harmonise the wording by referring to the corresponding article under FMDV (Article 8.8.38.). The Commission suggested a similar modification be made to the ASF chapter based on the same rationale.

¹ COWAN L., HAINES F.J., EVERETT H.E., CRUDGINGTON B., JOHNS H.L., CLIFFORD D., DREW T.W. & CROOKE H.R. (2015). Factors affecting the infectivity of tissues from pigs with classical swine fever: Thermal inactivation rates and oral infectious dose. *Veterinary Microbiology*, **176**, 1–9.

**REPORT OF THE MEETING OF THE OIE AD HOC GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY SURVEILLANCE
Paris, 3 – 5 October 2018**

The OIE *ad hoc* Group on bovine spongiform encephalopathy (BSE) surveillance (hereafter the Group) met from 3 to 5 October 2018 at the OIE Headquarters to provide independent analysis and advice to the OIE on the surveillance provisions applicable for the initial recognition and maintenance of controlled and negligible BSE risk status.

1. Opening

Dr Matthew Stone, Deputy Director General of the OIE, welcomed the Group convened to revise the provisions of the *Terrestrial Animal Health Code (Terrestrial Code)* Chapter 11.4. pertaining to BSE surveillance.

Dr Stone emphasised that the revision of the BSE standards was considered a priority for the OIE and its Members as the current standards may not be appropriate to the current BSE risk. Indeed, as a result of the successful implementation of effective control measures to mitigate the risk of infection, recycling and amplification of the prion, the incidence and global importance of classical BSE have markedly decreased over the past years. Within-country epidemics are clearly in decline and there is a need to revise OIE's standards pertaining to BSE surveillance accordingly.

Dr Stone insisted that whilst BSE might be a sensitive and political issue, the Group's proposals should be scientifically driven and risk-based. He also encouraged the Group to capture the rationale supporting its proposals and recommendations in its meeting report for the consideration of Members.

Dr Stone noted that this Group articulates with another BSE *ad hoc* Group focusing on BSE risk assessment which met in July 2018 and will meet again in November 2018, and that some experts participate in the two Groups to ensure a consistent revision of the overall BSE framework.

Dr Neo Mapitse, Head of the Status Department, thanked the experts for having signed the forms for undertaking of confidentiality and declaration of conflicts of interest, and noted that no conflict of interest had been declared.

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

Dr Noel Murray was appointed Chair and Dr Mark Stevenson was the 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. Considerations of the current provisions for BSE surveillance

The Group discussed the current provisions for BSE surveillance defined in Articles 11.4.20. to 11.4.22. of the *Terrestrial Code*.

3.1. Current provisions

The design prevalence for achieving and maintaining an official BSE risk status is set at either 1 per 50,000 cattle for negligible BSE risk status or 1 per 100,000 cattle for controlled BSE risk status.

Four subpopulations of cattle are identified for surveillance purposes: routine (or healthy) slaughter, fallen stock, casualty slaughter and clinical suspects. Samples should be collected from at least three of them.

A surveillance point value is assigned to each sample based on the age of the animal and the subpopulation from which it was collected. Specific surveillance point values were defined based on the likelihood of detecting infected cattle in a particular subpopulation within a certain age class as estimated by a statistical model (BSurvE Prattley *et al.* 2007¹) that was developed with data from the European Union (EU) at the peak of the BSE epidemic.

A minimum number of points to be collected (i.e., the surveillance points target) is determined based on the size of the adult (>24 months old) cattle population. The required number of surveillance points should be achieved over a maximum of seven consecutive years to substantiate a claim that the prevalence of BSE is at 1 per 100,000 or 1 per 50,000 design prevalence, or below, in support of the official recognition and maintenance of a controlled or negligible BSE risk status.

3.2. Historical perspective of the current provisions

The current surveillance provisions for BSE were developed at a time of great uncertainty regarding the global distribution of BSE and its prevalence within a country's cattle population. Furthermore, although initial studies had indicated that control measures such as a ban on feeding ruminants with meat-and-bone meal or greaves should be effective, just how effective they might be in controlling or eliminating BSE was yet to be demonstrated.

The Group acknowledged that BSE surveillance to date has generated a wealth of valuable information, particularly from the EU and Japan where much more extensive surveillance programs have been implemented than those recommended in Articles 11.4.20. to 11.4.22. of the *Terrestrial Code*. Essentially, all animals from each of the respective subpopulations above a certain age threshold including routine (or healthy) slaughter have been tested for BSE. Modifications have been made over the years, progressively increasing the minimum age of testing as the epidemic has declined. These programs have convincingly demonstrated the effectiveness of the various control measures as evidenced by a rapid and sustained decline in the incidence of classical BSE. Time series analysis carried out over the last 10-year period (2008–2017) showed a significant decreasing trend in the occurrence of classical BSE in the EU with an annual decrease of 38% in the proportion of cases per tested animals². In a recently published study³, a similar rate of decline was reported for the cases born after the “total⁴” feed ban (BARB) across EU. The consistent implementation of surveillance during a 17-year period (2001–2017) has allowed the year-by-year comparison and overall trend analysis of the incidence of BSE in the EU, showing a constant decline on the number of clinical cases of classical BSE, as illustrated in Figure 1.

¹ Prattley D, Cannon R, Wilesmith J, Morris R, Stevenson M. (2007). A model (BSurvE) for estimating the prevalence of bovine spongiform encephalopathy in a national herd. *Preventive Veterinary Medicine* 80:330-343. Doi: 10.1016/j.prevetmed.2007.03.007

² European Food Safety Authority (2017). Scientific report on the European Union summary report on surveillance for the presence of transmissible spongiform encephalopathies (TSE) in 2016. *EFSA Journal* 15(11):5069, 68 pp.

³ Arnold ME, Simons RR, Hope J, Gibbens N, Adkin AL. (2017) Is there a decline in bovine spongiform encephalopathy cases born after reinforced feed bans? A modelling study in EU member states. *Epidemiology & Infection* 145(11):2280-2286.

⁴ Under the total feed ban the feeding of all processed animal proteins (PAPs) was banned from feeding to all farmed animals.

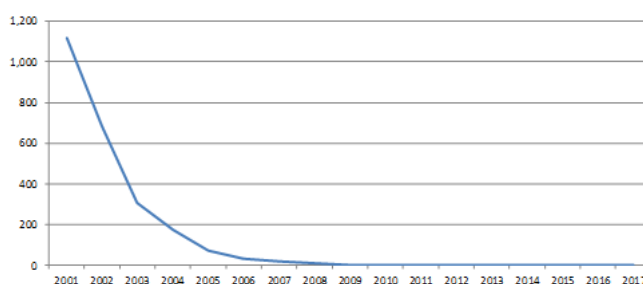


Figure 1: Number of clinical cases of classical BSE confirmed in the EU in the period 2011-2017⁵

When Canada reported its first case of classical BSE in 2003, the first report of an indigenous case of classical BSE had not occurred in any country worldwide in over 15 years. In the intervening years, although several Members have reported cases for the first time, they were all atypical BSE cases. Worldwide, 2017 was the first year in which no indigenous cases of classical BSE were reported. As stated in Article 11.4.1. of the *Terrestrial Code*, atypical BSE is a condition believed to occur spontaneously in all cattle populations at a very low rate and is excluded for the purposes of official recognition of a country's BSE status. Its detection in Members previously unaffected by classical BSE provides a surrogate indicator that they have been sampling at a sufficient intensity to detect classical BSE if it was actually present.

3.3. Lessons learned and implications for the future

The Group identified and discussed a number of issues that have arisen over the years that point to a need to review current BSE surveillance provisions, in particular:

- Surveillance has emerged as a significant roadblock for some low and middle-income Members in attaining an official BSE-risk status. As outlined in Section 3.1. of this report, for an official BSE risk status to be recognised by the OIE, a country must not only demonstrate through a risk assessment that appropriate measures have been taken to manage identified risks, but they must also demonstrate that they have met the relevant surveillance points target. For example, some Members may have been able to demonstrate that appropriate BSE control measures have been taken, but have failed to qualify for an official BSE risk status since they have not met their points target. This reflects a potential misalignment between the outcome from a risk assessment and the final categorisation of the BSE risk status of a country or *zone*. In such circumstances, BSE surveillance provisions arguably pose an artificial obstacle. Attempts to meet the surveillance points target can result in a disproportionate allocation of scarce resources as well as significant delays in achieving a particular status.
- The clinical suspect surveillance subpopulation is assigned a much higher point value than the other surveillance subpopulations. In an attempt to maximise the number of accumulated surveillance points, some Members have claimed more animals as clinical suspects than would appear to be reasonably justified. For example, cattle may be claimed as clinical suspects based solely on an ante-mortem inspection at slaughter without supporting evidence that the animals were affected by an illness that was refractory to treatment and displaying progressive behavioural changes or neurological signs.
- While the current provisions require that cattle be sampled from three of the identified four subpopulations, based on the reports on the annual reconfirmation assessments for maintenance of official status, not all Members have been doing so⁶. Historically, stratification into four subpopulations was based on European experiences, with point values based on age and subpopulation as elaborated

⁵ European Commission TSE surveillance database. The 2001-2015 annual reports are available at https://ec.europa.eu/food/safety/biosafety/food_borne_diseases/tse_bse/annual-reports_en. The 2016 annual report is available at <https://efsa.onlinelibrary.wiley.com/journal/18314732>

⁶ Annex 17 of the Report of the Scientific Commission for Animal Diseases in February 2017, and Annex 18 of the Report of the Scientific Commission for Animal Diseases in February 2018.

in BSurvE. While such an approach might be suitable for those Members where cattle are intensively reared and subjected to regular observation, in more extensive systems where cattle are not monitored closely, it may be difficult to stratify cattle into these streams. Situations would inevitably arise where an animal might be considered to be a clinical suspect, yet if it was not observed for a period of time it may well be seen for the first time as a downer (non-ambulatory) or found dead (fallen stock). Under such circumstances assigning an animal to a particular surveillance subpopulation is highly dependent on when it was first observed in the continuum of a progression from clinical suspect to downer to fallen stock.

- It is apparent that Members with small cattle populations continue to struggle to reach their surveillance points target. It is also evident from the reports on the annual reconfirmation assessments for maintenance of official status⁶ that some Members are having difficulty in maintaining their points target. These Members have been cautioned of the shortfall in surveillance points and requested to rectify the situation in future years.
- An implicit assumption embedded in the current surveillance provisions is that the exposure risk in a cattle population of a country is essentially homogenous across and within cohorts. As a result, the relative value of an animal in terms of detecting BSE is simply weighted by its age and corresponding surveillance subpopulation. Depending on the particular local circumstances, some sectors of the cattle population may not have been exposed, such as those reared under extensive pastoral conditions, but they still remain as candidates for surveillance. Ideally, based on the results from an exposure assessment and assuming that contaminated feed is the only or the most likely source of the classical BSE agent, those sectors of the cattle population that have not been potentially exposed to feed potentially contaminated with ruminant meat-and-bone meal (MBM) should not be targeted for surveillance. Including cattle from unexposed sectors is not only inefficient, but inferences regarding the “standing” cattle population may also result to be uninformative.
- The surveillance point values in the current provisions are derived from BSurvE, which draws on estimates of the incubation period of BSE from the United Kingdom (UK) as well as data on the respective subpopulations from the EU in the early to mid-2000s. Concerns have been expressed that they may no longer reflect the likelihood of detecting infected cattle today, particularly in those Members on the tail end of an epidemic where the age of the few remaining BSE cases is progressively increasing and fewer animals are identified as clinical suspects. In addition, it is unlikely that they have ever been broadly applicable for many non-European countries, especially those with significantly different production systems.
- The implementation of the current surveillance provisions with a focus on achieving and maintaining a surveillance points target can be extremely costly. For example, in the EU, the average cost of detecting one BSE case between 2001 and 2004 was estimated to be 1.56 million Euros for the routine slaughter surveillance subpopulation and 0.07 million Euros for the risk animal surveillance subpopulations (fallen stock, casualty slaughter, and at *ante mortem* inspection)⁷. In the EU in 2008, the cost of detecting a single BSE case was 14.1 million Euros for cattle processed at abattoirs⁸ and in 2014 the cost of detecting a single case of BSE for the fallen stock surveillance subpopulation was 13 million Euros⁹. This has posed, and continues to pose, a significant barrier for Members where resources are limited and other more urgent animal health priorities predominate. Surveillance is, after all, just one of many pieces of evidence that should be taken into account in evaluating a BSE risk status. An important objective in defining surveillance requirements is to ensure that they are both achievable and implemented to the extent that is reasonably necessary without imposing an undue burden on Members.

⁷ The TSE roadmap. Brussels, 15 July 2005 COM(2005) 322 FINAL

⁸ The TSE roadmap 2. Brussels, 16 July 2010 COM(2010) 384 FINAL
https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_food-borne-disease_tse_road-map2.pdf

⁹ Using the estimated cost per sample of fallen stock in 2014 for the UK by Wall BA, Arnold ME, Radia D, Gilbert W, Ortiz-Pelaez A, Stärk KD, Van Klink E, Guitian J. (2017) Evidence for more cost-effective surveillance options for bovine spongiform encephalopathy (BSE) and scrapie in Great Britain. *Eurosurveillance* 22(32):30594

Overall, the Group concluded that the goals of BSE surveillance needed to be redefined. A great deal of experience has been gained with BSE over the last several decades, which means that the uncertainties that historically existed no longer prevail. It is now evident that the various risk mitigation measures, including feed bans, have been effective. The Group emphasised that while the current surveillance provisions have served their purpose adequately, they also have significant drawbacks. As alluded to in the preceding paragraphs, a point-based surveillance system has led to a number of unintended consequences. It can be expensive to implement and maintain, and has led to significant and perhaps insurmountable delays in some Members achieving controlled or negligible BSE-risk status. These Members are likely to be discriminated against in the international trade environment; especially those that could reasonably claim on the basis of a risk assessment, that the BSE risks are being effectively mitigated. Some Members have manipulated the points system to their advantage by claiming more clinical suspects than would appear to be justified. For others with small cattle populations, meeting their points target is an ongoing struggle.

4. Proposed changes for BSE surveillance

The Group discussed at length the role that BSE surveillance plays in support of initial recognition and maintenance of an official BSE risk status, together with the surveillance strategy that would be the most appropriate for the later phase of BSE epidemics in Members.

4.1. Defining a surveillance strategy for the future

The Group noted that, according to Article 11.4.1. of the *Terrestrial Code*, “For the purposes of official BSE risk status recognition, BSE excludes ‘atypical BSE’ as a condition believed to occur spontaneously in all cattle populations at a very low rate”. The Group therefore emphasised that BSE surveillance in support of the initial recognition and maintenance of an official BSE risk status should focus on classical BSE in cattle.

As outlined in Article 11.4.20. of the *Terrestrial Code*, under the current surveillance provisions there are one or more goals depending on the risk category of a country or *zone*: to detect BSE at a pre-determined design prevalence, to monitor the evolution of BSE including the effectiveness of mitigation measures such as a feed ban, and to provide sufficient information to provide support for a claimed BSE status. As discussed in Section 3.2. of this report, surveillance programs implemented over many years in those Members with classical BSE have provided critical insights into the evolution of BSE and have convincingly demonstrated the effectiveness of mitigation measures, particularly those associated with a feed ban. As a result, the Group concluded that since the relevant control measures for BSE are well-established and that sufficient evidence has been accumulated, the goals associated with monitoring the evolution of BSE and demonstrating the effectiveness of mitigation measures through surveillance have been met. Given that BSE is a rare disease, monitoring the effectiveness of measures through testing of individual animals for the presence of infection can be extremely expensive. To satisfy statistical requirements, very large sample sizes are required. For example, it was estimated that, in the absence of testing of routine slaughter, Cyprus would need to test 98.7% of their total standing cattle population to detect at least 1 case per 100,000 animals with a 95% confidence level; that would require that almost all the cattle population of Cyprus would have to die on farm and be tested in a single year to meet the requirements¹⁰. As a result, ongoing efforts would be more appropriately channelled into maintaining and monitoring the rigorous and continuous implementation of the various mitigation measures in the field. Furthermore, monitoring their implementation indirectly through surveillance is not a strategy that can be recommended given the long lag times involved as a result of the protracted incubation period for BSE. This approach does not allow for the rapid implementation of corrective actions.

The key goal of the current surveillance provisions has been to detect BSE, if it were present in a country at predetermined design prevalence of either 1 in 100,000 cattle (Type A Surveillance) or 1 in 50,000 cattle (Type B Surveillance). A points target is laid out in Article 11.4.22. of the *Terrestrial Code* (Table 1) based on the design prevalence and the size of the adult cattle population. If a Member meets its points target,

¹⁰ Source: European Food Safety Authority (2016). Evaluation of the revision of the BSE monitoring regime in Croatia. EFSA Journal 14(2):4399; 27 pp.

then it can be concluded that it is sampling at a sufficient intensity to detect BSE if it were present at the nominated design prevalence. This would in turn provide confirmation of the conclusions arising from the risk assessment by demonstrating the effectiveness of the risk mitigation measures. However, as discussed above, as a result of the prolonged incubation period for BSE, there is a considerable lag time involved. Furthermore, as discussed in Section 3.2. there are a number of challenges in implementing and maintaining these types of surveillance programs: they can be very expensive; it is difficult to justify the diversion of scarce resources to implement them in low and middle-income Members; the points system is subject to manipulation; and for a number of Members, particularly those with small cattle populations, it is an ongoing struggle to meet the points target.

Recognising these challenges, the Group considered two different options:

- Reduce the number of subpopulations from four to two: routine slaughter and a broad risk class by combining clinical suspects, casualty slaughter and fallen stock. This approach would address those issues identified in Section 3.2. associated with over-stratification and manipulation of the points system. Since the point value derived from BSurvE is simply a ratio of the probability that an infected animal would leave the population via subpopulation j at age t and test positive compared to the probability that an uninfected animal would leave via the same subpopulation at the same age, the various subpopulations can be readily combined. The Group considered the point values estimated by an expert of the Group based on an update of BSurvE taking into account these two subpopulations and data from the EU.
- Target only the risk groups, including clinical suspects, casualty slaughter and fallen stock. Indeed, the Group took note, based on data from the EU, that the likelihood of detection of BSE cases at routine slaughter is extremely low compared with other subpopulations. In 2004, 11 million cattle were tested in the EU and 864 cases of BSE were confirmed. The surveillance stream that had the largest probability of detecting cases was the clinical suspects (5.6% of all tested clinical suspects resulted positive), followed by the 'risk group' composed of fallen stock, casualty slaughter and with observations at *ante-mortem* inspection (with 0.03%). However, only 0.002% of the animals tested at routine slaughter resulted positive¹¹. However, the Group pointed out that the prevalence of clinical cases is likely to be much lower nowadays than in 2004, and therefore considered that this approach would place too much emphasis on clinical suspects in the current epidemiological context. Furthermore, as emphasised in Section 3.3. of this report, experience has shown that higher points value for clinical suspects can result in manipulations of the points system by Members.

In addition to targeting certain subpopulations, further targeting of animals within those subpopulations could be considered by focussing on those sectors of the cattle population that are more likely to be exposed to feed potentially contaminated with ruminant MBM or greaves based on the outcome from a risk assessment that takes into account cattle husbandry, production, feeding and slaughter practices. For example, mature dairy or beef cattle reared as replacement heifer calves that were fed with commercially prepared milk replacer or starter rations, could be targeted for surveillance, whereas cattle reared exclusively on pasture would not. Under this scenario a risk-based surveillance strategy would be designed on a country-by-country basis in light of a thorough description of the cattle production system(s) present in each country and of the outcome of a risk assessment. Each Member would need to define a risk-based surveillance strategy fit for their purposes. This would address those concerns identified in Section 3.2. associated with testing animals, such as those raised in extensive pastoral systems that have never been exposed to potentially contaminated feed and would not yield any useful information.

Following extensive discussions of these options, including an analysis of the likely number of animals to test, the Group determined that these options would not resolve the underlying challenges associated with setting and meeting an overall points target that was both realistically achievable and did not have significant resource implications. The Group recognised that the points-based system has served its purpose reasonably well up to now, although there have been some difficulties and unintended consequences.

¹¹ https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_food-borne-disease_tse_ms-annual-report_2004.pdf

The Group was briefed on the outcomes of the first meeting of the *ad hoc* Group on BSE Risk Assessment from 3-5 July 2018, in particular about the categorisation of negligible BSE-risk status. Under the provisions proposed by this *ad hoc* Group, the BSE-risk status of a country would be determined from a detailed consideration of comprehensively documented risk assessment (entry assessment, exposure assessment, consequence assessment, and risk estimation). Two pathways were proposed for a country to demonstrate that the likelihood of the cattle population being exposed to the BSE-agent has been and continues to be negligible for at least 8 years: either, as a result of the husbandry and farming practices (e.g., extensive pastoral systems); or, based on the continuous and effective implementation of mitigation measures to prevent the recycling of the BSE-agent in the cattle population. Under these provisions, since the likelihood of the occurrence of classical BSE would have been determined to be negligible, the Group considered that a points-based surveillance system could no longer be justified as the level of investment required cannot be considered to be cost effective. It would also be disproportionate to the risk.

This position was further supported by a recent publication that estimated the time it would take for a surveillance program to detect a theoretical re-emergence of BSE in a cattle population. If both active and passive surveillance were implemented, it would take 15 years, whereas a system relying solely on passive surveillance would only be delayed by two more years¹². Considering the likely investment required to implement an active surveillance program, it is apparent that the costs would by far exceed those of a passive program, for very little additional gain in the likely time to detect disease re-emergence.

The Group concurred that surveillance should always have played a secondary role in evaluating the BSE-risk status of a country. The primary focus should be on a transparently documented and comprehensive risk assessment that includes a detailed evaluation of husbandry and farming practices as well as the continuous and effective implementation of relevant mitigation measures with the ongoing results of a surveillance program taken into account.

Overall, the Group concluded that a baseline level of surveillance should continue with the focus being on cattle identified with a clinical syndrome consistent with BSE (refractory to treatment, displaying progressive behavioural changes or neurological signs). This would include animals on a continuum of a progression from clinical suspect to downer to fallen stock with an appropriate supporting history. Such animals should be subject to compulsory notification supported by an awareness program and examination of brain samples in a laboratory as outlined in Articles 11.4.2. and 11.4.3. Such a surveillance strategy, referred to as passive surveillance, would have the goal of detecting a potential emergence or re-emergence of classical BSE in the cattle population.

5. Proposals for revised provisions for BSE surveillance

The Group revised the provisions for the initial recognition and maintenance of negligible (Article 11.4.3.) and controlled (Article 11.4.4.) BSE-risk status, as well as the detailed provisions for BSE surveillance (Articles 11.4.20. to 11.4.22.), in light of the surveillance strategy defined in Section 4 of this report.

5.1. Surveillance in support of the initial recognition and maintenance of BSE negligible risk status (Article 11.4.3. of the *Terrestrial Code*)

The Group determined that an ongoing robust passive surveillance program for BSE should be in place. Consistent with the recommendation of the *ad hoc* Group on BSE risk assessment, the Group recommended that should an indigenous case of classical BSE be detected, a follow up field epidemiological investigation should be undertaken to identify potential sources of exposure.

Consistent with the current provisions for BSE surveillance, the Group recommended that BSE surveillance should have been in place and documented for at least 7 years to achieve a negligible BSE risk status.

For the maintenance of negligible BSE-risk status, documentary evidence on the implementation of the passive surveillance program and its results should be provided each year.

¹² Simons R., Arnold M., Adkin A. (2017) Assessing the time taken for a surveillance system to detect a re-emergence of bovine spongiform encephalopathy in cattle. *Preventive Veterinary Medicine*, 13:48–54.

Article 11.4.3. (Negligible BSE risk) was revised to reflect these provisions.

The Group noted that revisions to the “BSE Questionnaire” (Chapter 1.8. of *Terrestrial Code*) and to the annual reconfirmation form for BSE would be needed to reflect the proposed changes in BSE surveillance in support, respectively, of the initial recognition and maintenance of an official negligible BSE risk status, and suggested this be addressed by the *ad hoc* Group on BSE risk assessment at its next meeting.

5.2. Surveillance in support of the initial recognition and maintenance of BSE controlled risk status (Article 11.4.4. of the *Terrestrial Code*)

The Group noted, that under the provisions proposed by the *ad hoc* Group on BSE risk assessment, countries and *zones* which can demonstrate compliance with the requirements for negligible BSE-risk status, but not yet for the relevant period of time, would qualify for recognition as having a controlled BSE risk. As such, controlled BSE-risk status would represent an intermediate step for Members as they work towards achieving negligible BSE-risk status. The Group fully supported this approach and therefore concurred that the nature of the surveillance provisions in support of the initial recognition and maintenance of a controlled BSE risk status should be similar to those in support of the initial recognition and maintenance of a negligible BSE risk status.

Article 11.4.4. (Controlled BSE risk) was revised to reflect these provisions.

The Group noted that revisions of the “BSE Questionnaire” (Chapter 1.8. of *Terrestrial Code*) and of the annual reconfirmation form for BSE would be needed to reflect the proposed changes in BSE surveillance in support, respectively, of the initial recognition and maintenance of an official controlled BSE risk status, and suggested this be addressed by the *ad hoc* Group on BSE risk assessment at its next meeting.

5.3. Detailed provisions for BSE surveillance (Articles 11.4.20. to 11.4.22. of the *Terrestrial Code*)

The Group revised Articles 11.4.20. to 11.4.22. of the *Terrestrial Code* pertaining to BSE surveillance.

For the sake of clarity, the Group recommended removing general considerations on surveillance not specific to BSE as well as avoiding redundancies between the different Articles pertaining to BSE surveillance. Therefore, the Group recommended defining the provisions for passive BSE surveillance in revised Article 11.4.20., and removing Article 11.4.21. and Article 11.4.22.

The Group recommended that passive surveillance for BSE should rely on the compulsory notification of any susceptible animal showing clinical signs suggestive of BSE in the whole territory, as well as the appropriate laboratory examination of any suspect case in accordance with the recommendations defined in Chapter 2.4.5. of the *Terrestrial Manual*. Furthermore, the Group stressed that a continuous awareness programme for BSE should be maintained to encourage reporting of all cases suggestive of BSE and to ensure the sensitivity of passive surveillance.

Regarding BSE clinical suspects, in light of the description of clinical signs usually associated with classical BSE cases as reported by the Animal & Plant Health Agency and others¹³, the Group updated the list of behavioural or clinical changes which should give raise to clinical suspicions of classical BSE. Clinical suspects would be animals identified with a clinical syndrome consistent with BSE (i.e., displaying progressive behavioural changes or neurological signs that are refractory to treatment). This would include animals on a continuum of a progression from clinical suspect to downer (or non-ambulatory) to fallen stock with an appropriate supporting clinical history. Clinical signs may include “*progressive behavioural changes that are refractory to treatment such as increased excitability, depression, nervousness, excessive and asymmetrical ear and eye movements, apparent increased salivation, increased licking of the muzzle, teeth grinding, hypersensitivity to touch or/and sound (hyperaesthesia), tremors, excessive vocalization,*

¹³ [1] Animal Health and Plant Agency (APHA). Clinical signs of bovine spongiform encephalopathy in cattle. February 2017. <https://science.vla.gov.uk/tse-lab-net/documents/clinical-signs-bse--cattle-video.pdf>, [2] Konold G, Bone S, Ryder S, Hawkins AC, Courtin F, Berthelin-Baker C. (2004) Clinical findings in 78 suspected cases of bovine spongiform encephalopathy in Great Britain T. *Veterinary Record*. 155: 659-666, [3] Saegerman C, Speybroeck N, Roels S, Vanopdenbosch E, Thiry E, Berkvens D. (2004) Decision support tools for clinical diagnosis of disease in cows with suspected bovine spongiform encephalopathy. *Journal of Clinical Microbiology*. 42(1):172–178, [4] Winter MH, Aldridge BM, Scott PR, Clarke M. (1989) Occurrence of 14 cases of bovine spongiform encephalopathy in a closed dairy herd. *British Veterinary Journal*. 145(2):191-194.

panic-stricken response, and excessive alertness; postural and locomotory changes such as abnormal posture (dog sitting), abnormal gait (particularly pelvic limb ataxia), low carriage of the head (head shyness), difficulty avoiding obstacles; inability to stand and recumbency; generalised non-specific signs such as reduced milk yield, loss of body condition, weight loss, bradycardia and other disturbances of the cardiac rhythm". The Group noted that cases may display only some of these signs, which may also vary in severity, and that such animals should still be investigated as BSE clinical suspects.

Furthermore, the Group suggested that cattle of any age displaying behavioural or clinical signs consistent with BSE should be regarded as clinical suspects. At the current time, BSE clinical suspects, as defined in Article 11.4.21. point 1, are restricted to those aged over 30 months. However, there are instances of field BSE cases being detected below this age limit. Based on the UK data (as of September 2018), 52 cases out of a total of 181,135 cases were aged below 31 months, with the youngest aged just 20 months. As a precautionary measure and with increased reliance on passive surveillance, the Group recommended there should be a broader index of suspicion of disease with the removal of any age limit.

The Group emphasised that since BSE causes no pathognomonic clinical signs, all Members with cattle populations will observe individual animals displaying clinical signs consistent with BSE. All clinical suspects reported should be documented when applying for the initial recognition of an official BSE risk status as well as in support of the maintenance of an official BSE risk status in order to demonstrate that a sensitive passive surveillance for BSE has been implemented.

6. Further considerations

The Group suggested that the Group on BSE risk assessment should complement draft Article 1.4.3. point 4 to define the impact of the occurrence of indigenous case(s) of BSE on negligible BSE risk status, and drafted a proposal for the consideration of this Group.

The Group advised that the Group on BSE risk assessment should reassess the time periods defined in Article 1.4.3. (i.e., eight years for the risk assessment and for the control of feed, and seven years for mitigation measures including surveillance) and align them, if deemed appropriate.

The Group recommended that consistency should be ensured between the list of behavioural or clinical signs related to BSE defined in the revised Article 11.4.20. of the *Terrestrial Code* and those listed in Chapter 2.4.5. of the *Terrestrial Manual*.

The Group noted that due to the nature of BSE, OIE standards are likely to require reassessment in the future in light of new scientific evidence and the evolution of the global situation of BSE.

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.

7. Finalisation and adoption of the draft report

The Group reviewed and amended the draft report. The Group agreed that the report reflected the discussions.

.../Appendices

Appendix I

**MEETING OF THE OIE AD HOC GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY SURVEILLANCE
Paris, 3 – 5 October 2018**

Terms of Reference

Purpose

The purpose of this *ad hoc* Group is to provide independent analysis and advice to OIE on the surveillance provisions applicable for the initial recognition and maintenance of controlled or negligible BSE risk status.

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.

In light of the recommendation of the BSE risk assessment *ad hoc* Group, the responsibilities of this *ad hoc* Group will be to review scientific evidence, provide guidance and draft recommendations on the provisions for BSE surveillance (Chapter 11.4., Chapter 1.8., and provisions for annual reconfirmation), in particular:

1. Define the purpose, the need for, and the type(s) of surveillance for initial recognition and maintenance of status, taking into account the outcome of the risk assessment;
2. Give special attention to the cost-effectiveness of the surveillance provisions as well as to their global applicability (i.e., including to countries with small cattle populations and countries with limited resources);
3. Review literature which could inform the revision of the surveillance requirements as well as refinements to the existing model for BSE surveillance or the development of a new model; and
4. The revision of the BSE Questionnaire (Chapter 1.8. of the *Terrestrial Code*) to ensure consistency with the proposed revisions to Chapter 11.4. of the *Terrestrial Code*.

The potential impact of updated surveillance requirements on the status of countries or *zones* already having an officially recognised BSE risk status will be carefully considered.

Appendix II

**MEETING OF THE OIE AD HOC GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY SURVEILLANCE
Paris, 3 – 5 October 2018**

Agenda

1. Opening.
2. Adoption of the agenda and appointment of chairperson and rapporteur.
3. Review of the Terms of Reference (ToR) and definition of the work plan:
 - Considerations on the current provisions for BSE surveillance
 - Proposed change of paradigm for BSE surveillance
 - Proposals for revised provisions for BSE surveillance
 - Further considerations
4. Adoption of the report.

Appendix III

**MEETING OF THE OIE AD HOC GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY SURVEILLANCE
Paris, 3 – 5 October 2018**

List of participants

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**ELECTRONIC CONSULTATION OF THE OIE *AD HOC* GROUP ON THE EVALUATION
OF AFRICAN HORSE SICKNESS STATUS OF MEMBERS**

18 October 2018

The OIE *ad hoc* Group on the evaluation of the African horse sickness (AHS) status of Members (hereafter the Group) was consulted electronically on 18 October 2018.

1. Adoption of the agenda and appointment of chairperson and rapporteur

Dr Neo Mapitse, Head of Status Department, thanked the Group for its commitment and its extensive support towards the OIE in fulfilling the mandates given by Members.

Dr Morgane Dominguez, Status Department, thanked the experts for having signed the forms for undertaking of confidentiality and declaration of conflicts of interest. The declared interests were reviewed by the OIE and the Group and it was agreed that none represented a potential conflict in the evaluation of AHS status of Members.

The Group was chaired by Dr Beverley Parker and Dr James MacLachlan was the rapporteur with the support of the OIE Secretariat. The Group adopted the proposed agenda.

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

2. Evaluation of the maintenance of the official recognition of AHS free status

At the request of the Scientific Commission for Animal Diseases, the Group assessed one dossier from a Member for the maintenance of the official recognition of its AHS free country status. The Group concluded that this Member did not meet the requirements of the *Terrestrial Code*, and recommended this AHS free country status be suspended.

3. Adoption of the report

The Group reviewed and amended the draft report provided by the rapporteur and agreed to circulate the draft report electronically for comments before the final adoption. The Group agreed that the report captured the discussions.

Appendix I**ELECTRONIC CONSULTATION OF THE OIE *AD HOC* GROUP ON THE EVALUATION
OF AFRICAN HORSE SICKNESS STATUS OF MEMBERS****18 October 2018**

Terms of reference

The OIE *ad hoc* group on African horse sickness (AHS) status of Members (the Group) is expected to evaluate a dossier for the maintenance of a Member's official AHS free status.

This implies that the members of this Group are expected to:

1. Sign off the updated OIE Undertaking on Confidentiality of information
 2. Complete the Declaration of Interests Form and forward it to the OIE at their earliest convenience, and at least two weeks before the teleconference
 3. Evaluate the application for maintenance of an officially free AHS status
 - a. Prior to the teleconference
 - read and study in detail the dossier provided by the OIE;
 - take into account any other information available in the public domain that is considered pertinent for the evaluation;
 - summarise the dossier according to the *Terrestrial Animal Health Code* requirements, using the form provided by the OIE;
 - draft the questions whenever the analysis of the dossier raises questions which need to be clarified or completed with additional details by the Member;
 - send the completed form and the possible questions to the OIE, at least 10 days before the teleconference.
 - b. During the teleconference
 - contribute to the discussion with their expertise;
 - withdraw from the discussions and decision making when possible conflict of interest;
 - provide a detailed report in order to recommend, to the Scientific Commission for Animal Diseases, the maintenance or suspension of the AHS free status considered, and to indicate any information gaps or specific areas that should be addressed in the future by the Member.
 - c. After the teleconference
 - contribute electronically to the finalisation of the report
-

Appendix II

**ELECTRONIC CONSULTATION OF THE OIE *AD HOC* GROUP ON THE EVALUATION
OF AFRICAN HORSE SICKNESS STATUS OF MEMBERS**

18 October 2018

Agenda

1. Adoption of the agenda and appointment of chairperson and rapporteur
2. Evaluation of the maintenance of the official recognition of AHS free status
3. Adoption of report

Appendix III

ELECTRONIC CONSULTATION OF THE OIE AD HOC GROUP ON THE EVALUATION OF AFRICAN HORSE SICKNESS STATUS OF MEMBERS

18 October 2018

List of participants

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

Paris, 22 – 25 October 2018

A meeting of the OIE *ad hoc* Group on the Evaluation of Foot and Mouth Disease (FMD) Status of Members (hereafter the Group) was held at the OIE Headquarters from 22 to 25 October 2018.

1. Opening

Dr Matthew Stone, Deputy Director General for International Standards and Science 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. He acknowledged the amount of work before, during and after the ad hoc Group meetings and particularly for this Group on FMD as well as the efforts required in reviewing the applications.

Dr Stone informed the Group on the progress of activities related to the three main pillars of the sixth strategic plan and also explained the state of play in the preparation of the seventh strategic plan of the OIE for the periods 2021-2025.

Dr Min-Kyung Park, Deputy Head of the Status Department, thanked the experts for having signed the forms for undertaking of confidentiality and declaration on potential conflict of interests related to the mandate of the Group. The declared interests were reviewed by the OIE and the Group and it was agreed that none represented a potential conflict in the evaluation of FMD status of Members.

Dr Park introduced Dr Wael Sakhraoui, who joined the Status Department to work on the activities related to official disease status recognition.

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

The Group was chaired by Dr Manuel Sanchez and Dr David Paton acted as rapporteur, with the support of the OIE Secretariat. The Group endorsed the proposed agenda.

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

3. Evaluation of requests from Members for the status recognition of FMD free zones where vaccination is not practised

a) Bolivia

Bolivia has two FMD free zones (with and without vaccination) covering the whole territory of the country. In August 2018, Bolivia submitted a dossier for recognition of the department of Pando (which is currently recognised as a FMD free zone where vaccination is practised) as a FMD free zone where vaccination is not practised.

i) Animal disease reporting

The Group considered that Bolivia had a record of regular and prompt animal disease reporting.

ii) *Veterinary Services*

The Group acknowledged that the Veterinary Authority had current knowledge of, and authority over, all FMD susceptible animals in the proposed zone and in the country.

The Group was informed that Bolivia had received a Performance of Veterinary Service (PVS) evaluation and PVS Gap analysis mission respectively in 2008 and 2011. Based on the aforementioned PVS reports, Bolivia had set out its 2011-2015 strategic plan, which guided the progressive stages of eradication of FMD in the country as mentioned in the dossier.

The Group noted that Bolivia also had a PVS follow-up mission in 2014, as well as two PVS missions, with respect to veterinary legislation to strengthen the Veterinary Service.

Bolivia reported in its dossier the number of permanent and temporary staff at the departmental veterinary services and control posts of the proposed zone. The Group noted that a large proportion of the staff had temporary contracts, and suggested that Bolivia make sure to secure sufficient personnel for the continuous maintenance of the measures and integrity of the proposed free zone status.

iii) *Situation of FMD in the past 12 months*

The Group noted that the last outbreak of FMD in the proposed zone was in March 2000 and for the entire country was in March 2007.

iv) *Absence of vaccination and entry of vaccinated animals in the past 12 months*

The Group noted that the last vaccination in the proposed zone was carried out in June 2017. In accordance with Article 8.8.3. of the *Terrestrial Animal Health Code (Terrestrial Code)*, Bolivia informed the OIE in advance about the intended cessation of vaccination in the proposed zone.

Based on Administrative Resolution No. 117/2017 (issued in October 2017), which excludes the animals of Pando Department as part of the animal population to be vaccinated against FMD, the Group acknowledged that vaccination was prohibited by law in the proposed zone.

Whilst noting the system to control the movements between zones – free from FMD with and without vaccination – based on checkpoints and movement licenses, the Group recommended that Bolivia establish legislation stating that the introduction of animals vaccinated against FMD is not allowed into a FMD free zone without vaccination, in accordance with Article 8.8.2. of the *Terrestrial Code*.

v) *Surveillance in accordance with Articles 8.8.40 to 8.8.42.*

Bolivia described its passive surveillance based on reporting of suspicions. The proposed zone had four veterinary reporting units and 46 epidemiological units that in 2017 detected and treated 223 disease suspicions, although none of them were related to vesicular diseases.

The Group noted that a serological survey was performed in April-May 2018 in the proposed zone on 6-12 month old unvaccinated cattle. Based on the information provided in the dossier and to the follow-up questions raised, the Group concluded that the conducted survey comprising of a large proportion of unvaccinated cattle contributed additional information to demonstrate absence of FMD infection in the proposed zone.

vi) *Regulatory measures for the prevention and early detection of FMD*

The Group noted that the official procedure to control the movements of animals and products between zones recorded only a limited number of movements of non-vaccinated susceptible animals or their products into the zone since the cessation of vaccination in 2017.

The Group also took note of the procedures established by law in case of detection of illegal imports which would lead to confiscation and destruction, as well as of the number of seized animals and products moved illegally over the past years. The Group noted the availability of an animal identification system supporting the early detection of illegal introduction of live animals.

vii) *Description of the boundaries of the proposed free zone, if applicable*

The proposed zone correlates with the administrative boundaries of the Department of Pando. The proposed zone (Figure 1) borders the Brazilian States of Acre and Rondônia to the north, both recognised as FMD free zones where vaccination is practiced. To the south it is separated by the Madre de Dios river from the La Paz department, and by the Beni river from the Beni Department; to the east lies the Brazilian state of Rondonia, and to the west the Madre de Dios Department of Peru, whose status with respect to FMD is a free zone where vaccination is not practised.



Fig. 1. Department of Pando - proposed FMD free zone where vaccination is not practised (in hash marks) for potential recognition in May 2019.

viii) *Description of the boundaries and measures of a protection zone, if applicable*

Not applicable.

ix) *Description of the system for preventing the entry of the virus (into the proposed FMD free zone)*

The proposed free zone is surrounded by officially recognised FMD free zones or countries. The Group noted that checkpoints in the proposed zone were limited to two international and two internal locations. Bolivia described the movement trends of animals and animal products related to the proposed zone which was mainly constituted by a closed circuit, supplying the six slaughterhouses registered by National Service of Agricultural Health and Food Safety (SENASAG) within the Department of Pando.

Overall, the Group considered the described measures adequate to prevent the entry of FMD virus into the proposed zone. Nevertheless, the Group strongly reminded Bolivia that the introduction of vaccinated animals into the zone should not be allowed, in accordance with Article 8.8.2. of the *Terrestrial Code*.

x) *Compliance with the questionnaire in Article 1.11.3.*

The Group agreed that the format of Bolivia's dossier was compliant with the questionnaire in Article 1.11.3.

Conclusion

Considering the information submitted in the dossier and to the questions raised, the Group agreed that the application was compliant with the requirements of Chapter 8.8. and with the questionnaire in Article 1.11.3. of the *Terrestrial Code*. The Group therefore recommended that the proposed zone of Bolivia be recognised as a FMD free zone where vaccination is not practised.

Nevertheless, the Group underlined that, having a FMD free zone status where vaccination is not practised, introduction of vaccinated animals would lead to the suspension of the official FMD free status according to the current Article 8.8.2. of the *Terrestrial Code*.

b) Botswana

Botswana has five FMD free zones where vaccination is not practised, officially recognised by the OIE. In August 2018, Botswana submitted an application for Zone 7, to be recognised as a zone free from FMD where vaccination is not practised.

The FMD free without vaccination status of Zone 7 was recognised in May 2011 and suspended in June 2011 following the occurrence of an outbreak of FMD.

i) Animal disease reporting

The Group considered that Botswana had a record of regular and prompt animal disease reporting.

ii) Veterinary Services

The Group agreed that the Veterinary Authority had current knowledge of and authority over FMD susceptible animals in the proposed zone.

iii) Situation of FMD in the past 12 months

The Group noted that the last outbreaks in Zone 7 were in June 2011 (serotype SAT2) and that the previous 'FMD free without vaccination' status of the zone was consequently suspended. Botswana had carried out vaccination together with other control measures.

iv) Absence of vaccination and entry of vaccinated animals in the past 12 months

Vaccination in cattle was conducted in Zone 7 in 2011 in response to the outbreaks. From 2013, cattle were vaccinated with a purified vaccine from the Botswana Vaccine Institute. The Group noted that the vaccination had ceased in most of Zone 7 in 2014 but continued until February 2016 in a 20-kilometer strip next to the border with a neighbouring country. The Group noted that since the cessation of vaccination, introduction of vaccinated animals has not been allowed into Zone 7.

v) Surveillance for FMD and FMDV infection in accordance with Articles 8.8.40. to 8.8.42.

The Group was informed that active and passive surveillance were in place, and were performed in general schemes as well as with a targeted approach in the proposed zone. The dossier described two clinical suspicions that were investigated in the past year; clinical surveillance on farms was based on reports of suspicion raised by farmers and routine extension officers' surveillance. In addition, clinical surveillance was also in place through official quarantine of animals exiting Zone 7 to the export abattoir in Zone 6a (officially recognised FMD free zone without vaccination).

The Group was informed that after the last outbreaks in the proposed zone, systematic serological surveys were performed in 2014-2018. The survey of 2018 involved a general sampling of cattle and a targeted approach for cattle, goats, and wildlife (opportunistic) in the 20-km belt from the international border.

The Group received, as part of the additional information from Botswana, the Standard Operating Procedure (SOP) introduced in January 2018 for the follow-up of NSP reactors. The Group noted in the SOP that resampling and testing was required in the reactor animals only. The Group strongly recommended that the follow-up procedure in future cases of positive results should include clinical inspection, supplementary testing of the animals found seropositive and the in-contact animals, and epidemiological investigation in accordance with Article 8.8.42. Point 1 of the *Terrestrial Code*.

Upon the Group's request with regard to the NSP positive findings, Botswana provided maps showing sampling locations and those where NSP reactors were found; a table showing the number of animals sampled and resampled at each location was also provided. However, the Group noted that the number of animals sampled did not correlate to the number of animals present in accordance with the described sampling design. Furthermore, the follow-up visits to inspect and resample animals took place months after the initial sampling. In this regard, the Group was concerned that had infection been present, the delay in follow-up would have prevented timely control measures from being implemented.

Notwithstanding, the Group considered that the serological survey results did not suggest presence of undisclosed infection in unvaccinated animals.

The Group noted from the dossier that the FMD-testing laboratories in Botswana had not participated in recent proficiency testing and strongly encouraged their participation.

vi) *Regulatory measures for the early detection, prevention and control of FMD*

The Group noted sufficient regulatory measures described in the dossier for the early detection, prevention and control of FMD, as implemented in other zones already officially recognised as free from FMD.

vii) *Description of the boundaries of the proposed free zone*

The Group was informed on the boundaries of the proposed zone including a clear description of the barriers used for protecting the zone with fences and control points (Figure 2).



Fig. 2. Zone 7 - proposed FMD free zone where vaccination is not practised for potential recognition in May 2019.

viii) *Description of the boundaries and measures of a protection zone, if applicable*

Not applicable.

ix) *Description of the system for preventing the entry of the virus*

The Group was aware that the fences separating Zone 7 from neighbouring countries and adjacent zones were being regularly patrolled and maintained by the Veterinary Services. It was also mentioned in the dossier that there are 42 strategically placed disease control veterinary gates along a 1.5-metre double fence that surrounds Zone 7 to deter access by most FMD susceptible wild animals; the border with a neighbouring country with no officially recognised FMD status was also double-fenced.

The policy to trace and return stray susceptible livestock originating from infected neighbouring countries was also noted as an additional measure to prevent the potential introduction of FMD virus into Botswana. Botswana provided additional information on the confiscation of animals and their products at the international border posts.

x) *Compliance with the questionnaire in Article 1.11.3.*

The Group agreed that the format of Botswana's dossier was compliant with the questionnaire in Article 1.11.3.

Conclusion

Considering the information submitted in the dossier, the lapsed time since the last outbreaks and the answers from Botswana to the questions raised, the Group considered that the application was compliant with the requirements of Chapter 8.8. and with the questionnaire in Article 1.11.3. of the *Terrestrial Code*. The Group therefore recommended that the proposed zone of Botswana be recognised as a FMD free zone where vaccination is not practised.

Nevertheless, the Group would draw the attention of Botswana to the following recommendations and to provide updates when Botswana reconfirms its FMD status (also detailed in the relevant sections above):

- the risk of undisclosed infection in small ruminants should not be overlooked given the large numbers of goats and sheep present in the zone.
- FMD-testing laboratories participate regularly in proficiency testing schemes.
- NSP reactors found in surveys should be followed-up in a timely manner including collecting sera not only from the reactor animals but also from other in-contact animals in accordance with Article 8.8.42. Point 1 of the *Terrestrial Code*.

c) **Kazakhstan**

Kazakhstan has six FMD free zones officially recognised by the OIE: one zone where vaccination is not practised and five zones where vaccination is practised.

In August 2018, Kazakhstan submitted an application requesting the separation of the zone free from FMD without vaccination (covering Akmola, Aktobe, Atyrau, West Kazakhstan, Karaganda, Kostanay, Mangystau, Pavlodar and North Kazakhstan) into five separate zones free from FMD without vaccination (Figure 3).



Fig. 3. Proposed separation of the officially recognised FMD free zone where vaccination is not practised, into five FMD free zones (Zones I to V), for potential recognition in May 2019.

The following report combines the observations for the five zones and only differentiates them when necessary.

The Group requested additional information and received clarification from Kazakhstan.

i) Animal disease reporting

The Group considered that Kazakhstan had a record of regular and prompt animal disease reporting.

ii) Veterinary Services

The Group noted that a PVS follow-up evaluation mission was conducted in April 2018 but the report was not available to be shared with the Group. From the information available, the Group concluded that the Veterinary Services had the capacity to prevent and control FMD, should an incursion occur.

iii) Situation of FMD in the past 12 months

The Group noted that the last FMD outbreak within any of the five zones was registered in June 2011 in Zone 1 – West Kazakhstan region. According to the dossier, the last outbreaks in the four other proposed zones occurred as follows: in 2007 in Zone 2, in 2010 in Zone 4 and never occurred in Zones 3 and 5.

iv) Absence of vaccination and entry of vaccinated animals in the past 12 months

The Group acknowledged that no vaccination was carried out since 2011, when it was used in response to the last FMD outbreak. In connection with the official recognition of the FMD free zone without vaccination status recognised by OIE, Kazakhstan stated that no vaccination had been carried out in any of the five proposed zones.

The Group noted that movement of susceptible animals from the FMD free zones with vaccination into the FMD free zone without vaccination is prohibited by law and is under constant control of the Veterinary Service of the regions.

v) Surveillance for FMD and FMDV infection in accordance with Articles 8.8.40. to 8.8.42.

The Group considered the passive surveillance strategy adequate for an area free from FMD without vaccination. The Group acknowledged that Kazakhstan had continual activities to strengthen good awareness of the farmers; there is a compensation policy according to the market prices and the farmers have the legal obligation of reporting suspicions.

In addition, the Group noted that slaughtered animals must be, by law, subject to ante-mortem clinical examination and post-mortem veterinary examination of carcasses and organs. The Group appreciated the surveillance carried out at slaughterhouses.

Regarding the provided information on suspected cases registered during the last three years, the Group also noted that FMD was ruled out in all suspected cases on the basis of clinical symptoms and laboratory tests, including those for the detection of antibodies to NSP. Although it is not a strict requirement to conduct sero-surveillance for undetected infection in non-vaccinated populations, the Group noted that a NSP sero-survey was conducted in cattle and small ruminants. The Group emphasised the importance of a survey design that should clearly state which within-herd and between-herd design prevalence was used and include details on how the sample size was calculated. Whilst receiving the results and confirmation that all samples taken were negative, the Group would have appreciated a breakdown of data, including interim findings and mapping of all positive reactors to the NSP tests, possible clustering of reactors and details on how they were followed up to rule out infection with FMD virus.

The Group recommended that for any future design of serological surveys in demonstrating absence of infection, Kazakhstan should consider the design to be specific for each officially recognised zone.

vi) *Regulatory measures for the early detection, prevention and control of FMD*

In general, the Group considered that sufficient regulatory measures were described in the dossier for the early detection, prevention and control of FMD.

The Group noted that the number of reported FMD suspicions has decreased over recent years. The Group acknowledged Kazakhstan's efforts in raising awareness of FMD combined with a compensation system, but emphasised the importance of reporting of all suspicious cases to maintain a high level of sensitivity of the passive surveillance.

The Group acknowledged the contingency plan submitted by Kazakhstan in case of a FMD outbreak in the FMD free zones without vaccination. The Group noted that the procedure includes the imposition of quarantine with a stamping out policy of all susceptible animals, restriction of animal movements and disinfection measures as well as raising public awareness; the contingency plan excludes the use of emergency vaccination.

The Group noted the information related to importation of animals and their products into the country and the proposed zones with appropriate control measures described.

vii) *Description of the boundaries of the proposed free zone*

The Group noted that the delimitation of five zones was established and enforced by legislation in June 2018. The divisions of the zones are a combination of administrative boundaries and natural barriers.

The Group enquired about the boundaries of the proposed zones and further clarification was provided by Kazakhstan on how the separation was being managed.

viii) *Description of the boundaries and measures of a protection zone, if applicable*

Not applicable.

ix) *Description of the system for preventing the entry of the virus*

The Group noted that individual animal identification and registration was a key method to control movements between the zones.

The Group noted that a system is in place for individual numeric identification of animals of susceptible species. A veterinary passport is issued for a group of small ruminants (sheep, goats) and pigs with the individual number of each animal, and individual passports are issued for cattle. Farmers are obliged by law to ensure the identification and registration of farm animals with appropriate veterinary certificates, and to notify the authorities of the state veterinary supervision of newly acquired animals, progeny, and their slaughter and sale. There are financial incentives for complying with farm animal identification and penalties for non-compliance.

The Group noted that movement within and between the zones is limited in scale and is regulated by veterinarians issuing certificates. Kazakhstan provided summary tables from the check posts between the proposed and existing zones on the compliant movements of susceptible animals and also provided the number and reasons of the movements which were blocked due to non-compliances. There appears to be a close interaction between vets and enforcement bodies (police, customs). Trade in live animals and livestock products between zones with the same status is regulated via an Electronic System for Issuance of Veterinary Documents (EASU system) which records the point of departure and point of arrival.

x) *Compliance with the questionnaire in Article 1.11.3.*

The Group appreciated Kazakhstan's compilation of information into a single dossier and differentiating the parts when it relates to a particular zone amongst the five. The Group agreed that the format of the dossier was compliant with the questionnaire in Article 1.11.3.

Conclusion

Considering the information submitted in the dossier and the answers from Kazakhstan to the questions raised, the Group considered that the application was compliant with the requirements of Chapter 8.8. and with the questionnaire in Article 1.11.3. of the *Terrestrial Code*. The Group therefore recommended that the five proposed zones of Kazakhstan be recognised as FMD free zones where vaccination is not practised.

4. Evaluation of a request from a Member for the official recognition of FMD free zones where vaccination is practised status

The Group assessed a request from a Member for the recognition of two FMD free zone status where vaccination is practised. The Group concluded that the application did not meet the requirements of the *Terrestrial Code*. The dossier was referred back to the applicant Member.

5. Evaluation of requests from Members for the endorsement of their national official control programme for FMD

The Group assessed requests of two Members for the endorsement of their national official control programmes for FMD and considered that the dossiers did not meet the requirements of the *Terrestrial Code*. The dossiers were referred back to the respective applicant Members.

6. Review of the updated information provided by a Member with regard to its endorsed official control programme – particularly on the timeline and performance indicators – according to the current situation with regard to FMD.

Mongolia

Further to the request of the Scientific Commission, the Group assessed information provided by Mongolia with regard to the endorsement of the official control programme and the adjusted timeline and performance indicators according to the current FMD situation.

The detailed plan of the programme to control and eventually eradicate FMD in the country or zone

The Group acknowledged the modified (delayed) timeline due to the recent FMD outbreaks and the list of activities planned in 2019 in the three zones (western, central and eastern) designated by Mongolia as part of its progressive zonal approach in controlling and eradicating FMD.

While reviewing the activities for 2019, the Group found it difficult to give detailed feedback due to the brevity of the information provided. For example, the Group thought that it would have been useful to have more details on the intermediate steps already taken or required to improve the animal movement control through introduction of a new veterinary certificate system. Mongolia's plan indicated that this would be done by February 2019, but it was not clear if the system had been already developed and will be implemented by February. In addition, more detail was required on what was meant by 'purposive surveillance' and 'extensive purposive surveillance' respectively. These were some examples noted by the Group and not an exhaustive list of statements for which details were lacking.

Epidemiology of FMD in the country

Following the recent outbreaks, the Group recommended that Mongolia reconsider or provide a rationale to maintain the boundaries of the initially designated zones, according to the current risks. Mongolia should clarify the role and function of the central zone, and may also consider establishing a protection zone with vaccination to prevent the spread of infection to the free zone without vaccination in the west.

In accordance with the current FMD situation, clinical and serological surveillance should be better planned, with a clear procedure to follow-up the results. Mongolia should perform regular serological surveys in the vaccinated susceptible population. The results of any serological surveillance performed in the country should be provided to the OIE when annually reconfirming the endorsed programme; together with the details about the survey design followed for each of the zones including sample size calculation and the selection of the epidemiological units; for both NSP and immunity studies.

Vaccination and vaccines

The Group recommended that Mongolia should define a clear vaccination strategy, depending on the level of FMD risk in different areas of the country and on vaccine supply. Mongolia should ensure that sufficient supply of vaccines would be available in case of future outbreaks. The Group noted vaccine-matching studies were performed in response to the FMD outbreaks in 2017-2018.

With regard to Mongolia's vaccination strategy targeting high risk areas, the Group also emphasised that legally reinforced movement controls would be equally important. Given the extent of recent outbreaks, the Group found it counter intuitive to aim for reduced vaccination as described in the dossier.

Conclusion

The Group considered that Mongolia's endorsement could be maintained but strongly recommended to the Scientific Commission and OIE that Mongolia should provide more information on the following when reconfirming its endorsed control programme in November 2018 for consideration by the Scientific Commission in February 2019:

- Clarifications about the zoning strategy in line with the above mentioned comments made by the Group.
- More detailed information on the epidemiological situation regarding the recent FMD outbreaks, including investigations that have been performed to understand the introduction and spread of infection as well as control actions implemented, and follow-up actions to rule out ongoing virus transmission.
- Analysis of the available information on the vaccination status in the area(s) where outbreaks occurred in 2017-2018 including the vaccination coverage and results of immunity studies; the occurrence of outbreaks in vaccinated animals can help understand vaccine effectiveness.
- Clarification on the contingency plan – including provision for stamping out, emergency vaccination and other zoosanitary controls – to be better prepared for possible incursion of FMD virus and occurrence of outbreaks in the future.

7. Other matters

In October 2016, based on its experience assessing applications from OIE Members for official recognition of the FMD free status and repetitive shortcomings noted in the presentations of applied survey design and results in the dossiers, the Group had developed an outline that future applicant OIE Members could follow to clearly present this information in their dossiers.

With its additional experience since the development of this outline, the Group suggested modifications for consideration by the Scientific Commission and the OIE and furthermore recommended that it be easily accessible and displayed to help applicant OIE Members in presenting such information when applying for official recognition of FMD free status (cf Appendix IV).

8. Adoption of report

The Group reviewed the draft report and agreed to circulate it electronically for comments before the final adoption. Upon circulation, the Group agreed that the report captured the discussions.

.../Appendices

Appendix I

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

Paris, 22 – 25 October 2018

Terms of Reference

The OIE *ad hoc* group on foot and mouth disease (FMD) status of Members (the Group) is expected to evaluate the applications for official recognition of FMD free status and for endorsement of their official control programme of FMD received from Members in accordance with the Standard Operating Procedure for official recognition of disease status and for the endorsement of national official control programmes.

This implies that the experts, members of this Group are expected to:

1. Sign off the OIE Undertaking on Confidentiality of information, if not done before.
2. Complete the Declaration of Interests Form in advance of the meeting of the Group and forward it to the OIE at the earliest convenience and at least two weeks before the meeting.
3. Evaluate the applications from Members for official recognition of FMD free status and for endorsement of their official control programmes for FMD.
 - a) Before the meeting:
 - read and study in detail all dossiers provided by the OIE;
 - take into account any other information available in the public domain that is considered pertinent for the evaluation of dossiers;
 - summarise the dossiers according to the *Terrestrial Animal Health Code* requirements, using the form provided by the OIE;
 - draft the questions whenever the analysis of the dossier raises questions which need to be clarified or completed with additional details by the applicant Member;
 - send the completed form and the possible questions to the OIE, at least one week before the meeting.
 - b) During the meeting:
 - contribute to the discussion with their expertise;
 - withdraw from the discussions and decision making when possible conflict of interest;
 - provide a detailed report in order to recommend, to the Scientific Commission for Animal Diseases, i) the country(ies) or zone(s) to be recognised (or not) as FMD free ii) country(ies) to have (or not) the OIE endorsement of national official control programme for FMD, and to indicate any information gaps or specific areas that should be addressed in the future by the applicant Member.
 - c) After the meeting:
 - contribute electronically to the finalisation of the report if not achieved during the meeting.

In addition, at this meeting, the experts, members of this Group are expected to:

4. Consider the updated information provided by a Member with appropriate adjustments made to the official control programme – particularly on the timeline and performance indicators – according to the current situation with regard to FMD.
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Appendix II

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

Paris, 22 – 25 October 2018

Agenda

1. Opening
 2. Adoption of the agenda and appointment of chairperson and rapporteur
 3. Evaluation of requests from Members for official recognition of FMD free zones where vaccination is not practised status
 - Bolivia
 - Botswana
 - Kazakhstan
 4. Evaluation of a request from a Member for official recognition of FMD free zones where vaccination is practised status
 5. Evaluation of requests from Members for the endorsement of official control programme for FMD
 6. Review of the updated information provided by a Member with regard to its endorsed official control programme – particularly on the timeline and performance indicators – according to the current situation with regard to FMD
 - Mongolia
 7. Other matters
 8. Adoption of report
-

Appendix III

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

Paris, 22 – 25 October 2018

List of participants

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Appendix IV**Guidance document on presentations of applied survey design and results for applicant OIE Members for official recognition of FMD free status**

- 1) Objectives of the survey (e.g. detecting infection, prevalence estimation, population immunity, etc.)
- 2) Survey design:
 - a. Reference population (by species and area)
 - i. Total number of animals
 - ii. Definition of an epidemiological unit
 - iii. Types and description of different epidemiological units
 - iv. Number of epidemiological units, and where possible location of epidemiological units
 - v. Indicate how the reference population relates to the target population
 - b. Strategy for survey
 - i. Indicate if one stage or two stages
 - ii. Stratification and criteria for eligibility (according to age, size of epidemiological unit, etc.)
 - iii. Method for sample size calculation
 - iv. Parameters that influence sample size calculation:
 - Design prevalence: between and within epidemiological units (for sample size calculations of epidemiological units and animals)
 - Level of confidence
 - Level of precision (where relevant)
 - Laboratory test sensitivity and specificity
 - Herd sensitivity and specificity (where relevant)
 - v. Details on the method of selection of epidemiological units and animals (random, convenience, targeted, etc.)
 - vi. Description of laboratory tests performed; cut-off values used to determine positive results and their sensitivity and specificity (and whether validated or assumed)
 - vii. Timing of sampling indicating time period/dates and other relevant information (e.g. in relation to vaccination or disease risk)
 - viii. Description of follow-up of serological findings
- 3) Results
 - i. Deviation from original plan
 - ii. When, where and how many samples were actually taken
 - iii. Particularly for NSP surveys provide:
 - Tabulated results, broken down to epidemiological units showing animals present, animals sampled and results (indicating preliminary and confirmatory testing) including the dates of the farm visits and overall results (see an example in the Annex)
 - A break-down of the results by age group including those that tested positive and those that tested negative.

- Maps showing locations of epidemiological units in the reference population, those sampled and those with positive results
 - Details of control measures and epidemiological enquiries as part of the survey.
 - iv. For population immunity studies
 - Tabulated results by administrative division (or other suitable geographical division), serotype, age group, post vaccination interval and herd size if available.
 - 4) Conclusion in relation to the objective and compliance with provisions of the *Terrestrial Code*
-

ANNEXES

Annex I. Model for aggregate table for the presentation of the data related to FMD sero-survey, stratified by area, species, age and results of the sampling

Area	Number of holdings	Number of animals	Age group	Animals sampled	Animals tested	Results	
						Initial	Confirmatory
		cattle	6-12				
			12-24				
		Sheep	6-12				
			12-24				
		goats	6-12				
			12-24				
		pigs					
		others					

Annex II. Model table (at the level of epidemiological unit) for the presentation of data and follow-up studies of NSP sero-surveys, stratified by area, species and results in the initial sampling and follow-up studies

Total susceptible animals per epi. unit			Initial sampling			Follow-up studies					
Name of Epi. Unit (e.g. farm, village, etc.)	Total No. of animals present per species	Date sampling	No. of animal sampled	NSP results (screening or confirmatory testing)	Date of follow-up	No. of animals sampled	NSP results (confirmatory testing)	Probing samples	No. probing positive results	No. of animals clinically inspected	Epidemiological comments
	Cattle: xx										
	Goats: xx										
	Cattle:										
	Goat:										

**REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS EVALUATION OF MEMBERS
Paris, 29 – 30 October 2018**

A meeting of the *ad hoc* Group on Bovine Spongiform Encephalopathy (BSE) Risk Status Evaluation of Members (hereafter the Group) was held at the OIE Headquarters from 29 to 30 October 2018.

1. Opening

On behalf of Dr Monique Eloit, Director General of the OIE, Dr Neo Mapitse, Head of the Status Department, welcomed and thanked the Group for its commitment and the extensive support towards the OIE mandates. He acknowledged the amount of work before, during and after the *ad hoc* Group meeting and the efforts required in reviewing the dossiers and highlighted that the official recognition of disease status was an important activity for the OIE.

Dr Mapitse updated the Group on the progress of the 6th Strategic Plan of the OIE and referred to the advancement with regard to strengthening the procedures for the selection of members of the Specialist Commissions and *ad hoc* Groups.

Dr Mapitse reminded the Group on the significance and confidentiality of the dossiers received for official recognition and thanked the experts for having signed the updated forms for undertaking of confidentiality. He underlined the OIE procedures for protecting the confidentiality of information and for declaring potential conflicts of interest (by withdrawing themselves from the discussion/conclusion in case of a potential conflict of interest). No conflicts of interest were declared in this Group.

Dr Mapitse pointed out that whilst the evaluation of the BSE risk status of Members might be a politically sensitive issue, the Group's assessment should be driven by standards, science and evidence-based, and highlighted that the ongoing revision of the BSE Chapter should not impact the evaluation of the dossiers received by the Group. Dr Mapitse also encouraged the Group to capture the rationale supporting its decisions and recommendations in its meeting report for the consideration of Members.

The Group and the OIE welcomed Drs Lesley van Helden and Sara Perucho as new members in the Group.

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

Dr Ximena Melón was appointed Chair and Dr Lesley van Helden acted as rapporteur with the support of the OIE Secretariat. The Group endorsed the proposed agenda.

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

3. Evaluation of applications from Members for the official recognition of their negligible BSE risk status

3.1. Serbia

In August 2018, Serbia submitted a dossier seeking recognition as a country presenting a negligible BSE risk status.

The Group requested additional information and received clarification from Serbia. Points specifically discussed by the Group are summarised below:

a) *Section 1: Risk Assessment — Article 11.4.2. point 1*

▪ Risk assessment for entry of the BSE agent

The Group took note that from 2009 to 2018 importations of meat-and-bone meal (MBM) or greaves containing ruminant proteins into Serbia were prohibited unless intended for the manufacturing of pet food. In addition, imports of MBM were permitted only for those facilities approved by the Veterinary Service for pet food production, provided that imports were certified as not containing specified risk material (SRM) and mechanically separated meat. The Group noted that within the past eight years, only prepared pet food in original package was imported from undetermined BSE risk status countries.

The Group noted that live cattle were imported into Serbia from countries with a negligible or controlled BSE risk status as well as from countries with an undetermined BSE risk status within the past 7 years. The Group examined the sanitary requirements applicable to these importations and concluded that they were consistent with the requirements of Article 11.4.9. of the *Terrestrial Code*.

With respect to imports of products of bovine origin, the Group noted that various meat and meat products of bovine origin were imported from countries having a negligible, controlled or undetermined risk status for BSE. While most of the import requirements were compliant with the recommendations of Articles 11.4.10-11.4.12 of the *Terrestrial Code*, the Group noted that imports of “carcasses, half carcasses or half carcasses cut into no more than three wholesale cuts, and quarters containing no specified risk material (SRM) other than the vertebral column, including dorsal root ganglia” labelled as such were allowed from countries with a controlled or undetermined BSE risk status. Upon subsequent questioning, Serbia clarified that the aforementioned products were imported only for further processing and SRM were removed in the cutting plants.

Overall, the Group considered that the conclusion of the entry assessment was that the risk that the BSE agent could have entered Serbia during the interval covered by the assessment, although low, could not be considered negligible.

▪ Risk of recycling and amplification of the BSE agent

The Group noted that legislation defining a list of tissues and organs as SRM was introduced in 2006 and, while it had been modified to some extent over the years, it included all those materials listed in Article 11.4.14. of the *Terrestrial Code*. The Group noted that SRM, which are included in the definition of Category 1 material, were required to be removed in abattoirs, cutting facilities or authorised butcher shops, marked immediately upon removal and disposed of as Category 1 material, i.e., incinerated or processed by Category 1 rendering plants and subsequently incinerated or buried. Dead bovine animals and materials declared unfit for human consumption were also classified as Category 1 material and disposed of as such.

The Group noted that imported cattle, products derived from them and associated waste were treated in the same manner as if they were derived from domestic cattle.

The Group acknowledged that since 2006, SRM as well as non-SRM ruminant waste materials, which were rendered, had been processed under high temperature and pressure (133°C, for at least 20 minutes with a minimum absolute pressure of 3 bars). This is in compliance with the procedures for the reduction of BSE infectivity in MBM as outlined in Article 11.4.19. of the *Terrestrial Code*. The Group noted that since 2013, all MBM classified as Category 1 has been incinerated. However, the Group also noted that two rendering plants processing Category 1 material changed to another rendering method in 2014 and 2016 respectively. While this method would be unlikely to substantially reduce BSE infectivity, the Group acknowledged that the subsequent incineration of the resulting MBM would lead to the destruction of the BSE agent.

While only authorised feed production facilities were permitted to use ruminant MBM for the production of feed for swine and poultry from 2006 to 2011, the Group acknowledged that none of them produced feed for ruminants. Following the implementation of a total feed ban in April 2011 under which all terrestrial processed animal proteins (PAP) are prohibited from use in feed for food animals, only fish meal has been used in feed for poultry and pigs. In addition, from the information provided in the dossier as well as the responses by Serbia to additional questions, the Group acknowledged that following the introduction of the total feed ban only facilities producing fish feed were approved to use non-ruminant MBM and only pet food production plants, operating in dedicated and separate establishments, were allowed to process Category 3 ruminant material. The definition of Category 3 ruminant material in Serbia is consistent with that of the European Union. It consists of parts of slaughtered animals which are fit for human consumption but not used for human consumption for commercial reasons. The Group acknowledged that Serbia provided sufficient evidence to demonstrate that appropriate controls were in place to prevent cross-contamination of MBM in any livestock feed.

Overall, regarding the exposure assessment, the Group concluded that the risk of recycling and amplification of the BSE agent if it was present in Serbia's cattle population during the interval covered by the assessment had been negligible.

- Appropriate level of control and audit of the feed ban

The Group acknowledged that a ruminant-to-ruminant feed ban was introduced in Serbia in 2001 and extended to a mammalian-to-ruminant ban in 2005; followed by a total feed ban in April of 2011 whereby all processed animal protein of terrestrial animals was prohibited from being used in animal feed.

The Group noted that rendering facilities have been inspected multiple times each year and that feed mills were audited at least once a year according to the Veterinary Service's National Annual Inspection Plan. Moreover, since 2006, feeds were tested for the presence of MBM using microscopy. Considering that a total feed ban was in place since 2011, the Group agreed that microscopy would be sufficient to detect cross-contamination in ruminant feed. Since 2016, RT-PCR was used as an additional method for testing aquatic animal feed, where the inclusion of pig and poultry PAP was allowed, to screen for contamination with material of ruminant origin.

The Group reviewed the information provided on testing of feed for ruminants from 2010 to 2018 and acknowledged that all feed samples had tested negative for the presence of MBM. The Group noted that in case of non-compliance, corrective actions would include suspension of production or shipment, destruction of feed or diverting it for use for another purpose.

Overall the Group concluded that the appropriate legislation, control and audit of the proper implementation of the feed ban had been in force for at least eight years.

b) Surveillance according to Articles 11.4.20. - 11.4.22.

The Group noted that the surveillance undertaken over the seven-year period from 2012 to 2018 exceeded the minimum requirements of type B surveillance according to Article 11.4.22. on surveillance for BSE in the *Terrestrial Code*. Based on the information provided in the dossier, 49,127.92 surveillance points were collected, compared to a minimal requirement of 47,700 for an adult cattle population of 488,629 over two years of age.

The Group noted that Serbia's surveillance programme for BSE targeted all surveillance subpopulations and that samples reflected the cattle distribution in the country. While the Group acknowledged that Serbia did not claim an excess number of clinical cases, it was noted that some of the clinical signs reported in the dossier were not specific enough to raise legitimate concerns that an animal could be reasonably categorised as a clinical suspect according to Article 11.4.21. point 1 of the *Terrestrial Code*. In addition, the clinical signs were not specified for about 25% of the suspect cases reported. The Group recommended that more awareness campaigns should be conducted among all relevant stakeholders on the clinical signs of BSE to improve the specificity of passive surveillance.

c) Other requirements — Article 11.4.2. points 2–4

■ Awareness programme

The Group noted that an awareness programme on BSE was initiated in 1991 throughout the country, involving lectures, workshops and training courses, followed by the establishment of a group of BSE experts in 1997, to provide guidance to staff within the Veterinary Service and relevant stakeholders. The Group appreciated that a variety of communication tools, including film, manuals and flyers, were used to raise awareness among target audiences, such as staff of the Ministry of Agriculture, Forestry and Water Management, the Veterinary Directorate, diagnostic laboratories, official veterinarians, veterinary practitioners, veterinary students, slaughterhouse personnel as well as animal breeders, keepers and handlers, feed producers and importers. The Group concluded that this awareness programme met the requirements of the *Terrestrial Code*. The Group recommended that Serbia maintains the awareness activities and enhance their geographical distribution.

■ Compulsory notification and investigation

The Group noted that BSE was declared to be a notifiable disease under relevant legislation in 1991 and that a directive was in place outlining the procedures to be followed by animal keepers in case of suspicion of an infectious disease. The Group acknowledged that financial compensation would be provided for fallen stock if they tested positive for BSE, any animals killed due to a suspicion of BSE as well as the costs of transport and testing of samples from BSE suspect cases. Sanctions were envisaged for failure to report BSE cases. The Group therefore concluded that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

■ Laboratory examination

The Group noted that diagnostic testing for BSE was conducted in two laboratories accredited for TSE testing, namely the National Reference laboratory and, since 2007, the Scientific Institute of Veterinary Medicine of Serbia.

According to the additional information provided by Serbia, since 2005, clinical suspects as well as inconclusive or positive results from screening of healthy populations, fallen stock and casualty slaughter were subjected to confirmatory testing using at least one of Western immunoblot, histopathology or immunohistochemistry or a combination of these tests. Clinical

suspects could also be tested using a combination of rapid tests. The Group pointed out that according to Chapter 2.4.5. of the *Terrestrial Manual*, histopathology alone is not appropriate to define a sample as negative for BSE for any of the surveillance streams, either as a primary or as a secondary test. The Group recommended that Serbia undertake all laboratory tests for BSE using methods recommended by the *Terrestrial Manual*: i.e., immunohistochemistry, Western immunoblot or rapid tests as primary test, and immunohistochemistry or Western immunoblot as secondary test to confirm positive or inconclusive primary test results.

The Group also took note that in case of a positive result, samples would be sent to an OIE Reference Laboratory for BSE for confirmatory testing.

Overall the Group concluded that the laboratory examination for BSE carried out in Serbia could be considered to be compliant with the *Terrestrial Manual* for at least the preceding seven years.

d) BSE history in the country

The Group acknowledged that BSE had never been reported in Serbia.

e) Compliance with the questionnaire in Article 1.6.5.

The Group appreciated the well-structured and comprehensive dossier provided by Serbia and agreed that the dossier as submitted was compliant with the format of the questionnaire in Article 1.6.5. of the *Terrestrial Code*. However, the Group pointed out that the extensive number of appendices together with the citation of numerous legislative acts and regulations in the core dossier without an appropriate summary led to significant challenges in undertaking an evaluation of this application.

f) Conclusions

▪ Recommended status

Considering the information submitted in the dossier and Serbia's answers to follow-up questions raised, the Group concluded that the application was compliant with both the requirements of Article 11.4.3. and the BSE questionnaire of the *Terrestrial Code*. The Group therefore recommended that Serbia be recognised as a country with a 'negligible BSE risk status'.

4. Evaluation of applications from Members for the official recognition of their controlled BSE risk status

4.1. Ecuador

In August 2018, Ecuador submitted a dossier seeking recognition as a country presenting a controlled BSE risk status.

The Group requested additional information and received clarification from the Member. Points specifically discussed by the Group are summarised below:

a) Section 1: Risk Assessment — Article 11.4.2. point 1

▪ Risk assessment for entry of the BSE agent

With regard to the information on imports of MBM, greaves, or feedstuffs containing either, live cattle and products of ruminant origin, the Group appreciated the clarity and completeness of the information provided by Ecuador.

With regard to importations of feedstuff containing MBM, greaves and/or tallow during the past 8 years, the Group noted that only pet food that was pre-packed, retail ready, and labelled as not to be fed to ruminants, was imported into Ecuador from a single country with a negligible BSE risk status. Moreover, poultry meal and viscera, pork meal and poultry, pig and ruminant tallow were only imported from countries with either a negligible or a controlled BSE risk status.

The Group noted that imports of live cattle into Ecuador within the past 7 years were exclusively for reproductive purposes from four countries, all with a negligible BSE risk status. Furthermore, all imported live cattle were individually identified and their movements and final disposition were known. The Group examined the sanitary requirements applicable to these importations and concluded that they were compliant with the requirements of Article 11.4.6. of the *Terrestrial Code*.

With regard to imports of products of ruminant origin within the past 7 years, the great majority of the products were imported from countries with either an OIE negligible or controlled BSE risk status, with imports of hamburger meat from a single country with an undetermined BSE risk. These commodities were imported under sanitary conditions that met requirements of Article 11.4.12 of the *Terrestrial Code*, and were either destined for human consumption or classified as safe commodities.

Overall, the Group considered that the conclusion of the entry assessment was that the risk that the BSE agent could have entered Ecuador during the interval covered by the assessment could be considered to be negligible.

- Risk of recycling and amplification of the BSE agent, and appropriate level of control and audit of the feed ban

The Group noted that live cattle were only imported for reproductive purposes and none of them were destined for feed production, and that all individuals that died were buried or incinerated.

The Group requested additional information regarding the definition and removal of SRM. Ecuador indicated that they defined SRM as tissues listed in Article 11.4.14. of the *Terrestrial Code*, and that these were not explicitly defined in any legal instrument. The Group noted that SRM were not removed from the routine slaughter subpopulation as they were of commercial value and intended for human consumption. SRM were removed and destroyed from animals found dead in the pen prior to slaughter or during transportation to the slaughterhouse and were intended for feed industry (i.e., for feed production for non-ruminants). In the event of BSE clinical suspects, the carcasses including the SRM were destroyed or buried.

In the additional information provided with respect to the methods used to produce MBM, Ecuador indicated that raw ruminant materials used in the production of MBM were rendered under high temperature and pressure (133°C for at least 20 minutes with a minimum absolute pressure of 3 bars) after being reduced to a maximum particle size of 50 mm as a part of good manufacturing practices. However, Ecuador acknowledged that a legal framework does not exist regarding procedures to reduce infectivity, and that the rendering plants were not subject to official supervision.

The Group noted that according to Article 1 of Resolution N° 088 (published in the Official Gazette N°309 of 19 April 2001), feeding ruminants with domestic or imported meat, bones and blood meal of ruminant origin was prohibited across the national territory. In response to a follow-up question, Ecuador clarified that as greaves were not considered to be part of ruminant feed, there was no legal instrument prohibiting their use.

Regarding the measures that prevent cross-contamination of cattle feed, the Group noted that, due to the husbandry system in Ecuador, natural pastures were used as the main source of ruminant feed, with plant-based protein supplements for high milk-yielding cows. Moreover, from the additional information, it was noted that feeding of ruminants with fish, poultry and pig proteins was also allowed, and that ruminant MBM was allowed for the feeding of non-ruminants.

The Group noted that there were feed mills producing both feed for ruminants and for non-ruminants. To avoid cross-contamination, raw materials were identified according to their content, separate production lines were established, and final products containing ruminant MBM and tallow were labelled as not suitable for ruminant consumption.

The Group took note that the measures in place to prevent cross-contamination in feed mills were verified through annual visual and documental official inspections by an external body and the verification procedure was supervised by the competent authority, as stipulated in Resolution 066, which was just published in 2017. Moreover, the Group noted that the Plant and Animal Health Regulation and Control Agency started to conduct sampling inspections on feed for ruminants since 2017, and that a small-scale pilot study in 2017 revealed no cases of cross contamination.

Overall, regarding the exposure assessment, the evidence provided was not sufficient to demonstrate that an appropriate level of control and audit of both rendering establishments and feed mills had been in place for at least eight years. Therefore, the Group concluded that the risk of recycling and amplification of the BSE agent if it was present in Ecuador's cattle population during the interval covered by the assessment could not be considered negligible before 2017. Nevertheless, the Group pointed out that in accordance with Article 11.4.2. Point 1 b. of the *Terrestrial Code*, as the entry assessment did not identify a risk factor, the outcome of the exposure assessment would not impact the outcome of the risk assessment.

b) Surveillance according to Articles 11.4.20. - 11.4.22.

The Group noted that the surveillance undertaken over a five-year-period from 2014 to 2018 exceeded the minimum requirements of type A surveillance according to Article 11.4.22. on surveillance for BSE in the *Terrestrial Code*. Based on the information provided in the dossier, 340,270.66 surveillance points were collected, compared to a minimal requirement of 300,000 for an adult cattle population over two years of age of 1,938,308.

The Group appreciated the information provided by Ecuador with regard to the methods of dentition to age their cattle.

The Group took note that Ecuador's surveillance programme for BSE targeted at least three of the four surveillance subpopulations every year, except in 2014 when only routine slaughter and clinical suspects were sampled. While samples mostly reflected the cattle distribution in the country, it was noted that Galapagos islands were not represented in the surveillance. The Group recommended that Ecuador include samples also from this area, if relevant, in its surveillance plan. The Group commented on the heavy reliance on the testing of clinical suspects to accumulate surveillance points, which account for 99.5% of the points accumulated to date. However, the Group considered that Ecuador's definition of clinical suspects was in accordance with Article 11.4.21. point 1 of the *Terrestrial Code*.

c) Other requirements — Article 11.4.2. points 2–4

▪ Awareness programme

The Group acknowledged that the awareness programme in Ecuador initiated in the last quarter of 2014 with a national coverage. The Group appreciated that this programme, which has been continuously applied, appeared to be both comprehensive and broad in scope, covering all relevant sectors, and acknowledged that it was supported by a range of materials including leaflets and booklets. The Group concluded that this awareness programme has met the requirements of Article 11.4.2 of the *Terrestrial Code* since 2014.

Moreover, the Group also appreciated the thorough BSE Contingency Plan for Ecuador provided as an annex. The document included general aspects of the disease, the organization of the official veterinary service and coordination with public and private entities involved, detailing their activities and responsibilities to be better prepared for the efficient and effective care of an emergency caused by BSE.

- Compulsory notification and investigation

The Group noted that BSE has been compulsorily notifiable throughout the country since 2014 (Resolution 214 issued in 2013 and published in 2014), but that no associated compensation or any penalties existed. Nonetheless, the Group concluded that the system for compulsory notification and investigation has met the requirements of the *Terrestrial Code* since 2014.

- Laboratory examination

The Group noted the official definitions for BSE suspect cases and positive cases used in Ecuador for the purpose of identifying BSE clinical suspects and confirming BSE cases. The Group acknowledged that BSE diagnosis was conducted in an accredited laboratory (Laboratorio de Diagnóstico Animal de la Agencia de Regulación y Control Fito y Zoonosanitario Tumbaco) using a commercial Western immunoblot test listed in the OIE Registry since 2014. Moreover, from the additional information provided by Ecuador, positive laboratory findings would be sent to an OIE reference laboratory for confirmation. The Group acknowledged that the diagnostic procedure has complied with Chapter 2.4.5. of the *Terrestrial Manual* since 2014. The Group recommended Ecuador participate in an external proficiency testing programme.

d) *BSE history in the country*

The Group acknowledged that BSE had never been reported in Ecuador.

e) *Compliance with the questionnaire in Article 1.6.5.*

The Group appreciated the well-structured and comprehensive dossier provided by Ecuador and agreed that the submitted dossier was compliant with the format of the questionnaire in Article 1.6.5. of the *Terrestrial Code*.

f) *Conclusions*

- Recommended status

Considering the information submitted in the dossier and Ecuador's answers to the questions raised, the Group concluded that the application was compliant with the requirements of Article 11.4.4. and with the BSE questionnaire of the *Terrestrial Code*. The Group therefore recommended that Ecuador be recognised as a country with a 'controlled BSE risk status'.

4.2. Other Member request

The Group assessed another request from a Member for the recognition of its BSE controlled risk status. The Group concluded that this Member did not meet the requirements of the *Terrestrial Code* and the corresponding Member was referred back to the dossier.

5. Prion disease in dromedary camels

In response to a request from the OIE Scientific Commission for Animal Diseases, the Group discussed if the 'camel prion disease' reported by Babelhadj et al. 2018¹ should be considered as an emerging disease based on the criteria listed in the *Terrestrial Code*.

¹ Babelhadj B, Di Bari MA, Pirisinu L, Chiappini B, et al. (2018) "Prion disease in dromedary camels, Algeria" *Emerging Infectious Diseases* 24(6):1029. Available at: https://wwwnc.cdc.gov/eid/article/24/6/17-2007_article

An emerging disease in the *Terrestrial Code* is defined as ‘a new occurrence in an animal of a disease, infection or infestation, causing a significant impact on animal or public health resulting from: a) a change of a known pathogenic agent or its spread to a new geographic area or species, or b) a previously unrecognised pathogenic agent or disease diagnosed for the first time’.

While the Group agreed that, within this context, the prion disease reported by Babelhadj and colleagues (2018) could be considered a disease diagnosed for the first time, it was acknowledged that there was insufficient scientific evidence to determine its impact on either animal or public health. The Group discussed the meaning of ‘significant impact’ in the OIE’s definition of emerging disease, and concluded that its evaluation should not just be based on a consideration of the number of animals potentially infected or the prevalence of disease.

The Group recalled the example of chronic wasting disease (CWD), where the impact on wild cervid populations may not be evident for decades. It was not until recently that it was proven that CWD had been driving population declines of wild mule deer and white-tailed deer over the last 30 years in parts of North America (Miller et al., 2008; Edmunds et al., 2016). The Group stressed that even though its geographic distribution kept on expanding each year, its importance had been overlooked.

The Group commended the scientific approach used by Babelhadj and colleagues (2018), and noted that the prevalence and impact of camel prion disease are yet to be investigated. From all accounts it is likely to have been underestimated in the camel population of Algeria, and probably other countries with dromedary camel populations. Considering that a misfolded prion protein had been identified as the causal agent, a potential risk for human and animal transmission cannot be excluded. Therefore, through an abundance of caution based on experiences with BSE and CWD, the Group concluded that this disease should not be overlooked and that it warrants further investigation.

For the aforementioned reasons, further investigations are needed to ensure a more comprehensive evaluation of the distribution and impact of camel prion disease on both animal and public health. The Group concluded that there is sufficient justification to consider it as an emerging disease and that it should be notified to the OIE, when detected by a Member, according to Article 1.1.4 of the *Terrestrial Code*. In addition, the Group recommended that Members pursue further investigation of the disease and gain more knowledge through research to monitor its presence in countries with camel populations as well as to clarify its likely origin and its zoonotic potential. However, considering that there were still significant gaps in the understanding of the epidemiology of the disease, the Group stressed that that Members should not be requested to implement specific control measures if an event was notified.

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.

Appendix I

**MEETING OF THE OIE AD HOC GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS EVALUATION
OF MEMBERS
Paris, 29 – 30 October 2018**

Terms of Reference

The OIE *ad hoc* Group on bovine spongiform encephalopathy (BSE) risk status of Members (the Group) is expected to evaluate the applications for official recognition of BSE risk status received from Members.

This implies that the experts, members of this Group, are expected to:

1. Sign off the updated OIE Undertaking on Confidentiality of Information in advance of the meeting of the Group and forward it to the OIE (disease.status@oie.int) at their earliest convenience and before they receive the working documents of the meeting.
 2. Complete the Declaration of Interests Form in advance of the meeting of the Group and forward it to the OIE at their earliest convenience and at least two weeks before the meeting.
 3. Evaluate the applications from Members for official recognition of BSE risk status:
 - a) Before the meeting:
 - read and study in detail all dossiers provided by the OIE;
 - take into account any other information available in the public domain that is considered pertinent for the evaluation of dossiers;
 - summarise the dossiers according to the *Terrestrial Animal Health Code* requirements, using the form provided by the OIE;
 - draft the questions whenever the analysis of the dossier raises questions that need to be clarified or completed with additional details by the applicant Member;
 - send the completed form and the possible questions to the OIE at least one week before the meeting (i.e., no later than 19 October 2018).
 - b) During the meeting:
 - contribute to the discussion with their expertise;
 - withdraw from the discussions and decision making when possible conflict of interest;
 - provide a detailed report to recommend to the Scientific Commission for Animal Diseases the country(ies) or *zone(s)* to be recognised (or not) as having a BSE risk status and to indicate any information gaps or specific areas that should be addressed in the future by the applicant Member.
 - c) After the meeting:
 - contribute electronically to the finalisation of the report if not achieved during the meeting.
 4. Considering a paper on the detection of prion disease in dromedary camels, provide:
 - a) an opinion on whether this disease should be considered as an emerging disease as defined in the *Terrestrial Code*, and if so
 - b) recommendations for the correct monitoring of the event in potentially affected countries.
-

Appendix II

**MEETING OF THE OIE AD HOC GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS EVALUATION
OF MEMBERS
Paris, 29 – 30 October 2018**

Agenda

1. Opening
 2. Adoption of the agenda and appointment of chairperson and rapporteur
 3. Evaluation of applications from a Member for the official recognition of its negligible bovine spongiform encephalopathy (BSE) risk status
 - a. Serbia
 4. Evaluation of application from two Members for official recognition of their controlled BSE risk status:
 - a. Ecuador
 - b. Other Member
 5. Detection of prion disease in dromedary camels
 6. Adoption of the report
-

Appendix III

**MEETING OF THE OIE AD HOC GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS EVALUATION
OF MEMBERS
Paris, 29 – 30 October 2018**

List of participants

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**MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION
OF CONTAGIOUS BOVINE PLEUROPNEUMONIA STATUS OF MEMBERS
Paris, 13 – 14 November 2018**

A meeting of the OIE *ad hoc* Group on the Evaluation of Contagious bovine pleuropneumonia (CBPP) Status of Members (hereafter the Group) was held at the OIE Headquarters from 13 to 14 November 2018.

1. Opening

Dr Min Kyung Park, Deputy Head of Status Department, welcomed and thanked the Group for its commitment and its extensive support towards the OIE in fulfilling the mandates given by Members. Dr Park also thanked and welcomed Dr Alec Bishi who was participating throughout the meeting electronically.

Dr Park reminded the Group on the sensitivity and confidentiality of the dossiers received for official recognition and thanked the experts for having signed the forms for undertaking of confidentiality. Dr Park reminded the experts on the OIE procedures for protecting the confidentiality of information and for declaring potential conflicts of interest (by withdrawing themselves from the discussion/conclusion in case of a potential conflict of interest).

Dr Park highlighted the importance of the quality of the report that will be scrutinised by Members, before adopting the proposed list of countries and zones free from CBPP.

Dr Park introduced Drs Marija Popovic and Hernan Oliver Daza, responsible for the activities related to official status recognition for CBPP.

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

The Group was chaired by Dr François Thiaucourt and Dr Flavio Sacchini acted as rapporteur, with the support of the OIE Secretariat. The Group endorsed the proposed agenda.

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

3. Evaluation of requests from Members for the status recognition of CBPP free countries

a) Peru

In September 2018, Peru submitted a dossier for the official recognition of its CBPP free status based on historical grounds.

The Group requested additional information and received clarification from Peru.

i) Animal disease reporting

The Group acknowledged that Peru had a record of regular and prompt animal disease reporting and that CBPP was a notifiable disease for at least the past 10 years in accordance with Article 1.4.6. of the *Terrestrial Animal Health Code (Terrestrial Code)*.

The Group took note that the Veterinary Services of Peru published the animal disease epidemiology reports each week on its website. The Group was informed from the dossier that the reporting system provided information on notifiable disease occurrence (suspected and confirmed), as well as on localisation, progressive notification number, number of susceptible animals, number of cases, number of deaths, confirmed laboratory results and disease distribution map of the country.

The Group acknowledged that the notification system was supported by a legal framework with national legislation listing the notifiable diseases in the country and establishing the obligation to notify any suspicion or detection of disease within twelve hours to the competent authority. The Group also noted Resolution 881 of the Andean Community of Nations (CAN) that establishes a list of exotic diseases for the Andean sub-region, which includes CBPP.

ii) *Veterinary Services*

The Group noted that the Veterinary Services was in charge of conducting zoosanitary surveillance activities based on notifications for any suspected cases of notifiable and exotic diseases in the country.

The Group took note that at central level, activities were regulatory and strategically managed through the following bodies: i) Sub-directorate of Risk Analysis and Epidemiological Surveillance responsible for implementing and maintaining the Integrated System for Animal Health Management (SIGSA), providing weekly epidemiological information on notifiable diseases and laboratory confirmation; ii) Sub-Directorate of Animal Quarantine responsible for control and inspection of livestock imports, as well as of products and by-products of animal origin. It also oversees the internal movements of livestock at the national level; and iii) Sub-directorate for Disease Control and Eradication responsible for implementation of actions for prevention, control and eradication of diseases prioritised by the Veterinary Services at regional and sub-regional level.

The Group also noted that the Veterinary Services of Peru relies on 25 decentralised Executive Directorates or Decentralised Agencies to coordinate the implementation of the general policy and plans for animal disease control and surveillance at the regional and sub-regional level. Peru informed in its dossier that each decentralised body had a staff responsible for carrying out animal health interventions at the field level.

iii) *Situation of CBPP in the past 24 months*

The Group acknowledged that CBPP has never been reported, and therefore Peru was eligible for historical freedom from CBPP as described in Article 1.4.6. of the *Terrestrial Code*.

iv) *Absence of vaccination in the past 24 months*

The Group noted that the importation of vaccine against CBPP was prohibited and no vaccination against CBPP had ever been implemented in Peru.

v) *Surveillance in accordance with Articles 11.5.13. to 11.5.17.*

The Group acknowledged that there was no specific surveillance for CBPP due to the fact that CBPP had never been reported in Peru. The Group noted that within 24 hours of receiving notification of a suspected outbreak of a disease, a specialist had to record all the information gathered and required by the SIGSA. The Group took note that this information included, sample collection and laboratory investigations following an established procedure. Peru informed the Group that the samples would be immediately sent to the Animal Health Diagnostic Centre (UCDSA) for safekeeping until they could be sent to an OIE Reference Laboratory for CBPP diagnosis.

Peru informed that the UCDSA of the Veterinary Service did not perform CBPP diagnosis and no private laboratory was authorised to perform CBPP diagnostic tests. Additionally, the Group noted that laboratories were not authorised to manipulate live *Mycoplasma mycoides* subspecies *mycoides* (Mmm).

The Group was concerned that the Veterinary Services did not have arrangements already established with a competent laboratory for CBPP confirmation (i.e. formal agreements with OIE Reference Laboratories for CBPP or other regional laboratories). The Group therefore recommended that Peru establish a clear procedure – indicating responsibilities, tasks, sampling procedures, sample management and storage, shipping and timelines – as well as to organise specific trainings for all laboratories supporting the Veterinary Service to ensure awareness of the protocol to be followed in case of CBPP suspicions.

The Group acknowledged that there was a veterinarian responsible for each slaughterhouse conducting *ante- and post-mortem* inspections; any suspicious clinical signs or pathological lesions would be reported to the Veterinary Services within 12 hours following the detection of suspicions and sampled for laboratory testing.

Whilst details were not given on the number of lung samples taken for laboratory testing for mycoplasma isolation or for other differentials for pneumonia in cattle such as *Pasteurella* or *Mannheimia*, the Group acknowledged that the risk of introduction was negligible and the described measures in place were sufficient.

Overall, the Group agreed that pathological surveillance was sufficient to substantiate the absence of CBPP.

vi) *Regulatory measures for the prevention and early detection of CBPP*

The Group acknowledged that in accordance with the CAN Decision 195 (25 November 1983), the importation of live animals and semen in this sub-region was prohibited from all CBPP infected countries. The Group noted that the procedures for the import of live animals included inspection of documents followed by quarantine and issuance of an Internal Transit Health Certificate (CSTI) that allows tracing back of imported animals. The Group also noted that movement of animals was registered in the SIGSA. The Group was informed that the personnel at the control posts are required to update and register information in the SIGSA to provide regarding the animals entering the country.

The Group noted the involvement and different roles of the public and private sectors in disease surveillance. Peru informed that in case of a suspicion of CBPP, the affected premise would immediately be put under restriction with disinfection of the facilities pending the release of the laboratory results. The Group noted that in case of confirmation of CBPP, Peru would implement additional sanitary measures such as quarantine, declaration of a sanitary emergency, and a stamping out policy. However, the Group was concerned as there was no information provided if such a protocol was officially written and if there was any legal document specifying these steps.

Whilst the Group noted that there was no unique animal identification system, all cattle subjected to movement were required to be identified and to be inspected for the issuance of a CSTI. Data generated from the CSTI are registered in SIGSA and accessible for epidemiological investigations. The Group acknowledged that the Veterinary Services have established 54 Quarantine Control Posts throughout the country which were strategically located according to livestock movement-patterns and production systems.

vii) *Compliance with the questionnaire in Article 1.10.1.*

The Group agreed that Peru's dossier was compliant with the questionnaire in Article 1.10.1. of the *Terrestrial Code*.

Conclusion

Considering the information submitted in the dossier and the answers received from Peru to the questions raised, the Group considered that the application was compliant with the requirements of Chapter 11.5., Article 1.4.6., and with the questionnaire in Article 1.10.1. of the *Terrestrial Code*. The Group therefore recommended that Peru be recognised as a country historically free from CBPP.

The Group recommended that information on the following be submitted to the OIE when Peru reconfirms its CBPP status (also detailed in the relevant sections above):

- Adjusted contingency plan including the chain of actions specifically targeted to CBPP, from the point of detection of clinical suspicion, immediate diagnosis for agent isolation and confirmation using molecular techniques (i.e. PCR), to the point of implementation of control measures;
- Demonstrate evidence of awareness programmes and trainings for CBPP and their effectiveness.

b) Uruguay

In September 2018, Uruguay submitted a dossier for the official recognition of its CBPP free status based on historical grounds.

The Group requested additional information and received clarification from Uruguay.

i) Animal disease reporting

The Group acknowledged that Uruguay had a record of regular and prompt animal disease reporting and that CBPP was a notifiable disease for at least the past 10 years in accordance with Article 1.4.6. of the *Terrestrial Animal Health Code (Terrestrial Code)*.

The Group acknowledged that all persons of public and private sectors dealing with animals were responsible for notifying occurrence of animal diseases and that this information was registered in a National Information System for Animal Health (SISA).

ii) Veterinary Services

The Group noted that the Veterinary Service of Uruguay was the competent animal health authority for planning and implementing animal health programmes for the prevention, monitoring, control and eradication of animal diseases. From the information in the dossier, the Group noted that the Veterinary Service of Uruguay was divided as follows:

- Animal Health Division (DSA) responsible to maintain, protect and improve the health of the animals as well as to carry out the control and certification of sanitary and hygienic-sanitary conditions of the entry, import and export of animals, genetic material, products and by-products of animal origin. DSA includes 19 regional offices and 22 local offices distributed in six regions;
- Animal Industry Division in charge of guaranteeing conformity and safety of meat, meat products, by-products, derivatives and other foods of animal origin for export and non-export; and
- Veterinary Laboratories Division (DILAVE) responsible for laboratory diagnostic support to the Veterinary Service. DILAVE has a central laboratory in Montevideo and three regional laboratories.

From the dossier, the Group was informed that there was coordination between public and private veterinarians through the National System of Accreditation of Independent Veterinarians aimed at improving efficiency and optimising the use of resources in the delivery of animal health services. The Group noted that this accreditation programme included the active participation of veterinary professionals in animal health programmes, support in animal health emergencies, collaboration in epidemiological surveillance and certification for national, regional and international markets.

Overall, the Group considered that the Veterinary Services had current knowledge of and authority over the livestock population in the country.

iii) *Situation of CBPP in the past 24 months*

The Group acknowledged that no cases of CBPP were registered in the past 25 years and therefore, Uruguay would be eligible for historical freedom from CBPP as described in Article 1.4.6. of the *Terrestrial Code*. The Group also noted that the two neighbouring countries were officially recognised as free from CBPP.

iv) *Absence of vaccination in the past 24 months*

The Group acknowledged that the manipulation or possession of etiological agents of diseases that did not exist in the country was prohibited as per legislation since 21 May 1997.

v) *Surveillance in accordance with Articles 11.5.13. to 11.5.17.*

The Group noted that disease surveillance at the farm level was carried out by the DSA through its local and regional offices. Uruguay reported that these activities consisted of inspection of livestock establishments, animal assembly points, animal transit controls and monitoring of suspected cases of disease. The Group noted that clinical inspections were systematically carried out by accredited veterinarians and by the official service during the movement of animals for slaughter in exporting meat plants and for the field. The Group also noted that controls on animals were performed before animal movements within the national territory, for domestic supply, fairs, shows, passage through official health posts, or for activities determined by other health programmes. The Group highlighted the importance of pathological surveillance as the most effective approach for CBPP surveillance and emphasised that all suspect lesions detected at the slaughterhouses should be followed up by laboratory testing.

The Group noted that CBPP diagnosis was not performed in the country. Uruguay informed that in case of CBPP suspicion, samples would be sent to an OIE Reference Laboratory for CBPP and provided details of the procedure describing the collection, submission and shipment of samples for the confirmation of *Mycoplasma mycoides* subspecies *mycoides* (Mmm).

The Group noted that the Veterinary Service of Uruguay had different information systems to support disease monitoring and surveillance activities. Uruguay mentioned that a National Livestock Information System (SNIG) was in place which showed the distribution of livestock population and ensured the traceability of cattle from the establishment of origin to the customs or cold storage facility for meat. The Group noted that all information related to livestock was registered in the system and could be used for epidemiological investigation in case of suspected animal disease or outbreaks. Additionally, the Group took note that the SISA was used to manage the occurrence of animal diseases including CBPP in the country.

The Group considered that taking into account altogether the measures implemented by Livestock Controller Department and through the SNIG, Uruguay would guarantee animal traceability in case of potential disease outbreaks.

vi) *Regulatory measures for the prevention and early detection of CBPP*

The Group considered that mandatory notification, passive clinical and pathological surveillance together with the monitoring carried out during other animal health programmes (e.g. for foot and mouth disease, brucellosis, etc.) should allow a constant supervision of the animal health status.

The Group noted that the prevention system relied on importation of animals only from countries officially recognised free from CBPP.

The Group took note that the National Health Emergency System (SINAESA) was established in 2009 to carry out the activities required for the rapid control and eradication of exotic diseases. The Group also noted that the SINAESA was the specific and permanent authority responsible for coordination of public institutions in Uruguay regarding disaster risk management. However, the Group noted that there was no specific emergency plan for CBPP. The Group took note of the general measures to be applied in case of CBPP outbreak, which included access restrictions, isolation, quarantine,

disinfection, disposal of animals, restrictions on the movement of animals, bans on livestock events, use of biological measures (vaccination or sera), marking of animals, treatment, sanitation, partial or total sanitary culling. The Group appreciated that there was specific funding allocated in case of an emergency as well compensation to farmers.

vii) *Compliance with the questionnaire in Article 1.10.1.*

The Group agreed that Uruguay's dossier was compliant with the questionnaire in Article 1.10.1.

Conclusion

Considering the information submitted in the dossier and the answers received from Uruguay to the questions raised, the Group considered that the application was compliant with the requirements of Chapter 11.5., Article 1.4.6. and with the questionnaire in Article 1.10.1. of the *Terrestrial Code*. The Group therefore recommended that Uruguay be recognised as a country historically free from CBPP.

The Group recommended that information on the following be submitted to the OIE when Uruguay reconfirms its CBPP status (also detailed in the relevant sections above):

- Adjusted contingency plan including the chain of actions specifically targeted to CBPP, from the point of detection of clinical suspicion, immediate diagnosis for agent isolation and confirmation using molecular techniques (i.e. PCR), to the point of implementation of control measures;
- Demonstrate evidence of awareness programmes and trainings for CBPP and their effectiveness.

c) Other request

The Group assessed one additional request from a Member for the recognition of CBPP free country status. The Group concluded that the Member did not meet the requirements of the *Terrestrial Code* and the dossier was referred back to the respective applicant Member.

4. Other matters

The Group recommended to the OIE to develop guidelines on preparation of contingency plans, and possibly targeted to specific diseases including for CBPP.

The Group noted that the taxonomy of the pathogenic agent causing CBPP was not harmonised with the new nomenclature within the OIE documents, and strongly recommended to adjust the current taxonomy.

5. Adoption of report

The Group reviewed the draft report and agreed to circulate it electronically for comments before the final adoption. Upon circulation, the Group agreed that the report captured the discussions.

.../Appendices

Appendix I**MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION
OF CONTAGIOUS BOVINE PLEUROPNEUMONIA STATUS OF MEMBERS****Paris, 13 – 14 November 2018**

Terms of Reference

The OIE *ad hoc* Group on contagious bovine pleuropneumonia (CBPP) status of Members (the Group) is expected to evaluate the applications for official recognition of CBPP free status and for endorsement of their official control programme of CBPP received from three Members in accordance with the Standard Operating Procedure for official recognition of disease status and for the endorsement of national official control programmes.

This implies that the experts, members of this Group are expected to:

1. Sign off the OIE Undertaking on Confidentiality of information, if not done before.
 2. Complete the Declaration of Interests Form in advance of the meeting of the Group and forward it to the OIE at the earliest convenience and at least two weeks before the meeting.
 3. Evaluate the applications from Members for official recognition of CBPP free status and for endorsement of their official control programmes for CBPP.
 - a) Before the meeting:
 - read and study in detail all dossiers provided by the OIE;
 - take into account any other information available in the public domain that is considered pertinent for the evaluation of dossiers;
 - summarise the dossiers according to the *Terrestrial Animal Health Code* requirements, using the form provided by the OIE;
 - draft the questions whenever the analysis of the dossier raises questions which need to be clarified or completed with additional details by the applicant Member;
 - send the completed form and the possible questions to the OIE, at least one week before the meeting.
 - b) During the meeting:
 - contribute to the discussion with their expertise;
 - withdraw from the discussions and decision making when possible conflict of interest;
 - provide a detailed report in order to recommend, to the Scientific Commission for Animal Diseases, i) the country(ies) or zone(s) to be recognised (or not) as CBPP free ii) country(ies) to have (or not) the OIE endorsement of national official control programme for CBPP, and to indicate any information gaps or specific areas that should be addressed in the future by the applicant Member.
 - c) After the meeting:
 - contribute electronically to the finalisation of the report if not achieved during the meeting.
-

Appendix II

**MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION
OF CONTAGIOUS BOVINE PLEUROPNEUMONIA STATUS OF MEMBERS
Paris, 13-14 November 2018**

Agenda

1. Opening
 2. Adoption of the agenda and appointment of chairperson and rapporteur
 3. Evaluation of applications from Members for official recognition of contagious bovine pleuropneumonia (CBPP) free status
 - Peru
 - Uruguay
 - Other request
 4. Other matters
 5. Adoption of report
-

Appendix III

MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION OF CONTAGIOUS BOVINE PLEUROPNEUMONIA STATUS OF MEMBERS

Paris, 13-14 November 2018

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**REPORT OF THE SECOND MEETING OF THE OIE AD HOC GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT
Paris, 20-22 November 2018**

The OIE *ad hoc* Group on bovine spongiform encephalopathy (BSE) risk assessment (hereafter the Group) met for the second time from 20 to 22 November 2018 at the OIE Headquarters to continue providing 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 Neo Mapitse, Head of Status Department, welcomed the Group on behalf of Dr Monique Eloit, Director General of the OIE. He reported that the OIE Scientific Commission for Animal Diseases (Scientific Commission) supported the direction taken by the Group at its July 2018 meeting with regard to the revision of the risk-based provisions for the categorisation of official BSE risk status, and commended the Group for its achievements to date.

Dr Mapitse reminded the Group that the remaining issues to be addressed were as follows:

- Finalisation of the revision of Chapter 11.4. of the *Terrestrial Animal Health Code (Terrestrial Code)*. To do so, he encouraged the Group to take into consideration the recommendations of the OIE *ad hoc* Group on BSE surveillance which met in October 2018 and which works jointly with the present Group to achieve a comprehensive revision of the BSE standards. He also recommended the Group to give careful consideration to the recommendations of the OIE *ad hoc* Group on BSE which met in August 2016, in particular with regard to the revision of trade requirements;
- Revisions of Chapter 1.8. - Application for official recognition by the OIE of risk status for BSE (i.e., “BSE Questionnaire”). For this, he emphasised that the BSE Questionnaire was a key tool for Members to document compliance with the requirements for the official recognition of a BSE risk status, and that a clear and concise questionnaire would not only support Members in providing well-documented dossiers, but would also consequently assist the OIE and the experts during the evaluation of the dossiers;
- Revision of the requirements for the maintenance of an official BSE risk status, including the BSE annual reconfirmation form.

Lastly, Dr Mapitse, thanked the experts for having signed the forms for undertaking of confidentiality and declaration of conflicts of interest, and noted that no potential conflict in the revision of BSE Standards was declared.

Dr Matthew Stone, OIE Deputy Director General for International Standards and Science, visited the Group during its meeting, and expressed the appreciation of the OIE of the extensive work being conducted in conjunction with the OIE *ad hoc* Group on BSE surveillance. Acknowledging the complexity and sensitivity of the issues being addressed, he commended the Group for its efforts to explain the detailed rationale supporting its proposals and recommendations in its meeting reports for the consideration of Members.

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

Dr Noel Murray was appointed Chair and Dr Stephen Cobb was the 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. Revision of Chapter 11.4

3.1. General provisions (Article 11.4.1.)

The Group highlighted the uncertainty associated with the origin of all BSE agents, including atypical BSE, the potential transmissibility of atypical BSE through contaminated feed and any zoonotic risk that might result from the recycling of atypical BSE agent in ruminant feed. The Group agreed that these considerations should be emphasised in Article 11.4.1. as they support some of the revised provisions proposed in Article 11.4.2. and Article 11.4.3. (see sections 3.2. and 3.3.a.v. of this report). Experts volunteered to provide a literature review on the risks of transmission of atypical BSE to be presented at the next meeting.

Currently, Chapter 11.4. states in Article 11.4.1. “For the purposes of official BSE risk status recognition, BSE excludes ‘atypical BSE’ as a condition believed to occur spontaneously in all cattle populations at a very low rate”. The group acknowledged that while the eradication of classical BSE might be feasible assuming its transmissibility via contaminated feed, the eradication of atypical BSE might remain elusive if cases occur spontaneously. Consistent with the Group’s proposed revisions from its previous meeting in July and to avoid confusion, reference to occurrence of a case of atypical BSE in relation to a country’s official BSE risk status should be made in Article 11.4.2 rather than in Article 11.4.1. While the occurrence of a case of atypical BSE, regardless of the origin of each case, would not impact a country’s BSE risk status by itself, it is nevertheless important to consider the potential recycling of all BSE agents, including atypical BSE, in the exposure assessment (as emphasised in the following section in the report). As a result, atypical BSE is not disregarded in the recognition of a country’s BSE risk status as the existing Article 11.4.1 implies. The Group therefore recommended removing this statement and clarifying in Articles 11.4.2. and 11.4.3. how atypical BSE should be addressed.

3.2. Provisions applicable to the BSE risk status of the cattle population of a country, zone or compartment (Article 11.4.2.)

According to the current provisions of Article 11.4.2. point 1.b., an exposure assessment should be conducted if a risk factor is identified by the entry assessment (i.e., “*If the entry assessment identifies a risk factor, an exposure assessment should be conducted*”).

As emphasised by the Group at its July 2018 meeting, and in the previous section of this report, because of the significant uncertainty regarding the likelihood of the recycling of the atypical BSE agent, an assessment of the likelihood of the cattle population being exposed to the BSE agents (classical or atypical) should be performed regardless of the outcome of the entry assessment.

3.3. Provisions applicable to the categorisation of official BSE risk status (Articles 11.4.3. to 11.4.5.)

At its first meeting, the Group began drafting the provisions applicable to the recognition of BSE risk status (Articles 11.4.3. to 11.4.5.). These provisions were complemented by the *ad hoc* Group on BSE surveillance which drafted recommendations on the surveillance for BSE to be implemented in support of the recognition and maintenance of negligible and controlled BSE risk status.

The Group addressed outstanding issues and continued the revision of Articles 11.4.3. to 11.4.5., as follows.

a) Negligible BSE risk (Article 11.4.3.)

i. Risk assessment

As emphasised in draft Articles 11.4.2. and 11.4.3., the determination of a BSE risk status should be based on a risk assessment. The Group clarified that the assessment should evaluate the likelihood of the BSE agents (classical and atypical) entering the country or zone and being present and recycled in the cattle population leading to the exposure of indigenous cattle to the infectious agent, taking into consideration the impact of livestock industry practices or the measures that have been implemented to mitigate any identified risk factors.

ii. Pathways to achieve a negligible likelihood of the BSE agent (classical or atypical) being recycled in the cattle population

At its July 2018 meeting, the Group proposed that one pathway to achieve a negligible BSE risk status would be through a negligible likelihood of the BSE agent being recycled in the cattle population as a result of “husbandry and farming practices”. The Group further discussed this pathway and determined that husbandry and farming practices alone may not sufficiently allow the assessment of the likelihood of the BSE agent being recycled in the cattle population. For instance, the details of feeding, slaughtering and rendering practices would also need to be assessed. The Group therefore clarified that broader “livestock industry practices” should be taken into consideration to fully characterise a BSE risk status. The details of livestock industry practices to be considered were described in draft Chapter 1.8.

iii. Duration to be covered by the risk assessment, surveillance, and risk mitigating measures

The Group discussed the time period that the risk assessment, the surveillance programme, and the risk mitigating measures should cover to demonstrate a negligible BSE risk status. Consistent with previous *ad hoc* Groups on BSE, the Group recommended that an eight-year period would be appropriate considering that the upper 95th percentile incubation period for classical BSE is estimated to be seven years, and that the risk should have been mitigated for more than an incubation period. It was noted that in countries at the tail of the BSE epidemic, the incubation period may (artificially) appear to be longer as a result of the control measures that have been implemented. However, this should not be considered to be a globally applicable trend and would not justify a revision of the time period to be covered by the risk assessment and the risk mitigating measures.

In accordance with the recommendation of the *ad hoc* Group on BSE surveillance, the Group determined that to improve the consistency of BSE standards, it would be appropriate that the duration for which surveillance has been conducted prior to the official recognition of a BSE risk status be aligned with the duration for which the BSE risk should have been effectively mitigated (i.e., 8 years).

iv. Demonstration of the implementation of a ruminant-to-ruminant feed ban

The Group reviewed the provisions drafted at its July 2018 meeting which proposed that a risk assessment should have demonstrated that either the likelihood of cattle population being exposed to BSE agents has been negligible as a result of its livestock industry practices or each identified risk has been effectively and continuously mitigated, and, in addition, it should be demonstrated that neither meat-and-bone meal nor greaves derived from ruminants have been fed to ruminants. The Group re-affirmed their agreement that a feed ban may not always need to be legislated to provide an appropriate level of assurance.

While reviewing draft Article 11.4.2., some experts denoted that point 2 (i.e., “*It has been demonstrated through documented evidence that for at least 8 years neither meat-and-bone meal nor greaves derived from ruminants have been fed to ruminants*”) was, to a certain extent, redundant with point 1 (i.e., “*A risk assessment as described in Article 11.4.2., has been conducted and the Member Country has demonstrated that, for at least 8 years, either the likelihood of cattle population being exposed to BSE agent is negligible as a result of its husbandry and farming practices, or each identified risk has been effectively and continuously mitigated*”). Indeed, should meat-and-bone meal or greaves derived from ruminants have been fed to ruminants, the likelihood of cattle population being exposed to BSE agents would not be negligible as a result of its livestock industry practices, nor would each risk of exposure have been mitigated. These experts were of the opinion that the focus should be on the outcome of the consequence assessment, which is the likelihood of, and the extent of, any recycling of the BSE-agent in the cattle population. In consequence, it would not be necessary to have an independent provision under Article 11.4.3. explicitly requesting a feed ban.

Some other experts were of the opinion that it was justified to place an unambiguous emphasis on the need to demonstrate that neither meat-and-bone meal nor greaves derived from ruminants have been fed to ruminants, since (i) the presence of the atypical BSE agent in cattle populations is potentially ubiquitous, (ii) the oral route is the main route of transmission of classical BSE in cattle, and (iii) feed bans have proven to be effective in restricting BSE spread.

The Group could not reach a consensus on whether the need for a Member to demonstrate the implementation of a feed ban should be explicitly stated as an independent point within Article 11.4.3. (i.e., a separate point to the provision on risk assessment) or if it would be sufficient to rather implicitly consider it within the risk assessment (i.e., by indicating that the risk assessment should demonstrate a negligible likelihood of recycling). The Group decided that this issue would be further discussed at the next meeting.

v. *Impact of the occurrence of case(s) of BSE*

According to the current provisions of Article 11.4.3., the occurrence of a single indigenous case of classical BSE born less than 11 years ago not only prevents the recognition, but also leads to the suspension, of a negligible BSE risk status. The Group re-affirmed the opinion expressed at its July 2018 meeting that this requirement was not proportionate to the risk.

Considering that the occurrence of cases of atypical BSE and of imported cases of classical BSE would not necessarily imply a change in livestock industry practices nor a breach in the effective mitigation measures of identified risks in the country or zone, the Group recommended that these occurrences should not impact the official recognition or maintenance of a negligible BSE risk status, as long as those cases are completely destroyed. Consistent with the previous recommendations of the OIE *ad hoc* Group on BSE which met in August 2016, the Group agreed that the destruction of cases of atypical BSE was necessary to mitigate the potential risk of recycling and amplification of the atypical BSE agent in the feed chain.

Regarding the occurrence of indigenous cases of classical BSE, as emphasised in the report of the July 2018 meeting of the Group, the current requirement covering an 11-year period is neither considered proportionate to the risk nor is supported by robust scientific evidence. The Group therefore recommended that, in support of the recognition of a negligible BSE risk status, it would be reasonable to require that indigenous cases of classical BSE have not been born within the preceding eight years, which corresponds to at least 95% of the incubation period for classical BSE and ensures consistency with the time period recommend for surveillance and the implementation of risk mitigation measures.

With regard to the impact of the occurrence of indigenous cases of classical BSE in animals born less than 8 years ago in countries or *zones* recognised as having a negligible BSE risk status, the Group recommended that negligible BSE risk status could be maintained provided an investigation on the conditions of livestock industry practices or the measures for the effective and continuous mitigation of each identified risk, confirms that the likelihood of the BSE agent

being recycled within the cattle population continues to be negligible. Pending the outcome of such an investigation following the confirmation of a diagnosis of classical BSE, the negligible BSE risk status would be suspended and the conditions for a controlled BSE risk status would apply. In accordance with the OIE Standard Operating Procedures on suspension, recovery or withdrawal of official status, the outcome of the investigation would have to be favourably assessed by the Scientific Commission, within a maximum of 2 years after the detection of the case, for the negligible BSE risk status to be re-instated.

The Group took note that the revised Article 11.4.3. point 2.b. would need to be further revised to clearly state that if there has been an indigenous case of classical BSE in an animal born 8 or less years ago in a country or zone already recognised with a negligible BSE risk status, the Member could retain the status as long as an investigation confirms that the likelihood of the BSE agent being recycled within the cattle population remained negligible.

b) *Controlled BSE risk (Article 11.4.4.)*

The Group re-affirmed that for recognition as controlled BSE risk status, all of the requirements of Article 11.4.3. should be in place, but at least one of them has not been met for the preceding eight years.

c) *Undetermined BSE risk (Article 11.4.5.)*

The Group was informed that whilst undetermined BSE risk status is a default category for countries or zones that have not submitted an application for recognition of a BSE risk status or for those countries whose applications have not met the requirements for neither controlled nor negligible BSE risk, some Members have expressed confusion on the conditions associated with being identified as posing an undetermined BSE risk. The Group reviewed the definition of an undetermined BSE risk as proposed in their previous meeting (i.e., “*The BSE risk arising from the cattle population of a country, zone or compartment can be considered to be undetermined if it cannot be demonstrated that it meets the requirements of another category*”), and recognised that the statement “*can be considered to be undetermined*” might be a source of confusion. The Group clarified that, if a BSE risk is not recognised as negligible or controlled, then it is considered undetermined. Article 11.4.5. was revised accordingly.

d) *Surveillance (Article 11.4.20.)*

The representatives of the Specialist Commissions, expressed their agreement with the recommendations of the *ad hoc* Group on BSE surveillance that a points-based surveillance system could no longer be justified, and concurred that a baseline level of passive surveillance for BSE should be continuously implemented to identify cattle with a clinical presentation consistent with BSE, and the elimination of the requirements to conduct active surveillance on the risk groups (i.e., fallen stock and casualty slaughter) and on animals from the healthy slaughter subpopulation destined for human consumption. It was noted that the proper implementation of a sensitive passive surveillance program for BSE should be monitored and documented.

The Group took note of the report of the meeting of the *ad hoc* Group on BSE surveillance, and the main conclusions of this Group were outlined by the chair. The Group determined that it would undertake a more detailed review of Article 11.4.20. on Surveillance at its next meeting.

4. Revision of Chapter 1.8. (Application for official recognition by the OIE of risk status for BSE)

The Group built on the recommendations outlined in section 5 of the report of its July 2018 meeting to undertake a detailed revision of the “BSE Questionnaire” (Chapter 1.8.) consistent with the proposed changes to Articles 11.4.2. to 11.4.4. pertaining to the categorisation of BSE risk status.

The Group agreed that the revised questionnaire should be more concise but still comprehensive enough to support a fully informed assessment of compliance with the requirements for the recognition of a BSE risk status defined in Articles 11.4.3. and 11.4.4.

The experience of the experts of the Group who also participate in the OIE *ad hoc* Group on BSE Risk Status Evaluation of Members assessing applications for official recognition was useful to highlight sections of the current questionnaire that lack clarity and are commonly misinterpreted by applicant Members, that are not comprehensive enough to support a fully informed assessment, or, that are not relevant for an evaluation of the BSE risk status.

As defined in current Article 11.4.3., a BSE risk assessment described in Article 11.4.2. should be conducted and documented by the applicant Member. However, based on the experience of the OIE *ad hoc* Group on BSE Risk Status Evaluation of Members, applicant Members tend to provide extensive amounts of data, information, tables, and figures in their applications without undertaking a risk assessment. The Group extensively debated if the revised questionnaire should explicitly require the applicant Member to perform and document a risk assessment, or alternatively, if the questionnaire should require specific data to allow the *ad hoc* Group on BSE Risk Status Evaluation of Members to perform the risk assessment. The Group would refine the type, amount and granularity of the data and information to be included in the questionnaire at its next meeting.

4.1. Article 1.8.1. Veterinary system

Consistent with the current provisions of the BSE Questionnaire, the Group agreed that compliance of the Veterinary Services with the provisions of Chapters 1.1. (Notification of diseases, infections and infestations, and provision of epidemiological information), 3.1. (Veterinary Services) and 3.2. (Evaluation of Veterinary Services) of the *Terrestrial Code* would importantly contribute to achieving official recognition of a BSE risk status. However, the Group pointed out the difficulty of thoroughly assessing these horizontal capacities through the BSE questionnaire. The Group advised that, when possible, recent (i.e., not older than five years) Performance of Veterinary Services (PVS) Evaluation Reports, Evaluation Follow-up Reports and Gap Analyses should be provided to the OIE *ad hoc* Group on BSE Risk Status Evaluation of Members, in line with the Standard Operating Procedures for official recognition of disease status of Members, highlighting the information that supports compliance with the requirements for the requested risk status.

4.2. Article 1.8.2. Risk assessment

a) *Entry assessment*

The Group re-affirmed its previous position that detailed quantitative information (e.g., volume, statistics, etc.) on imported commodities was not informative for the entry assessment as long as they were either imported under conditions consistent with the recommendations laid out in Chapter 11.4. or where it can be demonstrated that an equivalent level of assurance was provided. The emphasis should be on documenting the measures applied to imported commodities depending on the BSE risk status of the country or zone of origin together with how the Competent Authority verifies compliance through supporting legislation, certification, and regulations.

The Group noted that in the Glossary of the *Terrestrial Code*, meat-and-bone meal is defined as “the solid protein products obtained when animal tissues are rendered, and includes any intermediate protein product other than peptides of a molecular weight less than 10,000 daltons and amino-acids”. The Group wondered if for the purposes of the Chapters 1.8. and 11.4., meat-and-bone meal and greaves should be defined differently. Two experts volunteered to propose revised definitions and to evaluate if these should apply to Chapters 1.8. and 11.4. only or throughout the *Code* (i.e., implying a revision of the Glossary definition). The outcome of this review will be presented at the next meeting.

The Group discussed the list of imported commodities which should be addressed in the entry assessment in light of their possibility of harbouring or being contaminated by the classical BSE agent. The Group agreed that for the entry assessment the importations of relevance were: live cattle, rendered products containing ruminant material (meat-and-bone meal, bone meal, blood meal, meat meal, greaves), feedstuffs containing rendered products of ruminant origin, and also fertilizers containing rendered products of ruminant origin as they may be used for a different purpose other than as a fertilizer).

The Group drafted questions for the applicant Members to document the measures applied to imported commodities of relevance depending on the BSE risk status of the country or zone of origin as well as the supervision of the implementation of these measures. The Group also drafted a table for the relevant information on these importations to be summarised by applicant Members (without having to provide detailed statistics on importations).

b) Exposure assessment

The section of the questionnaire addressing the exposure assessment was comprehensively reviewed, acknowledging that: (i) based on the applications submitted by Members, it was apparent that the current questionnaire did not provide sufficient guidance, and (ii) the need of a new section providing a framework for a detailed description of livestock industry practices that is relevant for all applications as well as for those countries seeking recognition via the newly proposed pathway for negligible BSE risk status.

The scope of the exposure assessment was defined considering that for all practical purposes, the principal route of transmission of classical BSE is through the ingestion of contaminated feed (as emphasised in Article 11.4.1.). The Group noted that rendering represents a critical risk factor in the exposure pathway. The exclusion of specified risk material (SRM) from rendering and the parameters of the rendering process should therefore be carefully assessed. Another factor relevant to the exposure assessment is the age of cattle that may be exposed to feed potentially contaminated with the BSE agent, as animals 12 months old or less are considered to be much more susceptible to infection.

Overall, the Group determined that the following components should be addressed in the exposure assessment:

- An assessment of the livestock industry practices with a particular emphasis on the practices related to feeding, slaughtering and rendering practices, and associated likelihood that cattle may be exposed to potentially contaminated feed; or
- An assessment of the effective and continuous mitigation of each identified risk, that includes:
 - o the assessment of the slaughter practices with a particular emphasis on the management of materials listed in Article 11.4.14. (i.e., “*commodities that should not be traded*”, also commonly referred to as “specified risk material (SRM)” by Members), and the associated likelihood that these materials, or other material cross contaminated by them, may enter the feed chain;
 - o an assessment of the nature and enforcement of a feed ban, and the associated likelihood that ruminants may be fed with meat-and-bone meal or greaves derived from ruminants;
 - o an assessment of the rendering industry (if any), and the associated likelihood that rendered products containing ruminant material may retain BSE infectivity;
 - o an assessment of feed industry, and the associated likelihood that feed for ruminant may be contaminated with ruminant material, including as a result of cross contamination.

5. Additional considerations

The Group could not complete its Terms of Reference at this meeting. It was agreed that a third four-day meeting would be convened to: finalise the revisions of Chapter 11.4. (Article 11.4.3 (i.e., demonstration of the implementation of a ruminant-to-ruminant feed ban), Article 11.4.1ter, Articles 11.4.6. to 11.4.19, Article 11.4.20.), Chapter 1.8 (consequence assessment, risk estimation, Articles 1.8.3., and 1.8.4.), review the provisions for the annual reconfirmation of an official BSE risk status (i.e., annual reconfirmation form for BSE), assess the impact of the proposed revisions on the status of countries and zones having an official BSE risk status, and consider a request from the European Serum Products Association.

The Group emphasised the importance of effective communication, education and training that would need to be undertaken by the OIE on the proposed revised BSE standards to ensure an adequate understanding by Members in support of their adoption, and subsequent implementation.

6. Finalisation and adoption of the report

The Group reviewed and amended the draft report. The Group agreed that the report reflected the discussions.

Appendix I

**SECOND MEETING OF THE OIE AD HOC GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT
Paris, 20-22 November 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.

This *ad hoc* Group previously met from 3 to 5 July 2018 at the OIE Headquarters, and assessed:

- The risk with regard to the BSE agent, by revising Articles 11.4.1., 11.4.2., and 11.4.23. to 11.4.29. of the *Terrestrial Code*, and
- The relevance of the current categorisation of BSE risk status (Articles 11.4.3. to 11.4.5. of the *Terrestrial Code*), considering factors such as the different requirements applicable to the recognition and maintenance of a risk status, the prevailing epidemiological situation, the impact of the duration of an effective feed ban, and the relevance of a zoning or compartmentalisation approach.

During its second meeting, this *ad hoc* Group will continue to review:

1. The requirements applicable to the categories of BSE risk status and corresponding requirements for risk-based categorisation, with particular attention to:
 - i. The durations to be covered by the risk assessment and the feed ban (as recommended by the surveillance *ad hoc* group),
 - ii. The recommendations of the *ad hoc* Group on BSE surveillance (3 to 5 October 2018) with regard to the surveillance provisions to obtain and maintain a BSE risk status,
 - iii. The comments from the European Serum Product Association (ESPA), and
 - iv. The potential impact of the new requirements on the status of countries or *zones* already having an officially recognised BSE risk status.
 2. The requirements for trade applicable to the different categories of BSE risk status (revision of Articles 11.4.6. to 11.4.19. of the *Terrestrial Code*).
 3. 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.
 4. The list of specified risk materials (SRMs), if appropriate, in light of the recent scientific knowledge (revision of Article 11.4.14. of the *Terrestrial Code* on recommendations on commodities that should not be traded).
 5. The revision of the BSE Questionnaire (Chapter 1.8. of the *Terrestrial Code*) and the annual reconfirmation form to ensure their full consistency with the proposed revisions to Chapter 11.4. of the *Terrestrial Code*.
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Appendix II

**SECOND MEETING OF THE OIE AD HOC GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT
Paris, 20-22 November 2018**

Agenda

1. Opening.
 2. Adoption of the agenda and appointment of chairperson and rapporteur.
 3. Review of the Terms of Reference and definition of the work plan:
 - Revision of Chapter 11.4.
 - Revision of Chapter 1.8.
 - Revision of the annual reconfirmation form
 4. Adoption of the report
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Appendix III

**SECOND MEETING OF THE OIE AD HOC GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT
Paris, 20-22 November 2018**

List of participants

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**ELECTRONIC CONSULTATION OF THE OIE AD HOC GROUP
ON THE EVALUATION OF PESTE DES PETITS RUMINANTS STATUS OF MEMBERS
27 November 2018**

The OIE *ad hoc* Group on the evaluation of the peste des petits ruminants (PPR) status of Members (hereafter the Group) was consulted electronically on 27 November 2018.

1. Adoption of the agenda and appointment of chairperson and rapporteur

Dr Neo Mapitse, Head of Status Department, thanked the Group for its commitment and its extensive support towards the OIE in fulfilling the mandates given by Members. He acknowledged the amount of work before, during and after the *ad hoc* Group meeting and the efforts required in reviewing the dossiers and highlighted that the official recognition of disease status was an important activity for the OIE.

Dr Mapitse reminded the Group on the significance of confidentiality and declaration of conflict of interest for official recognition and thanked the experts for all having signed the forms for the undertaking of confidentiality and declaration of interests. No conflicts of interest were declared in this Group.

The Group and the OIE welcomed Drs Abdenacer Bakkouri and Sith Premashthira as new members of the Group. The Group was chaired by Dr Giancarlo Ferrari and Dr Henry Wamwayi was the rapporteur with the support of the OIE Secretariat. The Group adopted the proposed agenda.

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

2. Evaluation of an application from a Member for the official recognition of PPR free status

2.1 Croatia

In September 2018, Croatia submitted an application for the official recognition of its PPR free status based on historical grounds. The Group requested additional information and received clarification from Croatia.

i) Animal disease reporting

The Group acknowledged that Croatia had a record of regular and prompt animal disease reporting to the OIE. From the information provided in the annexes of the dossier, the Group noted that reporting of suspicions or positive cases of any animal disease, including PPR, had been mandatory in the country as per legislation for more than ten years. The Group appreciated that financial compensation would be provided in case animals were slaughtered for PPR eradication purposes and that penalties were foreseen for failure to report PPR suspected cases.

From the dossier and the additional information provided, the Group noted that education activities for veterinarians performing sampling, either during active or passive surveillance, were conducted annually with the most recent training taking place in May 2018. In addition, farmers were regularly reminded of their obligation to report any clinical signs of disease and animal deaths to veterinarians. The Group also noted that, following the recent occurrence of the disease for the first time in an European Union country, information on PPR passive surveillance and preventive measures was provided to veterinarians and veterinary inspectors during a veterinary congress in October 2018. The Group commended Croatia for this initiative but noted that there was no specific training/awareness

campaign on PPR intended for stakeholders other than veterinarians, as acknowledged by the country. Therefore, the Group recommended that Croatia develop an awareness programme dedicated to PPR and intended for all relevant stakeholders, including farmers, slaughterhouse workers and veterinary paraprofessionals, to increase the sensitivity of the passive surveillance.

ii) *Veterinary Authority*

The Group appreciated the information on demographics and geographical distribution of domestic small ruminants in Croatia presented in a map and tables by County. The Group noted that a comprehensive system was in place for the identification of susceptible animals and movement control, which would allow for traceability if PPR was introduced into Croatia. In particular, it was noted that all animal farms must be registered by the Croatian Agriculture Agency (CAA). Sheep and goats are identified at individual animal level and registered in the Unique Register of Domestic Animals (URDA) national database. A passport with the individual identification number is issued for each animal. All small ruminant movements are recorded in a database and accompanied by the animal's passport and a veterinary health certificate. The Group also noted the presence of 11 approved animal markets and five assembly centres for sheep and goats, as illustrated in relevant maps.

The Group also took note of the detailed information regarding veterinary legislation on disease prevention and control measures, outlining the responsibilities and involvement of different stakeholders in their implementation.

The Group acknowledged that the Croatian Veterinary Authority had current knowledge of, and authority over, all domestic sheep and goats in the country.

iii) *Situation of PPR in the past 24 months*

The Group noted that PPR had never been reported in Croatia. Therefore, Croatia was eligible to claim historical freedom from PPR in accordance with Article 1.4.6. of the *Terrestrial Code*.

iv) *Absence of vaccination in the past 24 months and no entry of vaccinated animals*

The Group noted that vaccination against PPR had never been conducted in Croatia and was prohibited *as per* legislation since 2007.

v) *Importation of domestic ruminants and their semen, oocytes or embryos is carried out in accordance with relevant articles of Chapter 14.7.*

From the information provided in the dossier and Croatia's response to requests for additional information, the Group noted that imports of live small ruminants and their semen, oocytes or embryos were only allowed into Croatia from countries with an official PPR free status.

With regard to imports of fresh meat and meat products from sheep and goats, the Group noted that fresh meat had been imported into Croatia from a country without an official PPR free status. The Group examined the sanitary requirements applicable to these importations, which were provided as additional information, and concluded that they were consistent with the requirements of Article 14.7.17. of the *Terrestrial Code*.

The Group took note of the seven border inspection posts approved to check all consignments of live animals, products of animal origin and feed of animal and non-animal origin into the European Union.

In response to a question raised on possible illegal importations of small ruminants, Croatia clarified that no illegal imports of live animals susceptible to PPR had been detected during the past five years. The Group appreciated that Croatia had identified two different patterns for potential illegal animal movements (i.e., "*intentionally*" and "*inadvertently*") and agreed that the procedures to be applied in case of detection of such illegal imports were satisfactory.

The Group concluded that import control procedures for animals and animal products in Croatia were in accordance with the requirements of the *Terrestrial Code*.

vi) *Surveillance for PPR and PPRV infection in accordance with Articles 14.7.27. to 14.7.33. and with Chapter 1.4.*

The Group acknowledged that passive surveillance for PPR had been in place for at least ten years and that all sectors of livestock production, mainly farmers, but also staff in markets, fairs, and slaughterhouses were involved in it.

Whilst PPR had never been reported in the country and, therefore, pathogen-specific surveillance was not mandatory according to Article 1.4.6. of the *Terrestrial Code*, the Group commended Croatia for the serological surveillance for PPR conducted in 2018. From the additional information provided, the Group took note that the serological sampling plan was based on testing 59 samples from small ruminants per county, randomly selected from samples already collected for the brucellosis surveillance programme. The Group acknowledged that 1163 small ruminants from 264 farms had all tested negative for antibodies to PPR virus.

The Group noted that PPR serological testing, using a competitive ELISA test, was performed in the Croatian Veterinary Institute, which is formally accredited to ISO 17025 by the Croatian Accreditation Agency. In case of positive or doubtful results, a second set of samples would be collected and retested from the same group of animals, using a 2% prevalence of infection with a 95% level of confidence to determine the sample size. The Group appreciated that some positive sera had been reported, as this would fall within the expected normal range of the test [1- specificity]. The Group also acknowledged that in these cases, eventually identified as false positives, control measures, such as movements restrictions on the farms and resampling had been implemented.

The Group appreciated that Croatia participated in a European proficiency test for PPR and that the final report was provided.

With regard to wildlife, the Group noted that PPR susceptible wild species were present in Croatia, but an estimation of their population was not available. The Group commented that it would be an asset if wildlife samples were included in the serological surveillance, where possible.

vii) *Regulatory measures for the early detection, prevention and control of PPR*

The Group noted that the industry, producers, farmers, keepers, veterinarians and veterinary paraprofessionals were involved in passive surveillance of animal diseases, including PPR and that failure to report PPR cases would attract sanctions.

The Group also took note of the regular inspections of animal holdings and adequate controls on the imports of livestock and livestock products into Croatia.

Furthermore, the Group noted that a contingency plan for specific animal diseases including PPR was in place, outlining the PPR related legislation as well as procedures to be followed and measures to be implemented in case of occurrence of the disease. The Group also appreciated that Croatia was planning to organise a simulation exercise for PPR in the near future.

Therefore, the Group agreed that the necessary regulatory measures for early detection, prevention and control of PPR were in place and compliant with the requirement of the *Terrestrial Code*.

viii) *Compliance with the questionnaire in Article 1.12.1.*

The Group commended the well-structured dossier provided by Croatia and agreed that the submitted dossier was compliant with the format of the questionnaire in Article 1.12.1.

Conclusion

Based on the information submitted in the dossier and the answers provided by Croatia to the questions raised, the Group considered that the application was compliant with the requirements of Chapter 14.7. and with the questionnaire in Article 1.12.1. of the *Terrestrial Code*. The Group therefore recommended that Croatia be recognised as a PPR free country.

Recommendations to Croatia:

The Group recommended that Croatia:

- develop an awareness programme dedicated to PPR and intended for all relevant stakeholders, including farmers, slaughterhouse workers and veterinary paraprofessionals, to increase the sensitivity of the passive surveillance;
- maintain the exercise of testing samples from small ruminants randomly selected from samples collected for other purposes. It would be an asset if wildlife samples were included in this surveillance;
- finalise the simulation exercise planned for PPR;
- continue participating in proficiency tests for PPR.

3. Adoption of the report

The Group reviewed and amended the draft report provided by the rapporteur with the support of the OIE Secretariat and agreed to circulate the draft report electronically for comments before the final adoption. The Group agreed that the report captured the discussions.

Appendix I

**ELECTRONIC CONSULTATION OF THE OIE AD HOC GROUP
ON THE EVALUATION OF PESTE DES PETITS RUMINANTS STATUS OF MEMBERS**

27 November 2018

Terms of reference

The OIE *ad hoc* group on peste des petits ruminants (PPR) status of Members (the Group) is expected to evaluate an application received from a Member for the official recognition of a PPR free status.

This implies that the experts, members of this Group are expected to:

1. Sign the updated OIE Undertaking on Confidentiality of information
 2. Complete the Declaration of Interests Form and forward it to the OIE at least two weeks before the teleconference
 3. Evaluate the application for an official free PPR status
 - a) Prior to the teleconference:
 - read and study in detail the dossier provided by the OIE;
 - take into account any other information available in the public domain considered pertinent for the evaluation;
 - summarise the dossier according to the requirements of the *Terrestrial Animal Health Code*, using the form provided by the OIE;
 - identify questions emerging as a result of the analysis of the dossier which require further clarification and to be completed by the Member;
 - send the completed form and the list of identified possible questions to the OIE, at least 10 days before the teleconference.
 - b) During the teleconference:
 - contribute to the discussion;
 - withdraw from the discussions and decision making should a conflict of interest arise;
 - provide a detailed report in order to recommend to the Scientific Commission for Animal Diseases if the country should be (or not) recognised as PPR free, and to indicate any information gaps or specific areas that need to be addressed in the future by the applicant Member.
 - c) After the teleconference:
 - contribute electronically to the finalisation of the report.
-

Appendix II

**ELECTRONIC CONSULTATION OF THE OIE AD HOC GROUP
ON THE EVALUATION OF PESTE DES PETITS RUMINANTS STATUS OF MEMBERS
27 November 2018**

Agenda

1. Adoption of the agenda and appointment of chairperson and rapporteur
 2. Evaluation of an application from a Member for official recognition of a PPR free status
 - Croatia
 3. Adoption of report
-

Appendix III

**ELECTRONIC CONSULTATION OF THE OIE AD HOC GROUP
ON THE EVALUATION OF PESTE DES PETITS RUMINANTS STATUS OF MEMBERS**

27 November 2018

List of Participants

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**MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION
OF CLASSICAL SWINE FEVER STATUS OF MEMBERS
Paris, 04 – 06 December 2018**

A meeting of the OIE *ad hoc* Group on the Evaluation of Classical swine fever (CSF) Status of Members (hereafter the Group) was held at the OIE Headquarters from 04 to 06 December 2018.

1. Opening

Dr Matthew Stone, Deputy Director General for International Standards and Sciences of the OIE, welcomed and thanked the Group for its commitment and its support towards the OIE in fulfilling the mandates given by Members. Dr Stone acknowledged the amount of work before, during and after the *ad hoc* Group meeting in reviewing the dossiers and documenting the Group's assessment in the report.

Dr Stone highlighted the importance of the quality of the report to be scrutinised by Members before adopting the proposed list of countries free from CSF. He also encouraged the Group to continue providing detailed feedback to countries with a negative outcome to support them in identifying the main gaps and points for improvement, as well as providing informative recommendations to those countries with positive outcomes for further improvement in maintenance of their CSF free status.

Dr Stone highlighted the sensitivity and confidentiality of the dossiers received for official recognition and thanked the experts for having signed the forms for undertaking of confidentiality, as well as the declaration of potential conflict of interests related to the mandate of the Group. The declared interests were reviewed by the OIE and the Group and it was agreed that none represented a potential conflict in the evaluation of CSF status of Members.

Dr Stone mentioned about the current animal health situation of African swine fever (ASF) and how it has reinforced international standards on risk assessment and its management, and implementation of biosecurity measures on the farms, for which are commonly important and similar in parts with CSF.

The experts and the OIE welcomed Drs Sandra Blome and Vitor Gonçalves as new members of the Group.

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

The Group was chaired by Dr Vitor Gonçalves. Dr Trevor Drew acted as rapporteur, with the support of the OIE Secretariat. The Group endorsed the proposed agenda.

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

3. Evaluation of requests from Members for the status recognition of CSF free countries

a) Latvia

In October 2018, Latvia submitted a dossier for the official recognition of its CSF free status.

The Group requested additional information and received clarification from Latvia.

i) *Animal disease reporting*

The Group acknowledged that Latvia had a record of regular and prompt animal disease reporting and that CSF was a notifiable disease in the country as per legislation.

ii) *Veterinary Services*

The Group was informed that Latvia had a CSF expert group consisting of Food and Veterinary Service (FVS) representatives, representatives of the National Reference Laboratory, the State Forest Service, wildlife biologists, the Latvian pig keeper association, the Latvian Hunter association and the Joint Stock Company “Latvia’s State Forests”.

The Group considered that the Veterinary Services had knowledge and authority over domestic pig herds and current knowledge about the population and habitat of wild and feral pigs in the country.

In particular, the Group acknowledged the information on wildlife demographics in Latvia. The Group noted that wild boar (*Sus scrofa*) was the favoured and most abundant large game in Latvia representing nearly 70% of the annually hunted ungulates. The Group noted that the overall population declined considerably over the last four years (after the introduction of African swine fever into Latvia).

Latvia described four types of pig production in the country: large commercial farms with more than 200 pigs, small breeding farms, small fattening farms, and backyard farms with up to ten pigs for self-consumption.

The Group noted that all establishments with farmed animals were registered. Latvia informed that a unique identification number was assigned to each farm and that data on establishments and animals kept were recorded in a national computer database. Pigs were identified with an ear tag or tattoo displaying the unique registration number of the establishment (at the latest, prior to leaving the premises). The FVS was performing annual on spot controls of animal identification, registration and traceability. Latvia informed that these controls were intensified due to the eradication programmes for ASF and CSF.

The Group acknowledged that the main pattern of pig movement was from farm to slaughterhouse. The Group noted that all movements had to be notified 24 hours in advance to an official veterinarian and recorded in the Agricultural data centre database. All animals were subject to ante- and post-mortem inspection at slaughterhouses.

The Group noted that the FVS organised meetings with veterinarians, staff of State Forest Service, hunters and representatives of local municipalities on the CSF situation and necessary eradication measures in the defined infected and risk areas. Furthermore, Latvia informed that the FVS conducted awareness campaigns through press, radio and television and prepared the booklets and leaflets for pig owners/ keepers about both diseases, CSF and ASF.

iii) Situation of CSF in the past 12 months

The Group noted that the last outbreak of CSF in domestic pigs occurred in June 2014 and in March 2015 in wild boar.

iv) Absence of vaccination in the past 12 months

The Group acknowledged that vaccination of domestic pigs against CSF had ceased in Latvia in 1997, and vaccination against CSF was prohibited since 2004 as per legislation.

The Group noted that the oral vaccination of wild boar with CSF live attenuated vaccine was carried out in an area bordering countries with undetermined CSF status from May 2013 to November 2015. Latvia clarified that the last campaign of oral vaccination in wild boar was in November 2015.

v) Surveillance for CSF and CSFV infection in accordance with Articles 15.2.26. to 15.2.32.

The Group noted that passive surveillance was in place for all pig sectors in Latvia.

The Group noted that Latvia designated different areas along the border with neighbouring countries with undetermined CSF status with heightened surveillance, particularly in wild boar.

The Group acknowledged the information on the sampling strategy and results of serological and virological surveillance conducted in domestic pigs in Latvia. In response to the request of the Group, Latvia provided revised and more detailed information on false-positive results obtained on screening tests and details of follow-up actions taken on all suspicious and positive results and on how these findings were interpreted and acted upon to rule-out CSF.

The Group acknowledged that all hunted and wild boar found dead were tested for the presence of CSF antibodies by ELISA and CSFV genome by RT-PCR. The Group noted that additionally to the active surveillance, passive surveillance was in place and involved hunters and gamekeepers who were instructed to report all dead wild boar to the FVS.

The Group noted that laboratory diagnosis of the CSF was carried out at the national Animal Disease Diagnostic Laboratory and all diagnostic methods used for the laboratory diagnosis of the CSF were accredited standard methods in accordance with ISO/IEC 17025 with an exception of genome sequencing that was not accredited due to lack of samples. The Group acknowledged that the laboratory in Latvia participated regularly in the inter-laboratory proficiency testing organised by the OIE Reference Laboratory in Hannover, Germany. The Group concluded that Latvia had a sufficient level laboratory capability for CSF diagnosis in the country.

vi) Regulatory measures for the early detection, prevention and control of CSF

Latvia informed that the FVS performs risk analysis based on the information available on WAHIS and Animal Disease Notification System of the European Union and coordinates prevention measures in close collaboration with neighbouring countries.

From the information provided in the dossier, the Group noted that Latvia implemented the conditions prescribed by the European Union legislation with regard to the importation of pigs and pig products. The Group also noted that documentary, identity and physical checks were performed at the Border Inspection Posts. As part of a physical check, a laboratory test might be carried out in accordance with the national monitoring plans, to verify that the animal product does not contain any residues, contaminants, pathogens or other substances dangerous for animal and public health.

The Group was informed from the additional information received from Latvia that the biosecurity measures were mandatory for all farms, including backyard farms. Latvia also informed that there were continuous education campaigns conducted amongst pig producers to maintain the level of awareness in the country.

In response to the request of the Group, Latvia informed that the slaughter performed on non-commercial pig farms was intended for their own consumption.

Latvia provided a contingency plan with regard to the control of CSF. The Group took note that a general part of the contingency plan was updated at least once in two years whilst the operational manuals on control of specific diseases had to be updated at least every five years and more frequently in the case where there were changes in legislation or specific disease situations.

vii) *Consideration of wild and feral pigs, if present, in the surveillance programme and biosecurity measure of domestic and captive wild herds*

The Group took note that an outdoor housing system for domestic pigs was prohibited in Latvia since 2014, based on the biosecurity requirements described in the national legislation.

viii) *Compliance with the questionnaire in Article 1.9.1.*

The Group agreed that the submitted dossier was broadly compliant with the format of the questionnaire in Article 1.9.1. of the *Terrestrial Code*.

Conclusion

Considering the information submitted in the dossier and the answers from Latvia to the questions raised, the Group considered that the application was generally compliant with the requirements of Chapter 15.2. and with the questionnaire in Article 1.9.1. of the *Terrestrial Code*. The Group therefore recommended that Latvia be recognised as a CSF free country.

The Group recommended that information on the following be submitted to the OIE when Latvia reconfirms its CSF status (also detailed in the relevant sections above):

- Documented evidence on implementation of biosecurity at farms, particularly in small scale non-commercial farms. This information could include, but not be limited to, records and number of biosecurity inspections conducted with any detected non-compliance and follow-up actions taken;
- Reporting details of any veterinary investigations carried out, following reports from farmers or veterinarians in the backyard sector – including those where CSF was ruled out on clinical grounds.

b) Uruguay

In October 2018, Uruguay submitted a dossier for the official recognition of its CSF free status.

The Group requested additional information and received clarification from Uruguay.

i) *Animal disease reporting*

The Group acknowledged that Uruguay had a record of regular and prompt animal disease reporting and that CSF was a notifiable disease in the country as per legislation.

ii) *Veterinary Services*

The Group acknowledged that the official Veterinary Service of Uruguay consisted of three divisions: the Animal Health Division (DSA), the Animal Industry Division (DIA) and the Veterinary Laboratories Division (DILAVE), and had a network of zonal and local veterinary offices.

The Group noted that the information on pig population was recorded in the National System for Livestock Information (SNIG). The Group took note that there were three types of pig farms in Uruguay (breeding, fattening and farrow-to-finish). Uruguay informed that approximately 90% of pig producers had less than 50 animals and that pig production was concentrated in the south of the country, notably in the departments of Canelones and San Jose that account for 54% of the pig population in Uruguay.

The Group noted the pig demographics of Uruguay and the information on wild boar, feral pigs and their crossbreeds, which are spread throughout the country at a density between 0.52 to 1.17 animals/km². Uruguay provided additional information to describe the method used to estimate the population density. The Group noted that wild boars were introduced in Uruguay in the 1920s for hunting purposes and that, due to intentional release or escapes, they had spread throughout the country. Uruguay informed that keeping wild pigs in captivity had been authorised since 2001. The Group noted that there were two farms of wild boar that were regularly inspected by the Veterinary Service.

From the information provided in the dossier, the Group acknowledged that the collard peccary (*Pecari tajacu*) was the only native mammal from the family *Tayassuidae* in Uruguay and that their population comprised 450 peccaries kept in captivity in 15 parks and zoological gardens in 13 departments of the country. The Group took note that in 2017 the M'Bopicuá Park in Río Negro released 100 peccaries into the wild and that these animals were subsequently monitored by the Veterinary Service.

The Group acknowledged that Uruguay had a group traceability system. Individual pig identification was specifically carried out with pedigree animals and was managed by the Rural Association of Uruguay. Although this was not an official system, records were controlled by the competent authorities. The Group took note that the producers had to make an annual declaration of their herds of cattle, sheep, pigs, horses and goats. The Group noted that all movements of any species of livestock were only permitted in conformity with the Property and Transport Guide, a document indicating the new owner or manager and the locations for the place of departure and arrival, along with descriptions of the categories, animal brandings, transporter, itinerary, etc., thus generating information for group traceability.

The Group noted that all abattoirs were under official veterinary inspection performed by the Veterinary Services. In addition, animal shows, auctions, fairs, and markets were subject to sanitary control by the Veterinary Services.

From the additional information provided by Uruguay, the Group noted that in 2016 and 2017 the awareness activities were targeted at hunters, producers and private practice veterinarians, focusing on animal disease surveillance in wild boar.

Overall, the Group considered that the Veterinary Services had knowledge and authority over domestic pig herds and current knowledge about the population and habitat of wild and feral pigs in the country.

iii) *Situation of CSF in the past 12 months*

The Group acknowledged that the last CSF outbreak in Uruguay was in November 1991. Therefore, Uruguay was eligible to claim historical freedom from CSF as described in Article 1.4.6. of the *Terrestrial Code*.

iv) *Absence of vaccination in the past 12 months*

The Group acknowledged that vaccination against CSF had ceased in Uruguay in October 1995 and since then was prohibited as per legislation.

v) *Surveillance for CSF and CSFV infection in accordance with Articles 15.2.26. to 15.2.32.*

The Group acknowledged that Uruguay had passive surveillance in place established for exotic diseases. Since pigs would not have immunity to CSF, detection of suspect cases could be based on clinical signs.

The Group noted from the dossier that CSF would be tentatively diagnosed by clinical observations and post-mortem lesions. The official Veterinary Service periodically undertook clinical inspections of pigs within the framework of activities such as the movement of animals to slaughter, ante-mortem inspection at abattoirs, shows, markets and other sites of animal gathering. The Group appreciated the detailed description provided by Uruguay on how CSF suspicions were followed up to rule-out CSF and reach a final differential diagnosis.

The Group noted that risk-based serological surveillance was conducted in June 2017, targeted at herds that had been positive for PRRS, including establishments that had imported breeding stock either in the form of live animals and/or semen. The sample design assumed a diagnostic test (ELISA) sensitivity of 98.8% and specificity of 99.9%, a 1% herd-prevalence and 3% within-herd prevalence. All samples tested negative. In addition, 92 wild boar samples, obtained from hunting parties, were processed by the Veterinary Services. Uruguay informed that, since 2012, it had carried out structured non-random surveillance in sentinel units, using the framework for foot-and-mouth disease surveillance for those establishments that contain pigs. The country informed that there were 58 establishments involved in the surveillance process, which were visited on an annual basis by the Veterinary Services.

The Group noted that Uruguay had a national reference laboratory for CSF diagnosis in the country, which was accredited to international standards.

vi) *Regulatory measures for early detection, prevention and control of CSF*

The Group acknowledged the good collaboration and coordination on prevention and control of animal health involving different regional organisations and initiatives.

The Group noted that only pigs from officially recognised CSF free countries were allowed into Uruguay. The Group also noted that there was an Import Committee responsible for preparing the requirements for the importation of products of animal origin, establishing details of the sanitary conditions of a general and specific order that must be met in order to allow entry into Uruguay.

The Group noted that 19 permanent official control posts were in place covering the main points of entry into the country for the purpose of zoosanitary and phytosanitary health controls.

From the information provided in the dossier, the Group concluded that when animals or products of animal origin were detected being illegally brought into the country, the Veterinary Authority had the power to permanently confiscate such products and assure their total destruction. The Group took note that there was no detection of illegal entry of pigs in 2016, 2017 and 2018. This permanent control was carried out through the sanitary barriers to prevent passengers and vehicles, by land, sea or air, from bringing animals or plants, their products and by-products into the country, without the corresponding official sanitary certification, as they represent the risk of introducing diseases and pests.

The Group acknowledged that swill feeding, and the removal of waste from the abattoirs that might be used as swill feeding, without prior treatment was prohibited as per legislation. Uruguay also provided additional information on the treatment protocol of swill and oversight to ensure compliance by producers. The Group noted that municipal authorities were responsible for the management of waste and for preventing animals from entering final waste disposal sites.

The Group noted that in case of an emergency, a specific and permanent body for the coordination of public institutions for the comprehensive management of disaster risks in Uruguay, the National Emergency System, comes into operation.

vii) *Consideration of wild and feral pigs, if present, in the surveillance programme and biosecurity measure of domestic and captive wild herds*

The Group noted that medium and large producers used fences and/or perimeter fences to avoid contact with wild pigs. The Group also noted that every farm in Uruguay must have a perimeter fence (there are no communal pastures). From the additional clarification received from Uruguay, the Group was informed that large pig farms had biosecurity plans in place to maintain measures to avoid contact with wild pigs. Uruguay also stated that semi-intensive or extensive farms were concentrated in the south of the country, where there were no forestry areas.

viii) *Compliance with the questionnaire in Article 1.9.1.*

The Group agreed that the submitted dossier was compliant with the format of the questionnaire in Article 1.9.1. The Group appreciated the well-structured dossier provided by Uruguay and commended the country for the comprehensive answers to the questions raised by the Group.

Conclusion

Considering the information submitted in the dossier and the answers received from Uruguay to the questions raised, the Group considered that the application was compliant with the requirements of Chapter 15.2., Article 1.4.6. and with the questionnaire in Article 1.9.1. of the *Terrestrial Code*. The Group therefore recommended that Uruguay be recognised as a historically CSF free country.

The Group recommended that information on the following be submitted to the OIE when Uruguay reconfirms its CSF status (also detailed in the relevant sections above):

- Enhanced disease notification system including the small-scale production sector and provide documented evidence of implementation.

c) Other requests

The Group assessed two additional requests from Members for the recognition of CSF free country status. The Group concluded that the Members did not meet the requirements of the *Terrestrial Code* and the dossiers were referred back to the respective applicant Members.

4. Evaluation of a request from a Member for official recognition of a CSF free zone status

a) Ecuador

In October 2018, Ecuador submitted a dossier for the official recognition of a CSF free zone for the Insular Territory of Galapagos (ITG).

The Group requested additional information and received clarification from Ecuador.

i) *Animal disease reporting*

The Group acknowledged that Ecuador had a record of regular and prompt animal disease reporting and that CSF was a notifiable disease in the country as per legislation.

ii) *Veterinary Services*

The Group noted that the Veterinary Service of the ITG was under the responsibility of the Biosecurity and Quarantine for Regulation and Control Agency for Galapagos (ABG) created in 2012. The ABG comprised staff working on inspection and quarantine, monitoring, zoosanitary surveillance and phytosanitary surveillance, food safety and the administrative area. The Group noted that the ABG consisted of a Central Office in Santa Cruz, and five insular Operative Technical Offices: three in the ITG (in Isabela, San Cristobal, Floreana) and two in continental Ecuador, in Quito and Guayaquil airports, to coordinate the goods transported from these places.

Ecuador informed that pig production in the ITG was predominantly of small-scale farrow-to-finish herds. The Group acknowledged that the domestic pig population in the ITG was very small, comprising 46 farms and 2432 animals as of 2017. The Island of Santa Cruz holds a large proportion of this population.

The Group noted that animal identification was not implemented in the ITG. However, the ABG conducted periodic animal surveys to determine the size of the animal population; the last census was conducted in 2014 and since then was periodically updated.

The Group noted from the additional information that movement of pigs between the islands of the ITG was prohibited and that pigs were raised for internal consumption in each of the islands of the ITG.

From the information provided in the dossier, the Group concluded that veterinary activities were mainly carried out by veterinarians from the national official services.

iii) *Situation of CSF in the past 12 months*

The Group acknowledged that the last CSF outbreak in the proposed zone of ITG was recorded in 1999.

iv) *Absence of vaccination in the past 12 months*

The Group acknowledged that vaccination against CSF had never been performed in the proposed zone and importation of vaccines against CSF was prohibited as per legislation.

v) *Surveillance for CSF and CSFV infection in accordance with Articles 15.2.26. to 15.2.32.*

The Group noted that in 2014, following the national census of pig population, the activities of the national swine health programme were renewed and included farm supervision, educational communication with producers and technicians and implementation of surveillance activities. Ecuador informed that in 2016 and 2018 serological surveys were conducted to demonstrate the absence of CSF in domestic pigs and feral pigs of the proposed zone. Ecuador informed that the study covered the four islands with pig production, and sampled animals from all registered farms. Ecuador stated that seropositive animals were found in seven out of 45 farms and were resampled and tested by antigen ELISA and resulted negative for CSFV. The Group expressed its concerns with regard to the follow-up testing approach as seropositive animals would not be expected to be positive for antigen. The Group therefore suggested to sample more animals of the same herd to be tested by antibody and antigen ELISA (or preferably RT-PCR) and to follow-up the serology by confirmatory tests, e.g. virus neutralization assays. The Group acknowledged that the complementary investigations on herds with ELISA positive animals should include pathogen detection not only in the reactor animals, but also the in-contact animals and animals which may be epidemiologically linked, in accordance with Article 15.2.28. of the *Terrestrial Code*.

The Group acknowledged that there was passive surveillance in place. The number of suspicions reported during the past twelve months was low, but the Group considered this was acceptable given the small size of the pig population in the ITG. Nevertheless, the Group strongly encouraged that Ecuador continued strengthening its CSF awareness and monitor the sensitivity of its passive surveillance.

Whilst there was no laboratory for CSF diagnosis in the proposed zone, the Group noted an established protocol for shipment of samples to the national laboratory in continental Ecuador, which was accredited in accordance with ISO 17025: 2017 standards. The Group took note of the ongoing work on the memorandum of understanding for regular inter-laboratory proficiency testing to be done under the Andean Sub-regional Program for the Prevention, Control and Eradication of CSF.

vi) *Regulatory measures for the early detection, prevention and control of CSF*

The Group acknowledged the coordination with neighbouring countries through the Andean Sub-regional CSF Control Strengthening Project.

The Group acknowledged that the introduction of all species of domestic and wild animals including pets from the mainland or from other countries into the proposed zone was restricted. The Group noted that there was no introduction of live animals into the ITG since 1994.

The Group noted that surveillance or quarantine control was carried out in the continental territory of Ecuador, at the airports in Quito and Guayaquil. The Group also noted that inspections were carried out at control points such as airports and ports, both from continental Ecuador (Quito and Guayaquil) and at the destination within the ITG on the inhabited islands. The Group noted that there are currently no regulations managing risks associated with swill feeding of pigs in the ITG, but given the controls on imports considered this was not a critical issue, though it should be addressed.

Ecuador provided a contingency plan for CSF that described all procedures to be followed in case of a CSF outbreak.

vii) *Consideration of wild and feral pigs, if present, in the surveillance programme and biosecurity measure of domestic and captive wild herds*

Ecuador reported that there were no wild pigs in the ITG and that feral pigs were present in three of the four populated islands (Santa Cruz, San Cristobal, and Isabela), with an estimated population of 10,000, of which 75% were in Isabela island. From the information provided by Ecuador and from public online sources, the Group also noted current efforts to eradicate wild and feral pig populations from some islands.

viii) *Compliance with the questionnaire in Article 1.9.1.*

The Group agreed that the submitted dossier was compliant with the format of the questionnaire in Article 1.9.1. The Group appreciated the concise dossier provided by Ecuador and commended the country for the comprehensive answers to the questions raised by the Group.

Conclusion

Considering the information submitted in the dossier and the answers from Ecuador to the questions raised, the Group considered that the application was compliant with the requirements of Chapter 15.2. and with the questionnaire in Article 1.9.1. of the *Terrestrial Code*. The Group therefore recommended that the proposed zone of the ITG be recognised as free from CSF.

Whilst the Group noted that movement of animals including pigs from continental Ecuador and other countries into the proposed zone was restricted, it strongly reminded that all movement of pigs and their products should continue to comply with Chapter 15.2. of the *Terrestrial Code*.

The Group recommended that information on the following be submitted to the OIE when Ecuador reconfirms its CSF status of the proposed zone (also detailed in the relevant sections above):

- Improvement of the follow-up investigation of any sero-positive reactors including the laboratory testing, visits and clinical inspections of the farm of origin as well as in-contact animals and animals which may be epidemiologically linked, in accordance with Article 15.2.28. of the *Terrestrial Code*;
- Participation in inter-laboratory proficiency testing for diagnosis of CSF;

- Establishing official regulations or legislation for the inactivation of CSFV in swill in accordance with Article 15.2.22. of the *Terrestrial Code*.

5. Other matters

While assessing the Members' applications, the Group noted that some clarity should be brought on the surveillance strategies and recommended a revision of Article 15.2.28. point 2) to provide clearer guidelines on investigations for follow-up and ruling out clinical suspicions.

The Group also suggested to develop the guidance for completing the OIE questionnaire for application for official status recognition in order to improve the clarity and conciseness of the dossiers.

6. Adoption of report

The *ad hoc* Group reviewed and amended the draft report. The Group agreed that the report would be subject to a short period of circulation to the Group for comments and adoption. Upon circulation, the Group agreed that the report captured the discussions.

.../Appendices

Appendix I**MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION
OF CLASSICAL SWINE FEVER STATUS OF MEMBERS****Paris, 4 – 6 December 2018**

Terms of Reference

The OIE *ad hoc* group on classical swine fever (CSF) status of Members (the Group) is expected to evaluate the applications for official recognition of CSF free status in accordance with the Standard Operating Procedure for official recognition of disease status.

This implies that the experts, members of this Group are expected to:

1. Sign off the OIE Undertaking on Confidentiality of information.
 2. Complete the Declaration of Interests Form in advance of the meeting of the Group and forward it to the OIE at the earliest convenience and at least two weeks before the meeting.
 3. Evaluate the applications from Members for official recognition of CSF free status.
 - a) Before the meeting:
 - read and study in detail all dossiers provided by the OIE;
 - take into account any other information available in the public domain that is considered pertinent for the evaluation of dossiers;
 - summarise the dossiers according to the *Terrestrial Animal Health Code* requirements, using the form provided by the OIE;
 - draft the questions whenever the analysis of the dossier raises questions which need to be clarified or completed with additional details by the applicant Member;
 - send the completed form and the possible questions to the OIE, at least one week before the meeting.
 - b) During the meeting:
 - contribute to the discussion with their expertise;
 - withdraw from the discussions and decision making when possible conflict of interest;
 - provide a detailed report in order to recommend, to the Scientific Commission for Animal Diseases, the country(ies) or zone(s) to be recognised (or not) as CSF free and to indicate any information gaps or specific areas that should be addressed in the future by the applicant Member.
 - c) After the meeting:
 - contribute electronically to the finalisation of the report if not achieved during the meeting.
-

**MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION
OF CLASSICAL SWINE FEVER STATUS OF MEMBERS**

Paris, 4 – 6 December 2018

Agenda

1. Opening
 2. Adoption of the agenda and appointment of chairperson and rapporteur
 3. Evaluation of requests from Members for official recognition of CSF free status
 - Latvia
 - Uruguay
 - Other requests
 4. Evaluation of a request from a Member for official recognition of a CSF free zone status
 - Ecuador
 5. Other matters
 6. Adoption of report
-

Appendix III

**MEETING OF THE OIE AD HOC GROUP ON THE EVALUATION
OF CLASSICAL SWINE FEVER STATUS OF MEMBERS**

Paris, 4 – 6 December 2018

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**REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP
ON ANIMAL AFRICAN TRYPANOSOMOSSES**

Paris, 15 – 17 January 2019

The second 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 15 to 17 January 2019.

1. Opening of the meeting

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

Dr Stone commended the Group for the progress made at its first meeting in March 2018, and indicated that the objective of this meeting was to finalise the draft chapter of the Terrestrial Animal Health Code (*Terrestrial Code*) on “Infection with animal trypanosomes of African origin excluding infection with *Trypanosoma evansi* and *T. equiperdum*”.

Dr Stone also thanked the experts for their commitment and for the work done in preparation of the meeting, in particular for assessing the different animal trypanosomes of African origin against the listing criteria of Chapter 1.2 of the *Terrestrial Code*.

The Group was reminded that they were nominated by the OIE Director General according to their internationally recognised expertise and geographically balanced representation, but they were not representing their own countries or institutions. Experts were asked to declare any actual or potential conflict of interest and to respect the confidentiality of the standard setting process.

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

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

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

3. Consideration of the feedback provided by the Scientific Commission, the OIE Wildlife Working Group and the OIE Headquarters secretariat

The Group took note of the feedback provided by the Scientific Commission, the OIE Wildlife Working Group and the OIE Headquarters secretariat on the outline and content of the draft chapter proposed during the first meeting of the *ad hoc* Group.

4 Finalisation of the Terrestrial Animal Health Code Chapter 8.Y. Infection with animal trypanosomes of African origin

Article 8.Y.1. General Provisions

The Group assessed the different species of animal trypanosomes of African origin against the listing criteria of Chapter 1.2. of the *Terrestrial Code*. The Group took note of the scientific evidence available and agreed that *T. vivax*, *T. congolense*, *T. simiae* and *T. brucei* matched the listing criteria. The Group made a remark to indicate that *T. congolense* includes *T. congolense* savannah, *T. congolense* forest and *T. congolense* Kilifi.; while *T. brucei* includes *T. brucei brucei*, *T. b. rhodesiense* and *T. b. gambiense*.; and *T. simiae* includes *T. simiae* Tsavo.

The Group also agreed on the fact that *T. godfreyi* does not match point 4 of Article 1.2.2. of the *Terrestrial Code* and therefore, should not be included in the case definition of this draft article. The Group's detailed assessment of the different species against the listing criteria of Chapter 1.2. of the *Terrestrial Code* is included as Appendix III.

The Group discussed whether other species of animal trypanosomes of African origin (*i.e.* *T. uniforme* and *T. suis*) should also be assessed against the listing criteria. It concluded that the current scientific information on these pathogens indicates that they are rarely reported, have limited distribution and cause limited impact and therefore do not play a significant role in the epidemiology of the disease. However, despite not being included in the case definition for the purpose of this chapter, it was recommended that *T. godfreyi*, *T. uniforme* and *T. suis* be considered in the surveillance system due to their potential interference in the diagnosis of the disease due to latent co-infection.

The Group emphasised that, under field conditions and with the current routine diagnostic methods, it may not always be possible to differentiate the species of trypanosomes involved in the infection. In these circumstances, the identification of any trypanosomes of the subgenera Duttonella, Nannomonas and Trypanozoon in susceptible animals should be reported to the OIE as infection with animal trypanosomes of African origin.

The Group agreed that the presence of genetic material specific to the pathogen(s) detected in a sample from a clinically affected animal, or epidemiologically linked to a confirmed case, should also be considered as a case of trypanosomosis.

The Group highlighted the zoonotic aspect of *T. brucei gambiense* and *T. brucei rhodesiense*, which are responsible for human African trypanosomosis, also known as sleeping sickness.

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

The Group took in consideration the feedback provided by the Wildlife Working Group and noted that, in the presence of vectors, wildlife can play a significant role in the epidemiology of the disease. The Group clarified that it does not seem possible to achieve and maintain freedom only in domestic animals when the infection is present in wildlife in the presence of competent vectors in the same area. Thus, the Group decided to remove the provisions for the declaration of freedom in domestic and captive wild animals and to only consider freedom under historical grounds or if the disease is not present in all susceptible animals in a country or zone.

The Group took note of the potential risk of disease introduction via the importation of live animals from infected countries, even if the appropriate risk mitigation measures were correctly implemented in the country of origin, due to the possible reactivation of the parasitaemia at destination after a situation of stress such as transport (Desquesnes, 2004)¹. It also assessed the biological and economic consequences of introducing infected animals in a free country via international trade. To eliminate the residual risk of introducing the disease in a free country or zone via the importation of animals from an infected country or zone, even if risk mitigation measures were implemented at origin as described in the draft Article 8.Y.6., the Group decided to draft specific provisions to be implemented at the quarantine station at destination and before releasing the animals (*i.e.* clinical observation, quarantine and laboratory testing).

¹ Desquesnes M. (2004). Livestock trypanosomes and their vectors in Latin America. OIE (World Organisation for Animal Health, Paris, France, p. 27. ISBN: 92-9044-634-X

Article 8.Y.3 bis Compartment free from infection with animal trypanosomes of African origin

The Group took note of Chapter 4.3. and 4.4. of the *Terrestrial Code* and agreed that the compartmentalisation concept could also be applied to animal trypanosomes of African origin.

It was pointed out that susceptible animals, in the free compartment, should be protected against the vectors by the application of an effective biosecurity management system and that the surveillance should be implemented in accordance with the Chapter 1.4. and the draft Articles 8.Y.13 to 8.Y.16.

Article 8.Y.4 Recovery of free status

The Group continued the discussion initiated during its previous meeting on the need to require serological tests, in addition to the treatment for the recovery of freedom after an incursion.

The Group noted that specific serum antibodies could last up to 6 months after an appropriate treatment is applied so the presence of serum antibodies would not necessarily indicate the presence of an ongoing active infection. It was agreed that the absence of antibodies in previously infected animals would provide additional evidence for the effectiveness of the treatment and therefore for the complete elimination of the parasites.

The Group concluded that, for the recovery of the free status after an incursion, the affected animals need to be either killed, slaughtered or treated. The official re-establishment of the free status should happen only after affected animals and exposed, susceptible animals (i.e. herdmates) have undergone monthly repeated serological and pathogen detection tests until both tests are negative for six consecutive months.

The Group agreed to provide specific surveillance recommendations for the recovery of freedom in the surveillance articles.

Article 8.Y.6. Recommendations for the importation of live animals from an infected country or zone

The Group took note of the concern expressed by the Scientific Commission about the recommendations to implement risk mitigation measures in the country or zone of destination. It was noted that for international trade, the *Terrestrial Code* mostly recommends measures to be implemented and certified at the exporting country.

The Group considered that the likelihood of importing an infected animal would be quite low after implementing the previously suggested risk mitigation measures in the country of origin (i.e.: quarantine, serological test, transport in vector-protected vehicle and clinical observation). It was also noted that importing *Trypanosoma spp.* infected animals into a free country or zone would have significant biological and economic consequences. However, the consequences would be less adverse if infected animals are imported into an already infected country or zone.

The Group decided to recommend mitigation measures to address the residual risk caused by a potential reactivation of parasitaemia after a period of stress during transport and at destination only in countries or zones that want to gain or maintain their free status (see above -draft Article 8.Y.3-). These recommendations would not apply for the importation of live animals into countries or zones not considered free.

The Group discussed at length the Scientific Commission's request to consider the merit and feasibility of providing recommendations for the importation of susceptible animals from infected countries or zones directly to slaughter. The Group assessed that, in the presence of competent vectors at destination, the risk of spreading the disease would not be negligible, even if the animals go directly to the slaughterhouse. The Group agreed that this type of movement would be considered safe only if the animals travel in vector-protected vehicles and if the animals are also protected against the vectors at the slaughterhouse. However, these recommendations were not considered practical. The Group concluded that the provisions of Article 8.Y.6. should apply when animals are imported directly to the slaughterhouse.

Article 8.Y.13. to Article 8.Y.16. Surveillance

The Group emphasised that the general purpose of surveillance should be (i) the demonstration of the absence, (ii) the early detection, or (iii) the measurement and monitoring of the prevalence and distribution of infections with animal trypanosomes of African origin in a country, zone or compartment;

Sentinel animals

The Group recognised the value of using sentinel animals as part of a surveillance system. It was noted that, in addition to using sentinel livestock units, the investigation of clinically suspect cases in highly susceptible animals such as dogs, donkeys or horses² could also be considered as part of the sentinel system.

Vector surveillance

The Group took in consideration the provisions of Chapter 1.5. and agreed to draft some specific vector surveillance recommendations for animal trypanosomoses of African origin.

The Group pointed out that, in the areas where cyclical transmission plays a role, the demonstration of absence of tsetse flies could support the claim for freedom. It was also noted that trapping vectors is one of the most reliable means to gather vector-related information. It was stressed that vector collection tools should be adapted to the local ecological conditions, species and group of the vectors.

The Group recommended that, when sentinel animals are used, vector surveillance should also be carried out at the same location.

Additional surveillance procedures for the recovery of the free status

The Group agreed that active surveillance should be implemented when a country or zone wants to recover the free status after an incursion. The target population for surveillance should include establishments located near or with epidemiological links to the outbreak, as well as screening the animals used to re-populate the affected establishments.

5. **Assessment of *T. evansi* and *T. equiperdum* against the criteria described in Chapter 1.2. of the *Terrestrial Code***

The Group assessed *T. evansi* and *T. equiperdum* against the criteria described in the *Terrestrial Code* chapter 1.2.

The Group noted the challenge for the detection and laboratory diagnosis of *T. equiperdum* due to the low parasitaemia and the chronic nature of the disease. However, it was pointed out that reliable means of diagnosis exist and are described in the *Terrestrial Manual*. Therefore, *T. equiperdum* fulfils the criteria 3 of Chapter 1.2 of the *Terrestrial Code*.

² (1) Cherdchutham, W., Desquesnes, M., Yangtara, S. & Jittapalpong, S. (2012) Clinical observations and efficacy of diminazene diaceturate and melarsamine hydrochloride for the treatment of surra in horses in Thailand. *Proceedings of the first Regional Conference of the Society for Tropical Veterinary Medicine (STVM): A change in global environment, biodiversity, diseases and health; 18-21 June 2012, Phuket, Thailand.*, 25.
 (2) Desquesnes, M., Holzmüller, P., Lai, D.H., Dargantes, A., Lun, Z.R. & Jittapalpong, S. (2013) *Trypanosoma evansi* and surra: a review and perspectives on origin, history, distribution, taxonomy, morphology, hosts, and pathogenic effects. *Biomed Res Int* **2013**, 194176. DOI: 10.1155/2013/194176.
 (3) Gill, B. (1977) Trypanosomes and trypanosomiasis of Indian livestock. *Indian Council of Agricultural Research, Edit. ICAR, New Delhi, 1977, A booklet* (first edition), 137 pages.
 (4) Rjeibi, M.R., Ben Hamida, T., Dalgatova, Z., Mahjoub, T., Rejeb, A., Dridi, W. & Gharbi, M. (2015) First report of surra (*Trypanosoma evansi* infection) in a Tunisian dog. *Parasite* **22**, 3. DOI: 10.1051/parasite/2015004.
 (5) Faye D, Pereira de Almeida PJJ, Goossens B, Osaer S, Ndao M, Berkvens D, Speybroeck N, Nieberding F, Geerts S (2001). Prevalence and incidence of trypanosomosis in horses and donkeys in the Gambia. *Vet Parasitol* 101:101–114.
 (6) Snow WF, Wachter TJ, Rawlings P (1996) Observations on the prevalence of trypanosomosis in small ruminants, equines and cattle, in relation to tsetse challenge, in the Gambia. *Vet Parasitol* 66:1–11.
 (7) A. Sow, I. Sidibé, M. Kalandi, A. Bathily, N. P. Ndiaye, M. Ouédraogo, M. M. M. Mouiche & G. J. Sawadogo (2012). Biochemical changes induced by natural infection of trypanosomosis in Burkinabese local donkey breeds. *Comp Clin Pathol* DOI 10.1007/s00580-012-1579-2.

Regarding *T. evansi*, the Group took note of the report of human cases in some people that lacked a functional trypanolytic factor, apolipoprotein L1 (APOL1) (Joshi et al, 2005, Truc et al, 2013)³ but also in an apparently healthy individual, with normal APOL1 enzymatic activity (Van Vinh et al., 2016)⁴. The Group discussed the impact and public health implication of the findings and finally concluded that *T. evansi* also fulfils the criteria 4a of Chapter 1.2.

The Group concluded, that, based on the current scientific knowledge, *T. evansi* and *T. equiperdum* match the listing criteria and recommended to include them in the OIE List.

The detailed assessments are included as Appendix IV.

6. Other matters

The Group noted the need for detailed guidance for tsetse flies surveillance and agreed on the need to develop specific guidelines considering the existing probabilistic models to demonstrate absence of tsetse flies.

The Group also discussed the purposes of the different diagnostic methods described in the *Terrestrial Manual* Chapter 2.4.17. It emphasised that the recommended methods for agent detection should be:

- (i) The thin stained smear because of its specificity to identify the sub-genus or species but noting its low sensitivity;
- (ii) The hematocrit centrifugation technique because of its sensitivity, but noting its low specificity (sub-genus or less);
- (iii) Molecular techniques because they are sensitive and highly specific. However, they may not be able to detect latent infections with low parasitemia.

The recommended method for antibody detection is the ELISA which presents a very high sensitivity to detect the immune contact of the host with the parasites, however, the interpretation of the results should consider the possible cross-reactions amongst pathogenic trypanosomes and *Leishmania* spp.

The Group noted that the *Terrestrial Manual* Chapter 2.4.17 was adopted in the absence of a *Terrestrial Code* chapter on animal trypanosomes of African origin. The Group advised that the *Terrestrial Manual* Chapter 2.4.17. should be amended to clearly indicate the fitness for purpose and limitations of the different laboratory diagnostic methods and to ensure correct alignment between the two chapters.

Finally, the Group briefly brainstormed to identify some knowledge gaps that, when addressed, may contribute to the improvement of the international standards and therefore the control of the disease. It is worth noting that, due to other priorities during this meeting, the Group was not able to conduct a prioritization exercise aimed at creating a comprehensive list of knowledge gaps. The following aspects were identified:

- Better understanding of the epidemiological role of other species of animal trypanosomes (*T. uniforme*, *T. suis* and *T. godfreyi*);
- Development of a standardised methodology to demonstrate local or regional environmental freedom from tsetse flies;
- Development of pan-trypanosomes antibody detection ELISA;

³ Joshi, PP, Shegokar VR, Powar RM, Herder S, Katti R, Salkar HR, Dani VS, Bhargava A, Jannin J, Truc P., (2005). Human trypanosomiasis caused by *Trypanosoma evansi* in India: the first case report. *Am J Trop Med Hyg.*; **73**(3), 491-5.
Truc,P, Buscher,P, Cuny,G, Gonzatti, MI, Jannin, J, Joshi, P, Juyal, P, Lun,Z-R, Mattioli, R, Pays, E, Teixeira,MMG, Touratier, L, Vincendeau, VP and Desquesnes,M. 2013. Atypical Human Infections by Animal Trypanosomes. *PLoS Neg Trop Dis.* **7**(9), e2256.

⁴ Van Vinh Chau N., Buu Chau L., Desquesnes M., Herder S., Phu Huong Lan N., Campbell J.I., Van Cuong N., Yimming B., Chalermwong P., Jittapalpong S., Franco J.R., Tue N.T., Rabaa M.A., Carrique-Mas J., Thanh T.P.T., Tran Vu Thieu N., Berto A., Thi Hoa N., Van Minh Hoang N., Canh Tu N., Khac Chuyen N., Wills B., Tinh Hien T., Thwaites G.E., Yacoub S. & Baker S., (2016). A clinical and epidemiological investigation of the first reported human infection with the zoonotic parasite *Trypanosoma evansi* in Southeast Asia. *Clin. Infect. Dis.*, **62**, 1002–1008. doi:10.1093/cid/ciw052

- Treatment decision guidelines, based on diagnostic tests;
- Epidemiology of trypanocidal drug resistance and genetic marker for trypanocidal drug resistance;
- Better understanding of the drivers for the persistence of cyclically-transmitted trypanosomes after the cyclical vector is eliminated, and the role of mechanical vectors in the epidemiology of the disease in areas where tsetse flies have been eliminated.

7. 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.

.../Appendices

Appendix I

MEETING OF THE OIE AD HOC GROUP ON ANIMAL AFRICAN TRYPANOSOMOSES
Paris, 15 – 17 January 2019

Agenda

1. Opening of the meeting
 2. Appointment of chairperson and rapporteur, and adoption of the agenda
 3. Consideration of the feedback provided by the Scientific Commission, the OIE Wildlife Working Group and the OIE Headquarters secretariat
 4. Finalisation of the *Terrestrial Animal Health Code* Chapter 8.Y. *Infection with animal trypanosomes of African origin*
 5. Assessment of *T. evansi* and *T. equiperdum* against the criteria described in Chapter 1.2. of the *Terrestrial Code*
 6. Other matters
 7. Adoption of the report
-

Appendix II

MEETING OF THE OIE AD HOC GROUP ON ANIMAL AFRICAN TRYPANOSOMOSES
Paris, 15 – 17 January 2019

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Appendix III

**Assessment of the different species of animal trypanosomes of African origin
against the listing criteria of Chapter 1.2. of the *Terrestrial Code***

Assessment of infection with *Trypanosoma brucei* spp (including *T. brucei brucei*, *T. b. rhodesiense* and *T. b. gambiense*, but excluding *T. evansi* and *T. equiperdum*) according to the criteria provided in the OIE *Terrestrial Animal Health Code* Chapter 1.2. Criteria for the inclusion of diseases, infections and infestations in the OIE list, Article 1.2.2.

The criteria for the inclusion of a disease, infection or infestation in the OIE list are as follows:

1) International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.

Yes ☒ No ☐

Scientific rationale:

T. brucei spp are mainly transmitted by biological vectors (tsetse flies), occasionally by mechanical vectors (tabanids, stomoxes and other haematophagous dipters) and *via* live animals and their products (fresh blood, meat, carcass etc) and possibly including using fomites such as needles (serial injections). *T. brucei* spp may be found in 36 African countries. So far, *T. brucei* spp have not been able to spread out of Africa, due to very limited mechanical transmission, it is considered to be mostly tsetse dependant for transmission and sustainable enzootic/endemic situation.

AND

2) At least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the provisions of Chapter 1.4.

Yes ☒ No ☐

Scientific rationale: Only 36 African countries, so far, have been found infected by *T. brucei* spp infection(s). Thus all other countries are free of autochthonous infection.

AND

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.

Yes ☒ but No ☐

Scientific rationale:

Reliable means of detection and diagnosis exist and a precise case definition is available to clearly identify *T. brucei* infection and/or disease, and allow them to be distinguished from other infections and/or diseases, however, it must be stated that:

- 1) In animals, *T. brucei* spp belong to a disease complex called Nagana, which is due to infection by one or several species of *Trypanosoma* including *T. vivax*, *T. congolense* and *T. brucei* spp, consequently, the disease Nagana does not necessarily require species identification to be identified itself;

- 2) in *Trypanosoma* infections, species identification is not always possible due to (i) limited sensitivity: when the parasitaemia is too low, species identification is not possible; and (ii) limited specificity of the diagnosis tools making sometimes difficult to distinguish species or subspecies of Trypanozoons (e.g. *T. brucei* spp from *T. evansi* and *T. equiperdum*). However, a positive molecular identification is reliable.

AND

4a) Natural transmission to humans has been proven, and human infection is associated with severe consequences.

Yes ☒ No ☐

Scientific rationale:

Two sub-species of *T. brucei* can infect humans *T. b. gambiense* and *T. b. rhodesiense*; they are responsible for a disease most often fatal (Büscher et al., 2017); diagnosis is crucial and not always reliable, although strongly needed due to the toxicity of treatments, especially for the meningo-encephalitic phase of the disease (stage 2). For *T. b. rhodesiense*, the existence and epidemiological relevance of the animal reservoir has been clearly demonstrated (Fèvre et al., 2001; Büscher et al., 2017), while for *T. b. gambiense* the epidemiological relevance of the existing animal reservoir is still unclear (Büscher et al., 2018).

OR

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.

Yes ☒ No ☐

Scientific rationale:

T. brucei spp infection is of a medium prevalence in cattle, but it can affect a large range of other domestic and wild hosts; it is one of the 3 *Trypanosoma* species responsible of the disease complex "Nagana", *T. brucei* spp are considered to have the lowest impact on animals compared to *T. vivax* and *T. congolense*, however, their real pathogenicities are poorly documented in livestock, probably hidden by the other 2 parasites mentioned, and, also because experimental handling of human pathogens is feared. Because of their zoonotic potential, control of *T. brucei* spp infections in livestock should be a priority, even if their pathogenicity is considered to be lower than those of *T. congolense* and *T. vivax*. Because they belong to a disease complex, the knowledge of the individual impact of *T. brucei* spp on livestock is limited, however, loss in milk, meat and manure production in cattle, horse, sheep and goats, are expected, similarly to other salivarian *Trypanosoma* species infections.

OR

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.

Yes ☐ No ☒

Scientific rationale:

Although some infections are commonly found in wildlife, *T. brucei* spp are not suspected to be of significant impact on wildlife, but the latter has a potential role of reservoir of the parasite.

Conclusion regarding *T. brucei* spp:

Does *T. brucei* spp match the listing criteria that are described in the *Terrestrial Animal Health Code* [Chapter 1.2.2](#)

Yes ☒ No ☐

Summary Conclusion:

Based on criteria 1, 2, 3 and 4b, *Trypanosoma brucei* spp fulfill all criteria to be included in the OIE list; however a remark must be made on criteria 3; if reliable means of detection and diagnosis do exist, and a precise definition case is available to clearly identify cases, **they do not always allow to distinguish *T. brucei* spp infections from other *Trypanosoma* infections, and, sometimes, from other infections**, due to limits in sensitivity and specificity of diagnosis tools. However, a positive molecular identification is reliable.

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Assessment of infection with *T. congolense* (*T. savannah*, *T. forest*, *T. kilifi*) according to the criteria provided in the OIE Terrestrial Animal Health Code Chapter 1.2. Criteria for the inclusion of diseases, infections and infestations in the OIE list, Article 1.2.2.

The criteria for the inclusion of a disease, infection or infestation in the OIE list are as follows:

1) International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.

Yes ☒ No ☐

Scientific rationale:

The trypanosomes pathogenic to livestock in Africa (*Trypanosoma congolense*, *Trypanosoma vivax*, and *Trypanosoma brucei*) are mainly cyclically transmitted by vector tsetse (*Glossina*) (Desquesnes and Dia, 2003) .

Where the hosts, vectors and parasites are present in a same area, the disease is present. Displacement of hosts (infected or not) or vectors (infected or not) by changes in ecological conditions or passive transport will spread the disease in the concerned zones.

(Allsopp et al., 2004; Radwanska et al., 2018)

AND

2) At least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the provisions of Chapter 1.4.

Yes ☒ No ☐

Scientific rationale:

As opposite to the first point, when hosts, vectors and parasites are not present together in an area, the disease will not be present or will disappear quickly. The eradication of the vectors in a specific zone will lead to the disappearance of the disease.

(Allsopp et al., 2004; Cecchi et al., 2014)

AND

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.

Yes ☒ No ☐

Scientific rationale

The identification of the parasite in a host is pathognomonic for the disease. Trustable molecular methods are available.

(Geysen et al., 2003; Odongo et al., 2016; Tran et al., 2014)

AND

4a) Natural transmission to humans has been proven, and human infection is associated with severe consequences.

Yes ☐ No ☒

Scientific rationale:

T. congolense has a broader range of hosts including livestock and game animals but is generally accepted to be non-infective to humans. It should however be mentioned that a mixed *T. b. gambiense*/*T. congolense* infection has been reported in a human (Truc et al., 1996 in: Radwanska et al., 2018)

OR

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.

Yes ☒ No ☐

Scientific rationale:

Trypanosoma (Nannomonas) *congolense* is probably the most prevalent and widespread pathogenic trypanosome in Sub-Saharan Africa, being found in ruminants, pigs, dogs and other domestic animals throughout the tsetse belt (Peacock et al., 2012).

T. congolense is responsible for the most important form of animal African Trypanosomoses in domestic animals such as bovines, equines, sheep, goats, camels and pigs (Ford, 1971)

T. congolense is the most important trypanosome affecting cattle in Africa. There are many different strains that vary in their virulence. As the disease progresses, animals develop a marked anaemia, hair coat becomes lustreless and stary, there is severe loss of bodily condition manifesting as sunken eyes, prominent vertebrae and ribs, wasted gluteal and crural muscles. In chronic cases reproduction is affected with calves failing to reach sexual maturity. Death may occur within a few weeks but usually takes months to a year.

The impact of the disease is supported by enough scientific data

(Allsopp et al., 2004; Shaw et al., 2014)

OR

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.

Yes ☐ No ☒

Scientific rationale:

Wildlife is known to be a reservoir for *T. congolense* but does not impact significantly the health of the games. It is, however, risky to breed livestock in the vicinity of a game reserve.

(Chitanga et al., 2013; Van den Bossche et al., 2011)

Conclusion regarding *T. congolense*:

Does *T. congolense* match the listing criteria that are described in the Terrestrial Animal Health Code [Chapter 1.2](#)?

Yes ☒ No ☐

Summary Conclusion:

Animal African Trypanosomoses caused by *T. congolense* should be included in the *Terrestrial code*

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Assessment of infection with *T. godfreyi* according to the criteria provided in the OIE Terrestrial Animal Health Code Chapter 1.2. Criteria for the inclusion of diseases, infections and infestations in the OIE list, Article 1.2.2.

The criteria for the inclusion of a disease, infection or infestation in the OIE list are as follows:

1) International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.

Yes ☒ No ☐

Scientific rationale:

Trypanosoma (Nannomonas) godfreyi is primarily confined to wild and domestic suids and is transmitted by tsetse flies in sub-Saharan Africa. Where the hosts, vectors and parasites are present in a same area, the disease is present. Displacement of hosts (infected or not) or vectors (infected or not) by changes in ecological conditions or passive transport will spread the disease in the concerned zones.

(McNamara et al., 1994; Gibson et al, 2001, Stevens and Brisse, 2004; Auty et al., 2012)

AND

2) At least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the provisions of Chapter 1.4.

Yes ☒ No ☐

Scientific rationale:

T. (N) godfreyi was first isolated in *Glossina mortisans submortisans* in The Gambia and has also been shown in Tanzania and Zimbabwe. Experimentally, *T. godfreyi* causes sub-acute infection in warthogs. As opposite to the first point, areas free of hosts, vectors and parasites are free of the disease. The eradication of the vectors in a specific zone will lead to the disappearance of the disease.

(McNamara et al, 1994;Stevens and Brisse, 2004)

AND

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.

Yes ☒ No ☐

Scientific rationale:

The identification of the parasite in a host is pathognomonic for the disease. A DNA probe specific for a *T. godfreyi* repeat (satellite) sequence is available.

(Masiga et al., 1996; Auty et al., 2012;Gibson et al. 2001,; Malele et al., 2003)

AND

4a) Natural transmission to humans has been proven, and human infection is associated with severe consequences.

Yes ☐ No ☒

Scientific rationale:

No reference is available about cases of transmission to human

OR

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.

Yes ☐ No ☒

Scientific rationale:

The presence of the parasite has been mainly reported in its invertebrate host in Sub-Saharan Africa, with few reports of in wildlife and domestic suids. It is mildly pathogenic (subacute disease in experimentally infected piglets)

(Stevens and Brisse., 2004; Auty et al., 2012, Hamill et al, 2013)

OR

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.

Yes ☐ No ☒

Scientific rationale:

Wildlife is known to be a reservoir for *T. godfreyi*, but the parasite does not impact significantly the health of wild suids.

(Stevens and Brisse., 2004; Auty et al., 2012, Hamill et al. 2013)

Conclusion regarding *T. godfreyi*:

Does *T. godfreyi* match the listing criteria that are described in the *Terrestrial Animal Health Code* [Chapter 1.2](#)?

Yes ☐ No ☒

Summary Conclusion:

Animal African Trypanosomosis caused by *T. godfreyi* should not be included in the Terrestrial Animal Health Code

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Assessment of infection with *Trypanosoma simiae* (including *T. simiae tsavo*) according to the criteria provided in the OIE Terrestrial Animal Health Code Chapter 1.2. Criteria for the inclusion of diseases, infections and infestations in the OIE list, Article 1.2.2.

The criteria for the inclusion of a disease, infection or infestation in the OIE list are as follows:

1) International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.

Yes ☒ No ☐

Scientific rationale:

Trypanosoma (Nannomonas) simiae is primarily but not solely confined to wild and domestic suids and is transmitted by tsetse flies in sub-Saharan Africa. It is the only species of trypanosome that is extremely pathogenic to domestic pigs, in which it causes acute and fatal disease outbreaks of short duration. Its name derives from its description from experimentally infected monkeys.

Where the hosts, vectors and parasites are present in a same area, the disease is present. Displacement of hosts (infected or not) or vectors (infected or not) by changes in ecological conditions or passive transport will spread the disease in the concerned zones.

(Hoare, 1972) (Claxton *et al.*, 1992) (Stevens & Brisse, 2004)

AND

2) At least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the provisions of Chapter 1.4.

Yes ☒ No ☐

Scientific rationale:

T. simiae infection(s) have only been found in Sub-Saharan Africa. Thus all other countries are free of autochthonous infection.

AND

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.

Yes ☒ No ☐

Scientific rationale:

Several studies based on the biochemical characterization of this species have better differentiated it from *T. congolense*. Gashumba *et al.* (1986), made a preliminary comparison of *T. simiae* and *T. congolense* based on the electrophoresis of six isoenzymes. All the enzymes showed different profiles between the two species. These results were reinforced by the observations by Sidibé (1996) based on 18 enzymatic systems and 24 RAPD primers. Species-specific probes for *T. simiae* show that the satellite DNA of *T. simiae* is distinct from that of *T. congolense* and other Salivarian trypanosomes (Majiwa and Webster, 1987).

Garside *et al.* (1995) had previously shown in that the *T. simiae* and *T. godfreyi* species of the subgenus *Nannomonas* do not possess the glutamic acid gene.

(Gashumba *et al.*, 1986) (Sidibé, 1996) (Majiwa & Webster, 1987) (Garside & Gibson, 1995)

AND

4a) Natural transmission to humans has been proven, and human infection is associated with severe consequences.

Yes ☐ No ☒

Scientific rationale:

No reference is available about cases of transmission to human

OR

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.

Yes ☒ No ☐

Scientific rationale:

T. simiae is the only species of trypanosome that is extremely pathogenic to domestic pigs, in which it causes acute and fatal disease outbreaks of short duration.

(Stevens & Brisse, 2004)

OR

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.

Yes ☐ No ☒

Scientific rationale:

Wildlife is known to be a reservoir for *T. simiae*, available evidence does not indicate that it has 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”.

(Claxton *et al.*, 1992)

Conclusion regarding *T. simiae*:

Does *T. simiae* match the listing criteria that are described in the *Terrestrial Animal Health Code* [Chapter 1.2](#)?

Yes ☒ No ☐

Summary Conclusion:

Animal African trypanosomosis caused by *T. simiae* should be included in the *Terrestrial Animal Health Code*

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Assessment of infection with *Trypanosoma vivax* according to the criteria provided in the OIE Terrestrial Animal Health Code Chapter 1.2. Criteria for the inclusion of diseases, infections and infestations in the OIE list, Article 1.2.2.

The criteria for the inclusion of a disease, infection or infestation in the OIE list are as follows:

1) International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.

Yes ☒ No ☐

Scientific rationale:

T. vivax is transmitted by biological vectors (tsetse flies), mechanical vectors (tabanids, stomoxes and other haematophagous dipters) and *via* live animals and their products (fresh blood, meat, carcass etc), and by fomites such as needles (serial injections). Originating from Africa where it is found in 37 countries, *T. vivax* was introduced to Latin America where its geographical spreading is continuing nowadays. It has a potential for further expansion to other geographical areas, including Europe and Asia.

AND

2) At least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the provisions of Chapter 1.4.

Yes ☒ No ☐

Scientific rationale:

Europe, Asia, Australia and North America are free of *T. vivax* infection.

AND

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.

Yes ☒ No ☐

Scientific rationale: Reliable means of detection and diagnosis exists, and a precise case definition is available to clearly identify *T. vivax* infection and/or disease, and allow them to be distinguished from other infections, however, it must be stated that:

- 3) *T. vivax* belongs to a disease complex called Nagana, which is due to infection by one or several species of *Trypanosoma*, including *T. vivax*, *T. congolense* and *T. brucei* spp, consequently, the disease Nagana does not necessarily require species identification to be identified itself;
- 4) A positive identification using clear blood smears or species-specific molecular tools allow to clearly identify cases, however, in *Trypanosoma* infections, species identification is not always possible due to limited sensitivity, when the parasitaemia is too low. Consequently, in areas of possible mixed infections, distinction of *T. vivax* from *T. evansi* infection (for example in buffaloes in Latin America) is not always possible. Similarly, distinction of *T. vivax* from *T. congolense* and Trypanozoon infections in Africa.

AND

4a) Natural transmission to humans has been proven, and human infection is associated with severe consequences.

Yes ☐ No ☒

Scientific rationale:

Only one case of human infection was reported in 1917; *T. vivax* is not zoonotic and must be considered only as a mammal restricted parasite.

OR

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.

Yes ☒ No ☐

Scientific rationale:

T. vivax infection is highly prevalent especially in cattle, but it can also affect a wide range of other domestic and wild hosts; it is the most prevalent *Trypanosoma* sp. in Africa and Latin America, due to high parasitaemia and thus very efficient mechanical transmission by biting flies (including tsetse flies in Africa) and must be considered as a first priority for control, even if its pathogenicity is considered to be lower than that of *T. congolense*. *T. vivax* infections are responsible for important loss in milk, meat and manure production in cattle, horse, sheep and goats, including buffaloes in Latin America.

OR

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.

Yes ☐ No ☒

Scientific rationale:

Although the infection is sometimes found in wild antelopes, *T. vivax* is not suspected to be of importance in wild life, but the latter has a potential role of reservoir of the parasite.

Conclusion regarding *T. vivax*:

Does *T. vivax* match the listing criteria that are described in the *Terrestrial Animal Health Code* [Chapter 1.2](#)?

Yes ☒ No ☐

Summary Conclusion:

Based on criteria 1, 2, 3 and 4b, *Trypanosoma vivax* fulfills all criteria to be included in the OIE list; however a remark must be made on criteria 3; if reliable means of detection and diagnosis do exist, and a precise definition case is available to clearly identify cases, they do not always allow to distinguish *T. vivax* infection from other *Trypanosoma* infections, and, sometimes, from other infections, due to limits in sensitivity of diagnosis tools. However, a positive identification is reliable.

It must be stated that another *Trypanosoma* species, very closely related to *T. vivax* has been described in the subgenus Duttonella: *T. uniforme*; however, very few reports on this parasite are available, so its prevalence is considered to be low, if ever. The potential pathogenic effects of *T. uniforme* on its mammalian hosts are considered close to those of *T. vivax*, however, due to limited reports, and possible misidentifications, it is suggested that *T. uniforme*, if ever identified, be considered as a variant of *T. vivax*.

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Appendix IV

Assessment of *T. evansi* and *T. equiperdum* against the criteria described in Chapter 1.2. of the *Terrestrial Code*

Assessment of infection with *Trypanosoma equiperdum* according to the criteria provided in the OIE Terrestrial Animal Health Code Chapter 1.2. Criteria for the inclusion of diseases, infections and infestations in the OIE list, Article 1.2.2.

The criteria for the inclusion of a disease, infection or infestation in the OIE list are as follows:

1) International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.

Yes ☒ No ☐

Scientific rationale:

T. (T.) equiperdum (Doflein, 1901) is the causative agent of dourine, it is generally transmitted by coitus between members of the Equidae family (horses and donkeys) (Stevens and Brisse, 2004). Seven dourine outbreaks were reported in Italy in 2011 (Pascucci et al, 2013). Epidemiological investigation of one of the outbreaks led to a Friesian stallion (index case) that had contacts with an infected mare, which had been imported from the Netherlands in 2009 (Calistri et al., 2013).

AND

2) At least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the provisions of Chapter 1.4.

Yes ☒ No ☐

Scientific rationale:

Dourine has a wide geographical distribution, and it has been considered endemic in North Africa, the Middle East, Eastern Europe, South America and Indonesia. Outbreaks in Italy (2011) were controlled by veterinary authorities (Pascucci et al, 2013; Calistri et al., 2013). New *T. equiperdum* strains have been reported in Venezuela (Sanchez et al, 2015), Ethiopia (Hagos et al, 2010) and Mongolia (Suganuma et al., 2016). North America has reported freedom of the disease and Oceania is free of the disease (Claes et al, 2005).

AND

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.

Yes ☒ No ☐

Scientific rationale:

Pathological lesions (oedematous plaques) are observed mainly in the reproductive organs, in the nervous system, and on the skin and are still considered as characteristic clinical signs of dourine, although they have been occasionally found in equids infected with *T. evansi*. Detection of *T. equiperdum*, by parasitological/molecular techniques, is usually difficult even in dourine positive equids, due to the low parasitemias in the blood or tissue fluids and the chronic nature of the disease. In addition, differential diagnosis of *T. evansi* in areas where surra is present lies on PCR based on kDNA maxicircle sequences, since

T. evansi lacks kDNA maxicircles. However, akinetoplastic strains of *T. evansi* have been described (Carnes et al, 2013). A highly sensitive real time PCR test has been used to detect *T. equiperdum* in tissues and fluid samples of naturally infected horses (Pascucci et al, 2013). The complement fixation test (CFT) and the indirect fluorescence antibody test (IFAT) are the OIE recommended tests for *T. equiperdum* infection (OIE, 2018). The complement fixation test (CFT) was used in North America in the successful campaign for the eradication of dourine (*Trypanosoma equiperdum* infection).

AND

4a) Natural transmission to humans has been proven, and human infection is associated with severe consequences.

Yes ☐ No ☒

Scientific rationale:

No infection of humans by *T. equiperdum* has been reported to date.

OR

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.

Yes ☒ No ☐

Scientific rationale:

There is no vaccine available for dourine (Gizaw et al, 2017) and infections with *T. equiperdum* have been considered incurable (Gillingwater et al., 2007), especially in the neurological stages (Hébert et al et al., 2018). If untreated, dourine is often fatal (Gizaw et al, 2017). Over 50% mortality rates have been reported for highly valued horses (breeders) and the disease can have devastating effects on the equine industry (Sidney et al. 2013). In Mongolia, where the prevalence of dourine was estimated at 7.6 and 6.7%, by CFT and ELISA, respectively, horses comprise 5.9% of the total livestock and horse meat production value per annum was estimated at approximately 48 million US\$, in 2013 (Davaasuren et al, 2017; Gizaw et al., 2017)

OR

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.

Yes ☐ No ☒

Scientific rationale:

Dourine has been shown to affect only horses, mules and donkeys. Zebras have tested positive by serology, but there is no conclusive evidence of infection (Brun et al 1998).

Conclusion regarding *T. equiperdum*:

Does *T. equiperdum* match the listing criteria that are described in the Terrestrial Animal Health Code [Chapter 1.2](#)?

Yes ☒ No ☐

Summary Conclusion:

T. equiperdum, as well as *T. evansi* have evolved from *T. brucei* in multiple occasions. *T. equiperdum* strains have been divided in two or more clades of distinct evolutionary origin (Carnes et al., 2013, Claes et al, 2015, Cuypers et al., 2017). Newly isolated *T. equiperdum* strains from outbreaks in Italy and in Mongolia have been reported (Pascucci et al, 2013, Suganuma et al, 2016).

Genomic and genetic studies have demonstrated that *T. equiperdum* has evolved at least once from *T. brucei* strains in Eastern Africa (Carnes et al., 2013, Cuypers et al, 2017). *T. evansi* and *T. equiperdum* are considered diskinetoplastic parasites because they have lost part (*T. eq*) or all the maxicircle kDNA (*T. ev*). Some authors have proposed that *T. evansi* and *T. equiperdum*, as the causative agents of *dourine*, be considered as sub-species of *T. brucei* (Lun et al. 2008, Lai et al, 2010, Carnes et al, 2013).

Based on criteria 1, 2, 3 and 4b, *T. equiperdum* fulfills all criteria to be included in the OIE list, however, confirmation of *Trypanosoma equiperdum* infection and dourine requires an overall evaluation of the clinical signs, positive parasitological and molecular identification and serological tests, as well as epidemiological data to distinguish infections with *T. equiperdum* from other *Trypanosoma* spp. of the Trypanozoon sub-genus.

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**Assessment of infection with *T. evansi* according to the criteria
provided in the OIE Terrestrial Animal Health Code Chapter 1.2. Criteria for the inclusion of diseases,
infections and infestations in the OIE list, Article 1.2.2.**

The criteria for the inclusion of a disease, infection or infestation in the OIE list are as follows:

1) International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.

Yes ☒ No ☐

Scientific rationale:

Trypanosoma (Trypanozoon) evansi (Steel, 1885; Babiani, 1888) is the first pathogen mammalian trypanosome to be described by Evans in 1880 (Hoare, 1972). *T. evansi* is mechanically transmitted by biting diptera (*Tabanus* and *Stomoxys* spp.), vampire bats, live animals or by their contaminated products (fresh blood, meat, carcass, etc), as well as by serial injections with infected needles. *T. evansi* infects a wide range of wild and domestic animal species, including camels, horses, donkeys, capybaras, buffaloes, cattle, goats, sheep, dogs and small rodents causing the disease known as Surra (Desquesnes et al, 2013, Desquesnes et al, 2013 a). Hence, the movement of infected animals, their products, vectors or fomites can spread the disease between countries.

AND

2) At least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the provisions of Chapter 1.4.

Yes ☒ No ☐

Scientific rationale:

T. evansi has not been reported in North America and Australia and is currently not present in continental Europe. *T. evansi* is present in Central and South America, North Africa, and Asia and has been occasionally reported in Europe (Desquesnes et al, 2009, Gutierrez et al, 2010).

AND

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.

Yes ☒ No ☐

Scientific rationale:

Clinical signs are not pathognomonic for Surra caused by *T. evansi*. A comprehensive list of confirmatory tests appears in the OIE terrestrial manual chapter 2.1.21 (OIE, 2018): microscopic examination of blood films, smears or biopsies, HCT, rodent inoculation, PCR, CATT, ELISA, among others. Parasitological and serological methods are used to identify *T. evansi* in acute or chronic infections. The sensitivity of serological methods based on VSG RoTat 1.2 is dependent on the expression of the specific VSG and varies with the host species. In multi-*Trypanosoma* spp. areas, serological cross-reactivity will limit the interpretation of the diagnostic tests. Evaluation of various primers that have been used to diagnose *T. evansi* infections by PCR showed that the TBR1/2 primers (Masiga et al., 1992) are the most sensitive and specific (Fernandez et al, 2009, Pruvot et al, 2010, Ashour et al., 2013). The EVAB and VSG Ro.Tat1.2 primers have been successfully used to identify the most abundant, *T. evansi* type A, as well as the type B present in dromedary camels, in Kenya and Ethiopia (Njiru et al, 2006, Birhanu et al. 2016) . Identification of *T. evansi* by PCR will be limited at low parasitaemia levels, especially in the chronic phase and in low-susceptibility hosts. In addition, diagnosis of naturally infected host material may require several PCR assays due to the genetic diversity of *T. evansi* (Kamidi et al, 2017) and the possibility of multiple infections by various *Trypanosoma* spp.

AND

4a) Natural transmission to humans has been proven, and human infection is associated with severe consequences.

Yes ☒ No ☐

Scientific rationale:

In general terms, humans possess innate immune mechanisms of protection (ApoL-1) against *T. evansi* and other trypanosomes. However, cases of “atypical human trypanosomosis” (a-HT) caused by *T. evansi* have been reported in patients that lack a functional trypanolytic factor and more recently (Joshi et al, 2005, Truc et al, 2013), in a previously healthy individual, with no Apo-L1 deficiency (Van Vinh et al., 2016). Clinical signs in humans infected with *T. evansi* are often transient, but some patients require treatment and the disease can be fatal. Further studies and surveillance must be carried out to assess its impact on humans.

OR

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.

Yes ☒ No ☐

Scientific rationale:

T. evansi infection is highly prevalent in camels and horses but it also affects other domestic and wild mammals in Asia, Africa and South America (Desquesnes et al, 2013, 2013a). Variation in virulence and pathogenicity of *T. evansi* isolates and strains, as well as the susceptibility of various hosts have been reported (Desquesnes et al, 2013). Further studies are needed to evaluate the direct and indirect economic impact (treatment and vector control) of *T. evansi* infections in domestic hosts (Desquesnes et al, 2013a)

OR

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.

Yes ☐ No ☒

Scientific rationale:

Almost all mammals have been shown to be susceptible to *T. evansi* infections, including wild carnivores, hunting dogs, deer, rabbits, wild pigs and rodents (Desquesnes, 2004). Wildlife clearly plays a role as reservoir for *T. evansi*, but the impact of these infections on the health of wildlife has not been clearly established.

Conclusion regarding *T. evansi*:

Does *T. evansi* match the listing criteria that are described in the *Terrestrial Animal Health Code* [Chapter 1.2](#)?

Yes ☒ No ☐

Summary Conclusion: Based on the OIE criteria for inclusion, trypanosomosis caused by *T. evansi* infection, known as surra or various local names, complies with criteria 1, 2, 3 and 4b and should be included in the OIE list of diseases.

Genomic and genetic studies have demonstrated that *T. evansi* has evolved from multiple *T. brucei* strains in various occasions, acquiring the ability to be mechanically transmitted (Carnes et al., 2013, Cuyppers et al, 2017, Kamidi et al., 2017). Some authors have proposed that *T. evansi* and *T. equiperdum*, the causative agents of dourine, be considered as sub-species of *T. brucei* (Lun et al. 2008, Lai et al, 2010, Carnes et al, 2013). *T. evansi* and *T. equiperdum* are considered diskinetoplastic parasites because they have lost part (*T. eq*) or all the maxicircle kDNA (*T. ev*). Akinetoplastic strains of *T. evansi* have also been described. Based on their minicircle, *T. evansi* strains have been further classified as type A or B (Njiru et al, 2006, Birhanu et al, 2016, Carnes et al., 2013). Some authors have recently proposed revising the taxonomy for *T. evansi* and other members of the *Trypanosoma* genus, since the term sub-species refers to groups of populations within the species “that are geographically and genetically differentiated” (Kamidi et al, 2017). On the other hand, Molinari and Moreno (2018) and Radwanska et al (2018) have recently proposed the “proper application of the principles of biological nomenclature” and the consequent nomenclature change of *T. evansi* for Surra-causing strains of *T. evansi evansi*.

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REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON ANTIMICROBIAL RESISTANCE
Paris, 16–18 January 2019

1. Opening

The OIE *ad hoc* Group on Antimicrobial Resistance (hereafter referred to as ‘the Group’) met from 16 to 18 January 2019 at the OIE Headquarters in Paris, France.

Dr Matthew Stone, Deputy Director General, International Standards and Science, welcomed participants and thanked them for their continued support and contribution to the 2nd OIE Global Conference on Antimicrobial Resistance (AMR), Putting Standards into Practice, held in Marrakesh, Morocco 29–31 October 2018. Dr Stone noted the high political profile of AMR and the large number of initiatives underway. He paid warm recognition to Tripartite partners at FAO and WHO and referred to the specific memorandum of understanding (MoU) signed in 2017 between the Tripartite agencies. As a follow-up, a 2-year collaborative work programme on AMR was developed, due to be endorsed in February 2019, at the Tripartite (FAO, WHO, OIE) executive meeting.

Dr Stone stressed the importance of AMR, which is reflected in some developments at the OIE. In particular, an OIE internal re-structuring has taken place to demonstrate the engagement of the OIE and its work-programme and to allow allocation of increased resources to focus on this area. The new OIE AMR and Veterinary Products Department, headed by Dr Elisabeth Erlacher-Vindel, illustrates this development.

Dr Stone noted the long-standing existence of the *ad hoc* Group on AMR. The ongoing importance of AMR has led the OIE to decide to recommend creation of a formal Working Group on AMR as the most appropriate structure going forward, replacing the current *ad hoc* Group on AMR. This formal Working Group would be discussed with the Council in February 2019, and if agreed, the OIE Director General would recommend its formation and membership to the World Assembly at the 87th General Session, to be held 26–31 May 2019. If the recommendation is accepted by the World Assembly, in accordance with the OIE’s Internal Rules for Working Groups, the Working Group would report to the Director General, who would ensure liaison with appropriate Specialist Commissions as required. The Director General would report the composition of the Working Group to the World Assembly each year, and the Chairperson would typically be invited to present their activities and work programme directly to the World Assembly. The OIE believes that AMR is such an important topic that this degree of transparency and accountability is appropriate and expected by our Members.

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 Dr Chris Teale as rapporteur.

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, including an update from members, in particular the publication of a new regulation EU 2019/6 within the European Union.

4. Second OIE Global Conference on Antimicrobial Resistance, Putting Standards into Practice: Recommendations

The Group noted the recommendations of the 2nd OIE Global Conference on AMR, held in Morocco in October 2018, which are available on the OIE website¹. Several recommendations are of particular importance to the Group, including expansion of the OIE List of antimicrobial agents of veterinary importance to include companion animals, and the sub-division of the List by different animal species.

The Group noted the recommendation for OIE Member Countries relating to restrictions on the use of certain antimicrobials (fluoroquinolones, third and fourth generation cephalosporins and colistin) and on the use of antimicrobial growth promoters.

The Group noted that the OIE will update the Assembly at the General Session in May 2019 on progress made and will present outline plans for addressing the recommendations.

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

The OIE informed the Group that a new staff position was open to support the development and management of the Antimicrobial Use (AMU) Database project. The Group considered that the move from spreadsheet format to a database would improve data collection, validation, analysis and reporting.

The systems for collecting antimicrobial quantities from France, United States of America and European Surveillance of Antimicrobial Consumption (ESVAC) were presented to the Group. It was noted that ESVAC uses Excel Spreadsheets that function with macros and can validate and upload the data to the database. The Group noted that in the development of the new OIE database system, similar validation and quality checks of the data could be included.

The Group discussed the possibility that in the future, the OIE AMU database could be designed to include national farm-level use data. It was emphasised that for these types of data, the OIE would need to collect additional data such as species, categories of animal, treatments for groups of animals or individual animals, doses, dosing frequency, days of treatment and animal population coverage. The important contribution of relevant stakeholders including the pharmaceutical industry in providing estimates on the breakdown of usage by the different animal species was noted.

The Group supported the creation of an expert group to assist the OIE regarding database development. Such a group would assist in defining objectives for the new database and also the outputs required to provide a detailed global perspective. The Group recommended that if possible a system should be developed that allows an entry-level minimum data contribution, but that also permits a step-wise development / progression to an advanced contribution.

6. OIE AMU Database: Presentation of the third OIE Annual Report on Antimicrobial Agents Intended for Use in Animals: Better Understanding of the Global Situation

The results of the third OIE Annual data collection were presented to the Group.

The Group noted the improvements in the number of participating countries since the first round of data collection (130 to 155 respondents), and the increased number of countries reporting quantitative data.

The report included an analysis of 91 countries in their antimicrobial quantities for 2015 adjusted by animal biomass.

The Report will be published on the OIE website mid-February 2019 in conjunction with an OIE press release.

¹ http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/AMR/A_2nd_OIE_Global_Conf_Recommendations.pdf

7. Overview of the preliminary results of the fourth round of collection of data on antimicrobial agents intended for use in animals

The very preliminary results of the fourth round of data collection were presented and, so far, the data sources and animal species covered by the data are similar to previous years. Member Countries also have the opportunity to update data reported in previous years.

The Group reviewed the structure of the report and agreed to maintain its existing format. The size of the report could be reduced by using hyperlinks to the OIE website covering background information.

8. Future development of the OIE List of Antimicrobial Agents of Veterinary Importance

The Group noted that the OIE aimed to update the OIE List of Antimicrobials of Veterinary Importance in accordance with the outcomes and recommendations of the 2nd OIE Global Conference on AMR, Morocco, 2018. The List was initially developed in consideration of those antimicrobials that were predominantly used in OIE Member Countries. The Group considered the List could provide a resource detailing the availability of authorised medicines in the different species and highlighting areas where there was a lack of availability of authorised antimicrobials for the treatment of animal diseases and specific species.

The Group agreed that there were considerable national differences in terms of the relative importance of different antimicrobials at the individual animal species level and that this made the development of a standardised global approach complex. The Group considered that one possible option could be to use the existing master (summary) list as a basis to develop species-specific lists. The Group agreed that the lists should be fit-for-purpose to guide decisions on responsible and prudent use.

The Group considered various options and suggested that future development of the List should consider:

a) Purpose/Aims/Objectives/Desired Outputs

- Target audience
- Use as a tool for risk analysis
- Use to support responsible and prudent use guidelines
- Provision of a global resource detailing indications/ usage by species at the global level

b) Methods / Approaches to further refine the List by species

- Development of additional criteria which are species related
- Inclusion of species specific comments to refine the List
- Provision of a rationale for the categorisation of importance of the antimicrobial classes at individual species level, including any potential impact on the overall categorisation of the antimicrobial class
- Development of questionnaires or other data capture procedures that accurately collect the desired information
- Presentation in the most appropriate format

Data sources should be those most relevant or appropriate considering the required outputs. The Group considered the potential sources of information that might be useful in refining the categorisation included:

- Experts in the field
- National regulatory authorities
- Information on legally authorised compounds
- Volumes of sales data
- Prudent use guidelines at individual species level
- Papers/ reports on availability of products
- Countries collected and published information on treatments and standard treatment regimes

- Industry – products authorised by species
- Residue limits to provide an indication of authorised compounds
- OIE Focal Points on Veterinary Products
- Major diseases and favoured treatment options
- The information used to update the OIE chapter on AMR surveillance
- The OIE *ad hoc* Groups reports on prioritisation of diseases for which vaccines could reduce antimicrobial use in animals

c) Challenges

- The distribution of animal populations and diseases varies which influences the need for different antimicrobial classes
- The availability of data will vary by species and countries
- Variations exist between countries and the development of a system suitable for all countries
- Access to different antimicrobial classes, vaccines and other tools might be difficult

The Group agreed that the primary audience of the List would be national veterinary services, including their public and private components. Existing initiatives in many countries could be utilised to develop the List acknowledging the need for collaboration with the pharmaceutical industry. Other relevant stakeholders would include veterinary statutory bodies and private veterinary associations, industry and governments.

The Group agreed that the development of the List should be started by working on one species. The List already covers avian species, which includes chickens and turkeys. The Group proposed that the initial phase should include refinement of the avian category to investigate chickens, an important food-producing animal occurring in almost all countries and for which data availability is considered to be high. The Group recommended that preliminary work would focus on this species in order to demonstrate that the proposed methods are robust.

In relation to categorisation, the Group noted that some categories on the existing List were applicable across all species, whilst others applied to a restricted range of species. Specific comments address this in the current List, which could be developed further by refining this aspect at the individual species level. The Group agreed that the format of the existing List should however be retained as far as possible.

9. Any other business

The extremely limited/absence of current development of new antimicrobials intended for use in animals was noted.

The Group also noted the importance of the establishment of robust criteria and procedures for determining resistance in veterinary pathogens and that whilst published methods covering many relevant combinations of antimicrobials and veterinary pathogens were available, a number of gaps remained.

As this was the final meeting of this *ad hoc* Group, Dr Monique Eloit expressed her gratitude to the members of the Group under the leadership of Dr Herbert Schneider, as Chair of the Group, and thanked them for their passionate dedication to supporting the OIE AMR work.

10. Adoption of report

The Group adopted the report.

.../Appendices

Appendix I

MEETING OF THE OIE AD HOC GROUP ON ANTIMICROBIAL RESISTANCE
Paris, 16–18 January 2019

Agenda

1. Opening
 2. Adoption of the agenda and appointment of the chairperson and rapporteur
 3. Roundtable from the participants on any new issues of interest for the Group
 4. Second OIE Global Conference on Antimicrobial Resistance, Putting Standards into Practice: Recommendations
 5. OIE AMU database: conversion from the spread sheet format to a database system
 6. OIE AMU Database: Presentation of the third OIE Annual Report on Antimicrobial Agents Intended for Use in Animals: Better Understanding of the Global Situation
 7. Overview of the preliminary results of the fourth round of collection of data on antimicrobial agents intended for use in animals
 8. Future Development of the OIE List of Antimicrobial Agents of Veterinary Importance in animals.
 9. Any other business
 10. Adoption of report
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Appendix II

MEETING OF THE OIE AD HOC GROUP ON ANTIMICROBIAL RESISTANCE

Paris, 16–18 January 2018

List of Participants

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REPORT OF THE ANNUAL RECONFIRMATION ASSESSMENTS FOR MAINTENANCE OF OFFICIAL DISEASE STATUS AND OF THE ENDORSEMENT OF NATIONAL OFFICIAL CONTROL PROGRAMMES

The Scientific Commission for Animal Diseases (the Commission) dedicated time during its February 2019 meeting to comprehensively review all annual reconfirmations provided by Members having an OIE endorsed national official control programme on the progress made, as well as a selection (approximately 10%) of the annual reconfirmations for officially recognised status of Members. The Commission pre-selected these annual reconfirmations at its September 2018 meeting based on the list of technical and administrative considerations according to the Standard Operating Procedures (SOP) on reconfirmations:

http://www.oie.int/fileadmin/Home/eng/Animal_Health_in_the_World/docs/pdf/SOP/EN_SOP_Reconfirmation.pdf.

A letter of reminder was sent in October 2018 by the OIE Director General to the Delegates of Members having at least one officially recognised disease status or an endorsed national official control programme. The pre-selected Members were also informed of their official status selected for a comprehensive review.

In accordance with the Standard Operating Procedures governing the official recognition of disease status, all annual reconfirmations were screened by the OIE Status Department, and when necessary, additional information was requested in accordance with the relevant provisions of the *Terrestrial Animal Health Code*. The annual reconfirmations that had not been selected for this comprehensive review by the Commission were further assessed by the OIE Status Department and a report was prepared and provided for the Commission's consideration and endorsement as presented below.

1. Maintenance of the AHS free status

1.1. Annual reconfirmations comprehensively reviewed by the Commission:

The annual reconfirmations for AHS free status of **Andorra, Azerbaijan, Cyprus, Oman, Qatar, Tunisia and United Arab Emirates** were selected for comprehensive review by the Commission. Specific comments made by the Commission were as follows:

Andorra: The Commission noted with appreciation the changes in the legislation of Andorra applicable to AHS regarding the importation of equids and the diagnostic methods for AHS.

Azerbaijan: The Commission expressed its concerns about the delay in providing the additional information requested by the OIE Status Department to support an informed assessment by the Commission. The Commission stressed that such a delay could lead to the suspension of an official status, and recommended Azerbaijan's reconfirmation for 2019 be comprehensively reviewed by the Commission.

Cyprus: The Commission appreciated the information provided on awareness activities conducted for AHS, and that serological surveillance for AHS was implemented. The Commission invited Cyprus to continue providing the results of the serological surveillance for AHS in its future annual reconfirmations.

Oman: The Commission noted in the annual reconfirmation submitted by Oman in 2017 that the diagnostic methods for AHS were not in accordance with the recommended methods as defined in Chapter 3.5.1. of the *Terrestrial Manual* (i.e., Complement Fixation Test (CFT) was used). The Commission noted from the information submitted by Oman that CFT was no longer used for AHS diagnosis and confirmed that the diagnostic method used in 2018 (i.e., only ELISA is authorised and used) was in accordance with Chapter 3.5.1. of the *Terrestrial Manual*.

Qatar: The Commission noted the changes in the testing regime for AHS of exported and imported equids. It was also noted that Qatar only imported from countries officially recognised free from AHS.

Tunisia: The Commission noted in the annual reconfirmation submitted by Tunisia in 2017 that AHS surveillance was being reinforced through the launch of a serological survey, risk-based sentinel surveillance, as well as vector surveillance. The Commission reviewed the information submitted by Tunisia and commended Tunisia for the successful reinforcement of AHS surveillance.

United Arab Emirates: The Commission expressed major concerns about the delay in providing the additional information repeatedly requested by the OIE Status Department to support an informed assessment by the Commission. In accordance with the Standard Operating Procedure on the reconfirmation of officially recognised disease status, the Commission stressed that this could result in the suspension of an official status. The Commission considered that the control measures for the importation of equids from countries not officially recognised free from AHS were in general compliance with the *Terrestrial Code*. The Commission recommended that information on the suspicions of AHS reported, the investigation and follow up related, as well as more detailed information on the import requirements be provided by United Arab Emirates when reconfirming its status in November 2019.

Conclusion: The Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 12.1. of the *Terrestrial Code* for the maintenance of the officially recognised AHS free status.

1.2. Annual reconfirmations screened by the OIE Status Department

The OIE Status Department reviewed the rest of the annual reconfirmations for AHS free status and reported the outcome of its analysis to the Commission as follows:

The annual reconfirmations for the following Members were reviewed:

Algeria	Denmark	Latvia	Philippines
Argentina	Ecuador	Liechtenstein	Poland
Australia	Estonia	Lithuania	Portugal
Austria	Finland	Luxembourg	Romania
Belgium	France	Malaysia	Singapore
Bolivia	Germany	Malta	Slovakia
Bosnia and Herzegovina	Greece	Mexico	Slovenia
Brazil	Hungary	Morocco	Spain
Bulgaria	Iceland	Netherlands	Sweden
Canada	India	New Caledonia	Switzerland
Chile	Ireland	New Zealand	Thailand
China (People's Rep. of)	Italy	North Macedonia	Turkey
Chinese Taipei	Japan	Norway	United Kingdom
Colombia	Kazakhstan	Paraguay	United States of America
Croatia	Korea (Rep. of)	Peru	Uruguay
Czech Republic	Kuwait		

The OIE Status Department informed the Commission that the annual reconfirmations that were received and assessed were compliant with the relevant provisions of Chapter 12.1. of the *Terrestrial Code*.

The Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 12.1. of the *Terrestrial Code* for the maintenance of the officially recognised AHS free status.

2. Maintenance of BSE risk status

2.1. Maintenance of the controlled BSE risk status

2.1.1. Annual reconfirmation comprehensively reviewed by the Commission:

The annual reconfirmation of **Greece** for its controlled BSE risk status was reviewed by the Commission. It was noted that Greece did not reach the BSE surveillance target points; however, the Commission acknowledged the efforts and actions taken by Greece to improve its BSE surveillance and an increase in the surveillance points compared to previous annual reconfirmations. The Commission strongly encouraged Greece to continue increasing its level of BSE surveillance and concluded that the controlled BSE status of Greece could be maintained with follow-up of its 2019 annual reconfirmation on the progress made.

2.1.2. Annual reconfirmations screened by the OIE Status Department

The OIE Status Department reviewed all annual reconfirmations for controlled BSE risk status and reported the outcome of its analysis to the Commission as follows:

The annual reconfirmations for the following Members were reviewed:

Canada	Ireland
Chinese Taipei	United Kingdom ¹
France	

The OIE Status Department informed the Commission that the annual reconfirmations that were received and assessed were compliant with the relevant provisions of Chapter 11.4. of the *Terrestrial Code*.

The Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 11.4. of the *Terrestrial Code* for the maintenance of the officially recognised controlled BSE risk status.

2.2. Maintenance of the negligible BSE risk status

2.2.1. Annual reconfirmations comprehensively reviewed by the Commission:

The annual reconfirmations of **Argentina, Denmark, Israel, Latvia and Nicaragua** were comprehensively reviewed by the Commission. Specific comments made by the Commission were as follows:

Argentina: The Commission appreciated the clear description provided by Argentina about the infractions reported in feed mills/rendering plants and appropriate corrective measures that were implemented in response to the infractions reported.

Denmark: The Commission commended Denmark on the transparency of the information provided regarding infractions reported in feed mills due to the insufficient separation of feed containing fishmeal and feed for ruminants. The Commission acknowledged that corrective actions were implemented and requested that Denmark provide an update, in the annual reconfirmation to be submitted in November 2019, on the improvements made to further prevent cross-contamination.

¹ United Kingdom: a zone consisting of England and Wales as designated by the Delegate of the United Kingdom in documents addressed to the Director General in September and October 2016; and a zone consisting of Scotland, re-instated with effect from 26 December 2016, as designated by the Delegate of the United Kingdom in a document addressed to the Director General in October 2016.

Israel: The Commission took note of the investigations as well as of the subsequent communications performed by Israel in response to the detection of a sample positive for mammal protein in a poultry feed mill in 2017. The Commission recommended Israel to continue monitoring the implementation of the measures to prevent feed contamination with mammal protein, and requested that an update be provided when submitting the reconfirmation in November 2019.

Latvia: The Commission acknowledged that the number of infractions reported by Latvia in feed mills or rendering plants had decreased in 2018 and appreciated that appropriate corrective measures were implemented in response to the infractions reported.

Nicaragua: Nicaragua's BSE negligible risk status was officially recognised in May 2018. The Commission examined the information provided by Nicaragua in support of the reconfirmation of its BSE risk status and assessed the progress made on the recommendations of the OIE *ad hoc* Group on the evaluation of BSE risk status of Members. The Commission commended Nicaragua for addressing the recommendations of the *ad hoc* Group. The Commission strongly encouraged Nicaragua to continue its efforts in the implementation of the recommendations and the maintenance of its negligible BSE risk status.

Conclusion: The Commission concluded that the annual reconfirmations of the above-listed Members were, in general, compliant with the relevant requirements of Chapter 11.4. of the *Terrestrial Code* for the maintenance of the officially recognised negligible BSE risk status.

2.2.2. Annual reconfirmations screened by the OIE Status Department

The OIE Status Department reviewed the rest of the annual reconfirmations for negligible BSE risk status and reported the outcome of its analysis to the Commission as follows:

The annual reconfirmations for the following Members were reviewed:

Australia	Hungary	Panama*
Austria	Iceland	Paraguay
Belgium	India*	Peru
Brazil	Italy	Poland
Bulgaria	Japan	Portugal
Chile	Korea (Rep. of)	Romania
China (People's Rep. of) ²	Liechtenstein	Singapore
Colombia*	Lithuania	Slovakia
Costa Rica	Luxembourg	Slovenia
Croatia	Malta	Spain
Czech Republic	Mexico	Sweden
Cyprus	Namibia	Switzerland
Estonia	Netherlands	United Kingdom ³
Finland	New Zealand*	United States of America
Germany	Norway	Uruguay

The OIE Status Department informed the Commission that the annual reconfirmations that were received and assessed were compliant with the relevant provisions of Chapter 11.4. of the *Terrestrial Code* for the maintenance of officially recognised negligible BSE risk status. However, the OIE Status Department raised the attention of the Commission to the Member marked with an asterisk (*). The corresponding annual reconfirmation was discussed during the Commission's meeting as follows:

² China (People's Rep. of): a zone designated by the Delegate of China in a document addressed to the Director General in November 2013, consisting of the People's Republic of China with the exclusion of Hong Kong and Macau

³ United Kingdom: Zone of Northern Ireland as designated by the Delegate of the United Kingdom in a document addressed to the Director General in September 2016

Colombia: The Commission noted that histopathology was the primary test used for all BSE surveillance streams. A proportion of samples was also tested by immunohistochemistry if histopathology was inconclusive for rabies or other diseases different to BSE. The Commission emphasised that in accordance with Chapter 3.4.5. of the *Terrestrial Manual*, histopathology is not appropriate for defining a sample as negative for BSE. The Commission recommended Colombia to revise the testing protocol for BSE to ensure compliance with the *Terrestrial Manual*. The Commission recommended Colombia's reconfirmation for 2019 be comprehensively reviewed by the Commission.

India: The Commission noted that histopathology was the primary test used in all BSE surveillance streams. Confirmation of positive and inconclusive primary test results for all subpopulations was done with a rapid test. The Commission emphasised that in accordance with Chapter 3.4.5. of the *Terrestrial Manual*, histopathology is not appropriate for defining a sample as negative for BSE, and rapid tests are not recommended as secondary or confirmatory tests. The Commission recommended India to revise the testing protocol for BSE to ensure compliance with the *Terrestrial Manual*. The Commission recommended India's reconfirmation for 2019 be comprehensively reviewed by the Commission.

New Zealand: The Commission noted that histopathology was the primary test used in three BSE surveillance streams (clinical suspects, fallen stock, and casualty slaughter). When histopathology 'could not rule out a BSE diagnosis' (i.e., when histopathology was not negative or was inconclusive), a rapid test was performed. The Commission emphasised that in accordance with Chapter 2.4.5. of the *Terrestrial Manual*, histopathology is not appropriate for defining a sample as negative for BSE, and rapid tests are not recommended as secondary or confirmatory tests. The Commission recommended New Zealand to revise the testing protocol for BSE to ensure compliance with the *Terrestrial Manual*. The Commission recommended New Zealand's reconfirmation for 2019 be comprehensively reviewed by the Commission.

Panama: The Commission noted that Panama did not reach the BSE surveillance target points, however the Commission acknowledged the continuous efforts and actions taken by Panama to improve its BSE surveillance had resulted in a notable increase in the surveillance points compared to previous years. The Commission commended Panama on this improvement and strongly encouraged Panama to maintain its efforts; it was recommended that supportive evidence on its progress is submitted when reconfirming its status in November 2019.

In addition, annual reconfirmations have been identified by the Status Department as not fully compliant with Point 4 of Article 11.4.22. of the *Terrestrial Code: Member Countries should sample at least three of the four subpopulations* (routine slaughter, fallen stock, casualty slaughter, clinical suspect). Nevertheless, these identified countries still reached the BSE surveillance target points. Considering that the OIE standards on BSE are under revision, including the surveillance provisions applicable for maintenance of controlled and negligible BSE risk status, the Commission concluded to maintain the negligible BSE risk status of these Members.

The Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 11.4. of the *Terrestrial Code* for the maintenance of the officially recognised negligible BSE risk status.

3. Maintenance of the CBPP free status

3.1. Annual reconfirmations comprehensively reviewed by the Commission:

The annual reconfirmations for CBPP free status of **Botswana** and **South Africa** were comprehensively reviewed by the Commission. Specific comments made by the Commission were as follows:

Botswana: The Commission took note that CBPP outbreaks were reported in 2018 in an area close to the international border of Botswana. The Commission commended Botswana for intensifying active clinical surveillance and reinforcing awareness activities in the corresponding high risk area. The Commission also acknowledged that veterinary regulations were being revised and that it was envisioned that the prohibition of vaccination against CBPP would be supported by legislation in the future. The Commission encouraged Botswana to provide a follow-up on these activities in the annual reconfirmation to be submitted in November 2019.

South Africa: Following the comprehensive review of South Africa's annual reconfirmation of its CBPP free status in 2017, the Commission stressed that all recommendations of the OIE *ad hoc* Group on the evaluation of CBPP status of Members should be addressed and also recommended that compliance with the protocol for active serological surveillance for CBPP should be strengthened and that the shortcomings in traceability for trace-back and -forward investigations should be addressed. The Commission examined the information provided by South Africa in support of the 2018 reconfirmation of its CBPP free status and assessed the progress made along these recommendations. The Commission appreciated that actions had been taken to implement agent isolation and confirmation using molecular techniques as well as to strengthen traceability to improve for trace-back and -forward investigations, and that, to a certain extent, awareness has been strengthened. However, the Commission reiterated its previous recommendation that compliance with the active serological surveillance protocol for CBPP should be strengthened in all provinces. In addition, the Commission encouraged South Africa to participate in inter-laboratory proficiency testing for the serological test methods used for CBPP.

Conclusion: The Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 11.5. of the *Terrestrial Code* for the maintenance of the officially recognised CBPP free status.

3.2. Annual reconfirmations screened by the OIE Status Department

The OIE Status Department reviewed the rest of the annual reconfirmations for CBPP free status and reported the outcome of its analysis to the Commission as follows:

The annual reconfirmations for the following Members were reviewed:

Argentina	Eswatini	New Caledonia
Australia	France	Portugal
Brazil	India	Singapore
Canada	Mexico	Switzerland
China (People's Rep. of)	Namibia ⁴	United States of America

The OIE Status Department informed the Commission that the annual reconfirmations were compliant with the relevant provisions of Chapter 11.5. of the *Terrestrial Code*.

The Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 11.5. of the *Terrestrial Code* for the maintenance of the officially recognised CBPP free status.

4. Maintenance of the endorsement of the official control programme for CBPP

The Commission reviewed the information provided by **Namibia** in support of the reconfirmation of its endorsed official control programme for CBPP. The Commission noted that in 2018, outbreaks of CBPP were reported in Namibia, outside of zone officially recognised free from CBPP⁴. The last reported occurrence of CBPP in Namibia was in 2015. The Commission noted with concern the delays in the confirmation of these outbreaks as well as in the notification to the OIE. The Commission highlighted the importance of prompt reporting of suspicions as part of the early warning system.

⁴ Namibia: one zone located south to the Veterinary Cordon Fence, designated by the Delegate of Namibia in a document addressed to the Director General in October 2015

The Commission noted that the target for farms inspections was not reached in 2018, and recommended Namibia to review and adjust this target to an achievable coverage. The Commission acknowledged that Namibia planned to implement risk based surveillance from 2019-2020 to strengthen CBPP surveillance. The Commission took note that the target vaccination coverage against CBPP was not reached in 2018 in several provinces. The Commission also noted that some activities of importance for the control programme such as the construction of a veterinary cordon fence at the border between Namibia and a bordering country as well as the construction of border control offices had been delayed. The Commission recommended Namibia document the progress made, particularly with regard to the aforementioned points, in the annual reconfirmation to be submitted in November 2019.

The Commission clarified that annual reconfirmations should focus on providing clear updates on the progress made and main achievements during the reporting period of the past year. Therefore, the Commission strongly encouraged Namibia, for future annual reconfirmations, to focus on the reporting period, the disease of relevance, as well as on the of respective areas (i.e., information on the CBPP free zone and information on the endorsed control programme should be reported separately and clearly in the respective annual reconfirmations).

The Commission considered Namibia's annual reconfirmation compliant with the relevant requirements of Chapter 11.5. of the *Terrestrial Code* for the maintenance of the endorsement of its official control programme for CBPP.

5. Maintenance of the CSF free status

5.1. Annual reconfirmations comprehensively reviewed by the Commission:

The annual reconfirmations for CSF free status of **Argentina, Bulgaria, Costa Rica, Romania and Slovakia** were comprehensively reviewed by the Commission. Specific comments made by the Commission were as follows:

Argentina: Argentina was officially recognised free from CSF in May 2018. The Commission examined the information provided by Argentina and appreciated the actions that had been initiated and the progress made to address the recommendations of the *ad hoc* Group.

Bulgaria: Bulgaria was officially recognised free from CSF in May 2018 after an OIE mission was conducted to assess compliance of the country with the *Terrestrial Code*. After the mission, Bulgaria had developed an action plan to address the recommendations of this mission and submitted a progress report with its 2018 reconfirmation. The Commission commended Bulgaria's efforts and the progress made on the implementation of actions addressing the recommendations of the mission.

Costa Rica: Costa Rica was officially recognised free from CSF in May 2018. The Commission examined the information provided by Costa Rica and appreciated the actions that had been initiated and the progress made to address the most recommendations of the *ad hoc* Group. Nevertheless, the Commission underlined the importance of having a national compensation system for strengthening the early warning system. The Commission recommended that Costa Rica's 2019 annual reconfirmation for CSF be included for comprehensive review to follow up on the progress made on the implementation of the recommendations of the *ad hoc* Group.

Romania: Romania was officially recognised as free from CSF in May 2017 after an OIE mission was conducted to assess the compliance of the country with the *Terrestrial Code*. Whilst noting the progress made and regulations established in following up with the recommendations of the mission, the Commission advised a follow-up mission to be conducted to monitor the implementation of these measures in the field. The Commission was informed that this mission was planned to take place in 2019.

Slovakia: The Commission acknowledged that active and passive surveillance were in place in domestic pigs and wild boars. However, the Commission noted that no clinical suspicions had been reported in domestic or in wild pigs. The Commission recommended that awareness for CSF be enhanced at field level to encourage the notification of suspicions taking into account the potential risk for neighbouring countries with undetermined CSF status. The Commission recommended that Slovakia provide information on the awareness activities and other actions taken to enhance notification of CSF suspicions and provide an update when submitting its annual reconfirmation in November 2019.

Conclusion: The Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 15.2. of the *Terrestrial Code* for the maintenance of the officially recognised CSF free status.

5.2. Annual reconfirmations screened by the OIE Status Department

The OIE Status Department reviewed the rest of the annual reconfirmations for CSF free status and reported the outcome of its analysis to the Commission as follows:

The annual reconfirmations for the following Members were reviewed:

Australia	Germany	Paraguay
Austria	Hungary	Poland
Belgium	Ireland	Portugal
Brazil ⁵	Italy	Slovenia
Canada	Japan	Spain
Chile	Liechtenstein	Sweden
Colombia ⁶	Luxembourg	Switzerland
Czech Republic	Mexico	The Netherlands
Denmark	New Caledonia	United Kingdom
Finland	New Zealand	United States of America
France	Norway	

The OIE Status Department informed the Commission that the annual reconfirmations were compliant with the relevant provisions of Chapter 15.2. of the *Terrestrial Code*.

The Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 15.2. of the *Terrestrial Code* for the maintenance of the officially recognised CSF free status.

6. Maintenance of the FMD free status

6.1. Annual reconfirmation comprehensively reviewed by the Commission

The annual reconfirmations for FMD free status of **Belarus, one zone of Brazil, Brunei, one zone of Chinese Taipei, Eswatini, one zone of Malaysia, Serbia⁷, Slovenia, Suriname and Ukraine** were selected for comprehensive review by the Commission. Specific comments made by the Commission were as follows:

Belarus: The Commission examined the information provided by Belarus in support of its 2018 annual reconfirmation, and appreciated that information on the passive surveillance implemented, including the criteria to raise suspicion for FMD and follow-up actions to rule out FMD was provided. The Commission also noted the sampling design and results of the serological surveillance conducted in 2018. However, the Commission recommended that, in the annual reconfirmation to be submitted in November 2019, the results of serological surveillance be presented including the positive NSP reactors and describing the procedure and investigations to rule-out FMD. The Commission also took note with appreciation that Belarus participated in interlaboratory proficiency tests with two OIE Reference Laboratories for FMD, and requested that the results be provided in the annual reconfirmation to be submitted in November 2019. The Commission strongly encouraged Belarus to conduct simulation exercises for FMD to strengthen its early warning system.

⁵ Brazil: one zone composed of the States of Rio Grande do Sul and Santa Catarina as designated by the Delegate of Brazil in a document addressed to the Director General in September 2014; one zone covering the States of Acre, Bahia, Espírito Santo, Goiás, Mato Grosso, Mato Grosso do Sul, Minas Gerais, Paraná, Rio de Janeiro, Rondônia, São Paulo, Sergipe and Tocantins, Distrito Federal, and the municipalities of Guajará, Boca do Acre, South of the municipality of Canutama and Southwest of the municipality of Lábrea, in the State of Amazonas as designated by the Delegate of Brazil in a document addressed to the Director General in September 2015

⁶ Colombia: one zone designated by the Delegate of Colombia in a document addressed to the Director General in September 2015

⁷ Excluding Kosovo administered by the United Nations

Brazil⁸: This extended zone was officially recognised free from FMD with vaccination in May 2018. The Commission reviewed the information provided on the risk-based serological surveillance conducted in 2018 as well as the results of follow-up clinical inspections and probang tests received after its meeting which were all concluded as negative to FMD virus. The Commission requested that any further test results be submitted to the OIE as soon as they become available. In addition, the Commission recommended Brazil to provide maps illustrating the locations sampled with reactor animals and to provide information on any investigations conducted on clustering when submitting the annual reconfirmation in November 2019. Lastly, the Commission noted that Brazil had an intention to merge one of the FMD free zones with vaccination (zone consisting of the former high surveillance zone and covering part of Mato Grosso do Sul), and reminded Brazil that in accordance with the Standard Operating Procedures for official recognition of disease status, Brazil should submit a formal request to the OIE to apply for the merging of these zones for official recognition by the World Assembly of Delegates.

Brunei: The Commission reviewed the information provided by Brunei on the surveillance for FMD implemented in 2018. The Commission was concerned about the decreased level of surveillance compared to previous years. The Commission strongly recommended that FMD surveillance be strengthened and requested that more detailed information be submitted on activities to strengthen the passive surveillance for FMD (such as the number of farms/holdings visited, the number of animals inspected, and the number of suspicions) as well as numbers of FMD susceptible populations present in the country when reconfirming Brunei's FMD free status in November 2019. The Commission recommended that Brunei's 2019 annual reconfirmation be included for comprehensive review by the Commission in February 2020.

Chinese Taipei: one zone with vaccination consisting of Kinmen County as designated by the Delegate of Chinese Taipei in a document addressed to the OIE Director General in September 2017): This zone was officially recognised free from FMD in May 2018. The Commission examined the information provided by Chinese Taipei in support of the reconfirmation of this FMD free zone and assessed the progress made along the recommendations of the OIE *ad hoc* Group on the evaluation of FMD status of Members. The Commission expressed serious concerns on the lack of actions to address the recommendations of the *ad hoc* Group. The Commission stressed that if the recommendations of the *ad hoc* Group were not addressed with appropriate justification, this could lead to the suspension of the official status. The Commission emphasised the importance of strict control of movements of FMD susceptible animals and their products between the two separate zones officially recognised by the OIE and recommended that documented evidence demonstrating continuous and effective controls of movement be provided when submitting the annual reconfirmation in November 2019. The Commission recommended that Chinese Taipei's annual reconfirmation be included for comprehensive review by the Commission in February 2020.

Eswatini: In September 2017, three buffaloes were imported from a country which is not free from FMD without import permits or health certificates. The Commission recommended for the maintenance of the FMD free status of Eswatini that: (i) these animals should remain permanently isolated and be continuously monitored under the authority of the Veterinary Services; (ii) the results of the annual testing of these animals be provided with the annual reconfirmation of Eswatini's FMD free status for at least 3 years. The Commission commended Eswatini's efforts in implementing the recommendations made by the Commission. The Commission reiterated its previous recommendations to keep the buffaloes in isolation under the authority of the Veterinary Services and to have them annually tested for FMD. The Commission recommended that Eswatini's annual reconfirmation to be submitted in November 2019 be closely followed up in this regard.

Malaysia: one zone without vaccination covering the provinces of Sabah and Sarawak as designated by the Delegate of Malaysia in a document addressed to the Director General in December 2003): The Commission took note of the results of the active serological surveillance for FMD conducted in 2018 in the zone. The Commission noted that frozen meat products of FMD susceptible species were imported from a country not free from FMD. The Commission stressed that importation of these commodities should be in compliance with the requirements of Article 8.8.22. of the *Terrestrial Code*. The Commission requested that documented evidence of compliance with these requirements be provided in the annual reconfirmation to be submitted in November 2019. The Commission also requested that evidence on the

⁸ Brazil: One extended zone with vaccination designated by the Delegate of Brazil in a document addressed to the Director General in September 2017, composed of the States of Amapá, Roraima, Amazonas, Pará, Rondônia, Acre, Espírito Santo, Minas Gerais, Rio de Janeiro, Sergipe, Distrito Federal, Goiás, Mato Grosso, Paraná, São Paulo, Bahia, Tocantins, Alagoas, Ceará, Maranhão, Paraíba, Pernambuco, Piauí, Rio Grande do Norte, and parts of Mato Grosso do Sul

regulations applicable for the control of movements of FMD susceptible animals and products into the free zone be provided in the 2019 annual reconfirmation. The Commission recommended a field mission to be conducted to assess compliance with the relevant requirements of Chapter 8.8. of the *Terrestrial Code* for the maintenance of FMD free status.

Serbia: The Commission commended Serbia for its prompt submission and for the quality of the information provided in support of the annual reconfirmation of its FMD free status.

Slovenia: The Commission reviewed the information on FMD surveillance provided by Slovenia and recommended that information on FMD suspicions detected at field level as well as on the investigations implemented to rule them out be documented in the annual reconfirmation to be submitted in November 2019.

Suriname: Suriname was officially recognised free from FMD in May 2018. The Commission appreciated the information provided by Suriname on the planned actions and progress made on the implementation of the recommendations of the OIE *ad hoc* Group on the evaluation of FMD status of Members. The Commission encouraged that Suriname continue to make progress on the recommendations and provide an update when submitting its annual reconfirmation in November 2019.

Ukraine: The Commission acknowledged the results of the samples tested as part of Ukraine's serological surveillance for FMD. The Commission recommended that, in the annual reconfirmation to be submitted in November 2019, the results of serological surveillance be presented including the positive NSP reactors and describing the procedure and investigations to rule-out FMD. The Commission also strongly encouraged Ukraine to conduct simulation exercises for FMD to strengthen its early warning system.

Conclusion: The Commission concluded that the annual reconfirmations of the above-listed Members and zones were compliant with the relevant requirements of Chapter 8.8. of the *Terrestrial Code* for the maintenance of the officially recognised FMD free status.

6.2. Annual reconfirmations screened by the OIE Status Department

The OIE Status Department reviewed the rest of the annual reconfirmations for FMD free status and reported the outcome of its analysis to the Commission as follows:

The annual reconfirmations for the following Members were reviewed:

Albania	El Salvador	Latvia	Philippines
Australia	Estonia	Lesotho	Poland
Austria	Finland	Lithuania	Portugal
Belgium	France	Luxembourg	Romania
Belize	Germany	Madagascar*	San Marino
Bosnia and Herzegovina	Greece	Malta	Singapore
Bulgaria	Guatemala	Mexico	Slovakia
Canada	Guyana	Montenegro	Spain
Chile	Haiti	New Caledonia	Sweden
Costa Rica	Honduras	New Zealand	Switzerland
Croatia	Hungary	Nicaragua	The Netherlands
Cuba	Iceland	North Macedonia	United Kingdom
Cyprus	Indonesia	Norway	United States of America
Czech Republic	Ireland	Panama	Uruguay
Denmark	Italy	Paraguay	Vanuatu
Dominican Republic	Japan	Peru	

Argentina: Three zones without vaccination

- one zone designated by the Delegate of Argentina in a document addressed to the Director General in January 2007;
- the summer pasture zone in the Province of San Juan as designated by the Delegate of Argentina in a document addressed to the Director General in April 2011;
- Patagonia Norte A as designated by the Delegate of Argentina in a document addressed to the Director General in October 2013;

Two zones with vaccination designated by the Delegate of Argentina in documents addressed to the Director General in March 2007 and October 2013, and in August 2010 and February 2014;

Bolivia: One zone without vaccination in the Macro-region of the Altiplano designated by the Delegate of Bolivia in documents addressed to the Director General in November 2011;

One zone with vaccination consisting of four merged zones covering the regions of Amazonas, Chaco, Chiquitania, Valles and part of Altiplano as designated by the Delegate of Bolivia in documents addressed to the Director General in January 2003 and March 2007, in August 2010, in August 2012 and in October 2013 and February 2014;

Botswana: Five zones without vaccination designated by the Delegate of Botswana in documents addressed to the Director General in August and November 2014 as follows:

- one zone consisting of Zones 3c (Dukwi), 4b, 5, 6a, 8, 9, 10, 11, 12 and 13;
- one zone consisting of Zone 3c (Maitengwe);
- one zone covering Zone 4a;
- one zone covering Zone 6b;
- one zone covering Zone 3b designated by the Delegate of Botswana in a document addressed to the Director General in August 2016;

Brazil: One zone without vaccination – State of Santa Catarina designated by the Delegate of Brazil in a document addressed to the Director General in February 2007;

Two separate zones with vaccination designated by the Delegate of Brazil in documents addressed to the Director General as follows:

- one zone covering the territory of State of Rio Grande do Sul (documentation of September 1997);
- one zone in State of Mato Grosso do Sul as designated by the Delegate of Brazil in documents addressed to the Director General in August 2010;

Chinese Taipei: One zone with vaccination covering Taiwan, Penghu and Matsu areas, as designated by the Delegate of Chinese Taipei in a document addressed to the Director General in August 2016;**Colombia: Two zones without vaccination**

- one zone designated by the Delegate of Colombia in documents addressed to the Director General in November 1995 and in April 1996 (Area I - Northwest region of Chocó Department);
- one zone designated by the Delegate of Colombia in documents addressed to the Director General in January 2008 (Archipelago de San Andrés and Providencia);

Ecuador: **One zone without vaccination** consisting of the insular territory of the Galapagos, as designated by the Delegate of Ecuador in a document addressed to the Director General in August 2014;

One zone with vaccination consisting of the continental Ecuador, as designated by the Delegate of Ecuador in a document addressed to the Director General in August 2014;

Kazakhstan: **One zone without vaccination** consisting of the regions of Akmola, Aktobe, Atyrau, West Kazakhstan, Karaganda, Kostanay, Mangystau, Pavlodar and North Kazakhstan, as designated by the Delegate of Kazakhstan in a document addressed to the Director General in August 2014;

Five separate zones with vaccination designated by the Delegate of Kazakhstan in documents addressed to the Director General in August 2016 as follows:

- one zone consisting of Almaty region;
- one zone consisting of East Kazakhstan region;
- one zone including part of Kyzylorda region, northern part of South Kazakhstan region, northern and central parts of Zhambyl region;
- one zone including southern part of Kyzylorda region and south-western part of South Kazakhstan region;
- one zone including south-eastern part of South Kazakhstan region and southern part of Zhambyl region;

Moldova: **One zone without vaccination** designated by the Delegate of Moldova in a document addressed to the Director General in July 2008;

Namibia*: **One zone without vaccination** designated by the Delegate of Namibia in a document addressed to the Director General in February 1997;

Turkey: **One zone with vaccination** designated by the Delegate of Turkey in a document addressed to the Director General in November 2009.

The OIE Status Department informed the Commission that the annual reconfirmations that were received and assessed were compliant with the relevant provisions of Chapter 8.8. of the *Terrestrial Code*. However, the OIE Status Department raised the attention of the Commission to the Members marked with an asterisk (*). These annual reconfirmations were discussed during the Commission's meeting as follows:

Madagascar: The Commission examined the information provided by Madagascar in support of the annual reconfirmation of its FMD free status together with the progress report provided on the implementation of recommendations of the OIE FMD mission conducted in 2017. At its September 2018 meeting, the Commission observed that the implementation of some recommendations of the mission were delayed due to the lack of available funding and emphasised that all recommendations pertaining to the strengthening of control of movements of susceptible animals and their products should be given a high priority.

The Commission noted that funds have been secured in 2019 to conduct active serological surveillance, strengthen surveillance at the borders, conduct awareness activities, print manuals on surveillance and meat inspection, and to acquire sampling equipment.

Considering that no serological surveillance for FMD was conducted in 2018, the Commission strongly recommended that passive clinical surveillance should be strengthened and requested documented evidence including the number of suspicions reported, follow-up procedures and tests performed to exclude FMD and reach a differential diagnosis, and on the procedures in place for early detection of FMD be provided to the OIE when submitting its next update of progress by 15 July 2019.

The Commission also noted that milk products were imported into Madagascar from countries not officially recognised free from FMD. The Commission stressed that importation of these commodities should be compliant with the requirements of Articles 8.8.24. and 8.8.25. of the *Terrestrial Code* and requested documented evidence of compliance be provided in the annual reconfirmation to be submitted in November 2019.

Namibia: The Commission noted that fresh or frozen meat and milk and milk products of FMD susceptible species were imported into Namibia, including into the free zone, from a country not free from FMD. The Commission stressed that importation of these commodities should be compliant with the requirements of Articles 8.8.22. to 8.8.24. of the *Terrestrial Code* and requested that documented evidence of compliance be provided in the annual reconfirmation to be submitted in November 2019.

The Commission concluded that, in general, the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 8.8. of the *Terrestrial Code* for the maintenance of the officially recognised FMD free status.

7. Maintenance of the endorsement of the official control programme for FMD

The annual reconfirmations of **China (People's Rep. of), India, Mongolia, Morocco, Namibia and Thailand** were comprehensively reviewed by the Commission. Specific comments made by the Commission were as follows:

China (People's Rep. of): An OIE mission to assess the progress of the endorsed official control programme was conducted in China in July 2018. China developed an action plan and submitted a progress report with its 2018 annual reconfirmation. The Commission acknowledged that China had started addressing some of the recommendations of the mission. However, the Commission noted the cessation of vaccination against FMDV serotype Asia 1, and drew China's attention to the recent occurrences of this serotype in the region. The Commission also noted PCR positive results in pigs in the absence of clinical signs with negative virus isolation. The Commission recommended these findings be closely followed up by China and requested more information on this issue be submitted as part of China's 2019 reconfirmation. The Commission strongly encouraged China to continue making progress on the recommendations of the OIE mission.

India: An OIE mission to assess the progress of the endorsed official control programme was conducted in India in June 2018. India developed an action plan and submitted a progress report with its 2018 annual reconfirmation. The Commission stressed that some recommendations of the mission should be given further consideration. In particular, the protocol of the sero-surveys, the procedure to follow up sero-positive reactors to NSP tests, the measures to strengthen control of movements of FMD susceptible animals and their products between States as well as the vaccination coverage, population immunity, and causes of the low protective immunity levels should be documented in the next progress report as part of its annual reconfirmation to be submitted to the OIE in November 2019.

Mongolia: The Commission reviewed the reconfirmation in light of the recommendations of the *ad hoc* Group on the evaluation of Members for the recognition of FMD status. The *ad hoc* Group was consulted on some critical points regarding Mongolia's endorsed official control programme, in particular its timeline and performance indicators according to the current FMD situation. The Commission acknowledged the efforts made by Mongolia and strongly encouraged to continue its efforts in controlling FMD in the country. The Commission requested Mongolia provide information on the progress made on the implementation of its planned activities for 2019, as well as on the detailed plan of activities to be implemented in 2020 when submitting the annual reconfirmation in November 2019.

Morocco: Following the comprehensive review of Morocco's endorsed official control programme for FMD in 2016 and 2017, the Commission recommended that NSP serological surveillance should target all susceptible species to detect virus circulation. No serological survey was conducted in 2018, however Morocco indicated that from April 2019, sheep, goats and cattle will be included in the NSP serological surveillance. The Commission commended Morocco on its commitment to include these species in the NSP serological surveillance. The Commission also took note of a study on vaccine efficacy conducted at the end of 2017 in young and adult cattle which demonstrated satisfactory vaccine efficacy against serotypes A and O. Another study on vaccine efficacy was conducted at the end of 2018, however the results were not yet available. The Commission recommended the results of the 2018 study on vaccine efficacy be provided, together with the results of the serological survey to be conducted in April 2019, when submitting the annual reconfirmation of Morocco's endorsed official control programme for FMD in November 2019.

Namibia: The Commission reviewed the information provided by Namibia in support of the reconfirmation of its endorsed official control programme for FMD. The Commission took note of the results of the cross-sectional post-vaccination sero-monitoring survey conducted in 2017 which showed an acceptable level of immunity for SAT1 and SAT2 but a lower level of immunity for SAT3. The Commission noted that Namibia planned to investigate the low antibody response to SAT3, and recommended the outcome of the investigation, and any corrective actions, be documented in the annual reconfirmation to be submitted in November 2019.

The Commission noted that the target for farms inspections was not reached in 2018, and recommended Namibia to review and adjust this target to an achievable coverage. The Commission acknowledged that Namibia planned to implement risk-based surveillance from 2019-2020 to strengthen FMD surveillance. The Commission took note that the target vaccination coverage against FMD was not reached in 2018 in several provinces. The Commission also noted that some activities of importance for the control programme such as the construction of a veterinary cordon fence at the border between Namibia and a bordering country as well as the construction of border control offices had been delayed. The Commission recommended Namibia document the progress made, particularly with regard to the aforementioned points, in the annual reconfirmation to be submitted in November 2019.

Furthermore, as emphasised for Namibia's annual reconfirmation of its free zone for FMD, the Commission stressed that importations of commodities from animals susceptible to FMD should be in compliance with the Articles 8.8.22. to 8.8.24. of the *Terrestrial Code* and requested that documented evidence of compliance be provided in the annual reconfirmation to be submitted in November 2019.

Lastly, the Commission clarified that annual reconfirmations should focus on providing clear updates on the progress made and main achievements during the reporting period of the past year. Therefore, the Commission strongly encouraged Namibia, for future annual reconfirmations, to focus on the reporting period, the disease of relevance, as well as on the of respective areas (i.e., information on the FMD free zone and information on the endorsed control programme for FMD should be reported separately and clearly in the respective annual reconfirmations).

Thailand: In February 2018, the Commission recommended an OIE mission to be conducted to assess the progress made along the endorsed official control programme for FMD as well as to assess the continuous compliance of Thailand with the relevant requirements of Chapter 14.7. the *Terrestrial Code* for the maintenance of a PPR free status. The Commission was informed that this mission was planned to be conducted in March 2019.

The Commission considered that the annual reconfirmations of the above-listed Members were compliant with the relevant provisions of Chapter 8.8. of the *Terrestrial Code* for an endorsed official control programme for FMD.

8. Maintenance of the PPR free status

8.1. Annual reconfirmations comprehensively reviewed by the Commission:

The annual reconfirmations for PPR free status of **Botswana, Madagascar, Mauritius, Philippines and Thailand** were comprehensively reviewed by the Commission. Specific comments made by the Commission were as follows:

Botswana: Following the comprehensive review of Botswana's annual reconfirmation of its PPR free status in 2017, the Commission emphasised that all recommendations of the OIE *ad hoc* Group on the evaluation of PPR status of Members should be addressed. The Commission examined the information provided by Botswana in support of the 2018 reconfirmation of its PPR free status and assessed the progress made along the recommendations of the OIE *ad hoc* Group. The Commission appreciated that the National Veterinary Laboratory was accredited for PPR and obtained satisfactory results obtained in interlaboratory proficiency testing for PPR. The Commission noted that results of retesting of inconclusive results in small stock were not yet available. The Commission recommended that Botswana provide evidence of the complete follow-up of inconclusive results in small stock when submitting its annual reconfirmation in November 2019.

Madagascar: Madagascar was officially recognised free from PPR in May 2018. The Commission assessed the information provided by Madagascar and on the progress made along the recommendations of the OIE *ad hoc* Group on the evaluation of PPR status of Members. The Commission acknowledged that actions have been initiated, or were planned, to address the recommendations of the *ad hoc* Group and recommended The Commission recommended that Madagascar's 2019 annual reconfirmation for PPR be included for comprehensive review to follow up on the progress made on the implementation of the recommendations of the *ad hoc* Group.

Mauritius: The Commission observed that, despite repeated requests for clarification by the OIE Status Department, the information provided on clinical surveillance, protocol for active surveillance, protocol for the follow up and investigation of suspicions, and awareness campaigns lacked the necessary details and clarity to support an informed assessment by the Commission. The Commission expressed some concerns on the current capacity of the Veterinary Services of Mauritius as well as its continuous compliance with the relevant requirements of Chapter 14.7. of the *Terrestrial Code* for the maintenance of the official PPR free status. The Commission therefore recommended that an OIE mission be conducted in the near future.

Philippines: The Commission noted that no suspicion of PPR had been reported in 2018 and recommended that documented evidence on the effectiveness of the early detection system to be provided in its next reconfirmation. Furthermore, the Commission requested that information on the chain of command and sequence of actions upon detection of a suspicion of PPR including for laboratory diagnosis be provided in the annual reconfirmation to be submitted in November 2019.

Thailand: In February 2018, the Commission recommended an OIE mission to be conducted to assess the continuous compliance of Thailand with the relevant requirements of Chapter 14.7. the *Terrestrial Code* as well as to assess the progress made along the endorsed official control programme for FMD. The Commission was informed that an OIE mission was planned to be conducted in March 2019.

The Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 14.7. of the *Terrestrial Code* for the maintenance of the officially recognised PPR free status.

8.2. Annual reconfirmations screened by the OIE Status Department

The OIE Status Department reviewed the rest of the annual reconfirmations for PPR free status and reported the outcome of its analysis to the Commission as follows:

The annual reconfirmations for the following Members were reviewed:

Argentina	France	New Zealand
Australia	Germany	Norway
Austria	Greece	Paraguay
Belgium	Hungary	Peru
Bolivia	Iceland	Poland
Bosnia and Herzegovina	Ireland	Portugal
Brazil	Italy	Romania
Canada	Korea (Rep. of)	Singapore
Chile	Latvia	Slovakia
Chinese Taipei	Liechtenstein	Slovenia
Colombia	Lithuania	South Africa
Cyprus	Luxembourg	Spain
Czech Republic	Malta	Eswatini
Denmark	Mexico	Sweden
Ecuador	Namibia ⁹	Switzerland
Estonia	Netherlands	United Kingdom
Finland	New Caledonia	United States of America
		Uruguay

⁹ Namibia: one zone located south to the Veterinary Cordon Fence, designated by the Delegate of Namibia in a document addressed to the Director General in November 2014

The OIE Status Department informed the Commission that the annual reconfirmations were compliant with the relevant provisions of Chapter 14.7. of the *Terrestrial Code*.

The Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 14.7. of the *Terrestrial Code* for the maintenance of the officially recognised PPR free status.

SUMMARY OF THE EXPERT ASSESSMENT FOR PED

Two experts participated in this consultation:

- Dr Ana María Carvajal Ureña (Member of the AHG on PED, June 2014, Spain)
- Dr Pascale Aubry (Member of the AHG on PED, June 2014, Canada)

The table below presents the expert assessment against the criteria listed in Chapter 1.2.

Experts	Ana María Carvajal Ureña ①	Pascale Aubry ②
CRITERION 1 : International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven	Yes	Yes
CRITERION 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.	No	No
CRITERION 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.	Yes	Yes
CRITERION 4a : Natural transmission to humans has been proven, and human infection is associated with severe consequences.	No	No
CRITERION 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.	Yes	Yes
CRITERION 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	Yes	Yes
CONCLUSION Does PED match the listing criteria that are described in the <i>Terrestrial Animal Health Code</i> Chapter 1.2	No	No

The experts agreed that Porcine Epidemic Diarrhoea (PED) **does not match** the listing criteria that are described in the *Terrestrial Animal Health Code* Chapter 1.2.

Hereby the scientific rationale underlying the expert assessment for each criterion; the replies of each expert are presented with a different colour.

Criterion 1: International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.

- 1 International spread of porcine epidemic diarrhoea virus has been demonstrated. Transmission among pigs usually occurs by a direct or indirect faecal-oral route. It has been clearly stated that this is a transboundary virus able to spread to neighbouring or even distant countries or continents (Lee, 2015).
The emergence of this coronavirus in the USA and its spread through this and other countries in north, central and south America has clearly demonstrated that this virus is able to travel via live animals or more probably via different faeces contaminated fomites. Very exhaustive research has been carried out to investigate the route used by this virus to reach the USA. Although feed was initially suspected, recent researches have concluded that flexible bulk containers or "feed totes" may have been involved in this entry and dissemination (Scott *et al.*, 2016). The role of transport vehicles in the dissemination of porcine epidemic diarrhoea virus throughout the USA has also been demonstrated (Lowe *et al.*, 2014). Also investigations after the first recent descriptions of porcine epidemic diarrhoea in Canada points towards a participation of faeces contaminated feed and vehicles in the spread of this virus (Pasick *et al.*, 2014) and the role of contaminated trucks in the spread of this virus have also been reported in Italy (Boniotti *et al.*, 2018).
- 2 PED has been found in the UK, Belgium, Czech Republic, Hungary, Korea, the Philippines, China, Italy, Thailand (Song & Park, 2012), Germany, Spain, and Japan (Pospischil *et al.*, 2002), Russia (Strizhakova *et al.*, 2017), USA and Canada (Kochhar, 2014), Austria and Slovenia (Steinrigl *et al.*, 2015), Vietnam (Vui *et al.*, 2015), Colombia, the Dominican Republic, Peru, Portugal, and Ukraine (Jarvis *et al.*, 2016), Ecuador (Barrera *et al.*, 2017), the Netherlands, Hungary, Bulgaria, France and Switzerland (Leidenberger *et al.*, 2017), and Mexico (Lara-Romero *et al.*, 2018).
It appears that the virus has spread from Asia to the USA in 2013, then on to neighbouring Canada and Mexico as well as further south to the Caribbean and South America (Steinrigl *et al.*, 2015). After decades during which PEDV was seldom reported in Europe, it seems that the disease has recently re-emerged in Europe from a low pathogenic USA strain (Steinrigl *et al.*, 2015).

Criterion 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.

- 1 Although there are some countries in which outbreaks of porcine epidemic diarrhoea have not been described in recent years, to my knowledge there is no scientific reference regarding surveillance to demonstrate the absence of this infection in these countries.
According to *Terrestrial Animal Health Code*, chapter 1.4 (Animal Health Surveillance), Article 1.4.6 (Surveillance to demonstrate freedom from disease or infection), a country or zone may be recognized as free of infection provided that the disease has been classified as a notifiable disease and there has been an early detection system implemented for all relevant species for at least the past 10 years. Also there should be in place measures to prevent infection introduction during the same period of time as well as evidences of negative status in the susceptible wildlife.
- 2 To our knowledge, no country has demonstrated freedom from PED.

Criterion 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.

- 1 Both virological and serological tests that allow the identification of porcine epidemic diarrhoea virus are available. Methods for detection and diagnosis of this viral infection have been extensively reviewed by Diel *et al.* (2016). Among virological tests, polymerase chain reaction (PCR)-based assays are the methods of choice for the diagnosis of porcine epidemic diarrhoea and have demonstrated high diagnostic sensitivity and specificity as well as a rapid turnaround of their results. They are usually performed on faecal or intestinal samples from animals suspected of being infected.

Regarding serology for the detection of porcine epidemic diarrhoea virus antibodies, there are also several assays including indirect fluorescent antibody assay or IFA, enzyme-linked immunosorbent assay (ELISA), virus neutralization assays or fluorescent microsphere immunoassay (FMIA). Several commercial tests are available. These tests are used to determine prior exposure of an animal or a group of animals to porcine epidemic diarrhoea virus or to evaluate the efficacy of interventions such as vaccination or feed-back to control the infection.

- ② Case definition and diagnostic test may vary with jurisdiction/country. Case definitions are usually based on the presence of clinical signs in an animal (or history of disease in the herd) as well as evidence of the presence of the pathogen in the animal/herd. Presence of the pathogen can be evidenced by PCR (Song & Park, 2012), virus isolation, and/or viral genetic sequencing. It is noted that the isolation of PEDV in cell culture is challenging and seldom successful (Shi *et al.*, 2017).

Criterion 4a: Natural transmission to humans has been proven, and human infection is associated with severe consequences.

- ① Porcine epidemic diarrhoea is not a zoonotic disease. So far, the infection and the associated disease has only been described in swine (Saif *et al.*, 2012) and wild boar (Lee *et al.*, 2016).
- ② To our knowledge, there is no evidence that PEDV can be transmitted to humans.

Criterion 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

- ① Significant impact on the health of domestic animals has been demonstrated in several countries or geographical areas or zones since the first descriptions of the disease.
In Europe, porcine epidemic diarrhoea outbreaks causing significant mortalities among piglets less than two weeks old were reported during the eighties and nineties; also during the winter of 2005-2006 in northern Italy (Martelli *et al.*, 2008) and more recently in Germany, the Netherlands, Belgium, France, Portugal, Italy, Spain or the Ukraine (Carvajal *et al.*, 2015; Choudhury *et al.*, 2016; Pensaert & Martelli, 2016).
Porcine epidemic diarrhoea has been reported in several countries in Asia since the early eighties, causing diarrhoea on swine farms and accounting for almost 50% of the cases of porcine diarrhoeal outbreaks in the region (Wang *et al.*, 2016). Moreover, since 2010, large-scale outbreaks of porcine epidemic diarrhoea have been described in the region, causing 80%-100% mortality rates among sucking piglets on affected farms (Wang *et al.*, 2016; Lee, 2015). Finally, in 2014, porcine epidemic diarrhoea was described for the first time in USA and spread through this country and other countries in north, central and south America. The impact of the disease on the pig industry in the US was significant with at least 7 million pigs died as a consequence of the infection during the first year of the epizootic (Choudhury *et al.*, 2016).
Altogether, this information allows us to conclude that porcine epidemic diarrhoea can have a significant impact on the health of swine 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.
- ② The impact of PED appears to vary with the strain/geographical area and time since introduction/re-emergence. With few exceptions, the recent European PEDV strains were low virulence strains (Leidenberger *et al.*, 2017), and the impact on the industry was low, with only a few sporadic cases where a higher mortality was reported (EFSA, 2014). In contrast, it was estimated that the annual decrease for U.S. economic welfare from PEDV summed across all effects ranges from US\$900 million to US\$1.8 billion (Paarlberg, 2014). However, this was estimated based on data from the beginning of the PED outbreak in the US (May 2013 to spring of 2014), and the number of cases has been decreasing since. One industry expert estimated that the impact of PEDV in 2015 has not been significant, and he was expecting 2016 to be similar.

In Canada, the provinces of Ontario and Manitoba were the most affected by PED, with only a few additional cases in the province of Quebec. An industry expert from Manitoba has estimated losses to the industry in the province of up to CA\$12 million (approximately US\$8.9 million). It is unknown how the estimation was conducted, and it is possible that it is simply an extrapolation from the US estimate, knowing that pork production in Canada represents approximately 17% of the US production (USDA-FAS, 2018). Given that Ontario had a similar number of PED cases and also a similar number of pigs as Manitoba, the losses are probably also similar in both provinces, which would amount to a total of CA\$24 million (approximately US\$17.8 million).

Overall, PEDV impact appears to be highest when the disease first enters a naïve population. Therefore, there might be a significant short-time impact at the country level following disease introduction/re-emergence, but the country-level impact is expected to lessen after a few years. The impact on directly affected farmers is likely to be higher.

Criterion 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

- ❶ Up to now, there is no scientific evidence of a significant impact of porcine epidemic diarrhoea on the health of wildlife.

A recent report described the presence of porcine epidemic diarrhoea virus using RT-PCR in 28 out of 287 samples collected on wild boar (*Sus scrofa*), 9.75%, in South Korea (Lee *et al.*, 2016) with no associated description of evident disease or mortality in the wild boar population. A recent research conducted in the Netherlands tested 101 blood samples of wild boars using an indirect ELISA for the detection of specific antibodies with no positive result (Dortmans *et al.*, 2018).

- ❷ To our knowledge, there is no evidence that PEDV can be transmitted to other species, except for wild pigs *Sus scrofa* (Lee *et al.*, 2016). However, wild pigs are often considered an invasive species and a threat to domestic pigs, other livestock and even humans due to their role as a reservoir for diseases such as pseudorabies (Aujeszky's disease), classical swine fever, African swine fever and tuberculosis. In addition, wild pigs are a very prolific species and it is unlikely that PEDV would be a threat to the viability of the population.

Summary Conclusion:

- ❶ Porcine epidemic diarrhoea meets criteria 1, 3 and 4b for listing in the *Terrestrial Animal Health Code* since international spread of porcine epidemic diarrhoea virus has been proven, reliable means of detection and diagnosis which allow the identification of infected animals are available and the disease has a significant impact on the health of swine, being able to cause production losses and mortality.

However, in my opinion, porcine epidemic diarrhoea does not meet criteria 2 since there is no reference of a specific surveillance to demonstrate the absence of this infection in any country.

- ❷ Given that condition 2) is not met (no country has demonstrated freedom from the disease or infection), PED does not match the listing criteria in the *Terrestrial Animal Health Code* Chapter 1.2.

In addition, it is not clear whether any of the criteria in 4 is met. The impact of the disease appears to vary with the strain/geographical area and time since introduction/re-emergence. It does not always have a significant impact at the level of the country. It is unlikely that PEDV would be a threat to the viability of a wildlife population.

SUMMARY OF THE EXPERT ASSESSMENT FOR CWD

Two experts participated in this consultation:

- Dr Gordon Mitchell (OIE CWD Reference Laboratory, Canada)
- Dr Sylvie Benestad (OIE CWD Reference Laboratory, Norway)

The table below presents the expert assessment against the criteria listed in Chapter 1.2.

Experts	Gordon Mitchell ①	Sylvie Benestad ②
CRITERION 1 : International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven	Yes	Yes
CRITERION 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.	No	Yes
CRITERION 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.	Yes	Yes
CRITERION 4a : Natural transmission to humans has been proven, and human infection is associated with severe consequences.	No	No
CRITERION 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.	Yes	No
CRITERION 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	Yes	Yes
CONCLUSION Does CWD match the listing criteria that are described in the <i>Terrestrial Animal Health Code</i> Chapter 1.2	No	Yes

The experts **disagreed** on whether or not Chronic Wasting Disease (CWD) matches the listing criteria that are described in the *Terrestrial Animal Health Code* Chapter 1.2.

Hereby the scientific rationale underlying the expert assessment for each criterion; the replies of each expert are presented with a different colour.

Criterion 1: International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.

- ① The international spread of CWD via the movement of live animals has been documented in several instances. The earliest evidence arose from a Canadian retrospective study investigating the presence of CWD in deer housed at the Toronto Zoo between 1973 and 2003. Several cases were ultimately detected between 1978 and 1981, and the most probable source of disease was determined to be the importation of preclinical animals into Canada from the United States (Dubé *et al.*, 2006). In 1996, CWD was detected in farmed elk in Saskatchewan, Canada, and the epidemiological investigation traced the likely origin of infection to the importation of preclinical elk from a farm in South Dakota, United States (Kahn *et al.*, 2004). Finally, CWD was inadvertently transported from Saskatchewan, Canada to Korea through the movement of farmed elk in 1997 (Sohn *et al.*, 2002; Kim *et al.*, 2005). More recently, CWD has been detected in Norway and Finland but the initial sources of infection, and relation to North American CWD, are not currently known (Benestad *et al.*, 2016).
 - Benestad SL, Mitchell G, Simmons M, Ytrehus B, Vikøren T. First case of chronic wasting disease in Europe in a Norwegian free-ranging reindeer. *Vet Res.* 2016; 47:88.
 - Dubé C, Mehren KG, Barker IK, Peart BL and Balachandran A. Retrospective investigation of chronic wasting disease of cervids at the Toronto Zoo, 1973–2003. *Can Vet J.* 2006; 47:1185–1193.
 - Kahn S, Dubé C, Bates L, Balachandran A. Chronic wasting disease in Canada: Part 1. *Can Vet J.* 2004; 45:397-404.
 - Kim TY, Shon HJ, Joo YS, Mun UK, Kang KS and Lee YS. Additional cases of chronic wasting disease in imported deer in Korea. *J Vet Med Sci.* 2005; 67:753–759.
 - Sohn HJ, Kim J-H, Choi K-S1, Nah J-J, Joo Y-S, Jean Y-H, Ahn S-W, Kim O-K, Kim D-Y and Balachandran A. A case of chronic wasting disease in an elk imported to Korea from Canada. *J Vet Med Sci.* 2002; 64:855–858.
- ② CWD has been introduced into Canadian farmed elk through the importation of infected animals from a farm in South Dakota (Kahn S, Dubé C, Bates L, Balachandran A. Chronic wasting disease in Canada: Part 1. *Can Vet J.* 2004;45(5):397-404). Similarly, South Korea has imported the disease to their country by importation living cervids (incubating the disease) to one of their zoos (Lee YH, Sohn HJ, Kim MJ, Kim HJ, Lee WY, Yun EI, Tark DS, Cho IS, Balachandran A (2013) Strain characterization of the Korean CWD cases in 2001 and 2004. *J Vet Med Sci* 75:95–98).

Criterion 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.

- ① Several countries are conducting varying forms of CWD surveillance in farmed and wild cervid populations, but I am not aware of any country that has amassed or reported sufficient data to credibly demonstrate freedom from CWD at this time. This will be particularly challenging to achieve with CWD, given the presence of the disease in wild and domestic cervids, the typically low prevalence of disease, live animal diagnostic test limitations, and the lack of available disease control measures. However, it is acknowledged that this situation may change in the future, as several countries, particularly in Europe, have recently initiated formal surveillance programs.
- ② There is a large surveillance on CWD going on in North America and several states have yet not detected the disease.

Criterion 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.

- ① Detection of CWD based on the visual inspection of animals alone is considered unreliable, as clinical signs are variable and often subtle, generally appear in the later stages of disease, and are common to numerous other infectious or degenerative diseases in cervids. Several reliable, validated diagnostic tests exist which can detect CWD in preclinical animals and clearly distinguish CWD from other diseases of cervids. These tests, including ELISA, immunohistochemistry and western immunoblot, are analogous to those routinely used in the statutory diagnosis of BSE and scrapie, and have been used in the diagnosis of CWD for many years in North America (e.g. Hibler *et al.*, 2003; Spraker *et al.*, 2002). Current surveillance programs rely on post mortem testing of brainstem and lymphoid tissues, and novel diagnostic tests are under development to more feasibly enable the detection of CWD in live animals. The definitive diagnosis of CWD is only be made following post mortem testing, and Canada currently functions under a working case definition based largely on the amalgamation of these post mortem diagnostic test results.
 - Hibler CP, Wilson KL, Spraker TR, Miller MW, Zink RR, DeBuse LL, Andersen E, Schweitzer D, Kennedy JA, Baeten LA, Smeltzer JF, Salman MD, Powers BE. Field validation and assessment of an enzyme-linked immunosorbent assay for detecting chronic wasting disease in mule deer (*Odocoileus hemionus*), white-tailed deer (*Odocoileus virginianus*), and Rocky Mountain elk (*Cervus elaphus nelsoni*). *J Vet Diagn Invest.* 2003; 15:311-9.
 - Spraker TR, O'Rourke KI, Balachandran A, Zink RR, Cummings BA, Miller MW, Powers BE. Validation of monoclonal antibody F99/97.6.1 for immunohistochemical staining of brain and tonsil in mule deer (*Odocoileus hemionus*) with chronic wasting disease. *J Vet Diagn Invest.* 2002; 14:3-7.
- ② The diagnosis of CWD is based on the detection of abnormal prion protein (PrP^{Sc}) and several methods are validated, reliable and commercially available and extensively used worldwide (<https://science.vla.gov.uk/tse-lab-net/test.html>).

Criterion 4a: Natural transmission to humans has been proven, and human infection is associated with severe consequences.

- ① There is currently no scientific evidence demonstrating the natural transmission of CWD from cervids to humans. Considerable effort has endeavoured to understand the zoonotic potential of CWD and this continues to be an important area of active investigation.
 - Waddell L, Greig J, Mascarenhas M, Otten A, Corrin T, Hierlihy K. Current evidence on the transmissibility of chronic wasting disease prions to humans-A systematic review. *Transbound Emerg Dis.* 2018;65(1):37-49.
 - Houston F, Andréoletti O. The zoonotic potential of animal prion diseases. *Handb Clin Neurol.* 2018;153:447-462.
 - Hannaoui S, Schatzl HM, Gilch S. Chronic wasting disease: Emerging prions and their potential risk. *PLoS Pathog.* 2017;13(11):e1006619.
- ② Infectious prions (PrP^{Sc}) has been detected in muscles from CWD sick animals (Rachel C. Angers, Shawn R. Browning, Tanya S. Seward, Christina J. Sigurdson, Michael W. Miller, Edward A. Hoover, Glenn C. Telling Prions in Skeletal Muscles of Deer with Chronic Wasting Disease. *Science* 24 Feb 2006:Vol. 311, Issue 5764, pp. 1117, DOI: 10.1126/science.1122864) and it is evident that a large population Of North America has been orally exposed to prions through consumption of meat. Due to uncertainties about the incubation period, exposure, and clinical presentation, the possibility that the CWD agent might cause human disease cannot be absolutely eliminated. Nevertheless, after 50 years of experience of CWD in North America, human case investigations and epidemiologic studies have not managed to find any no link between CWD in cervids and prion diseases in humans. The frequency of Creutzfeldt Jacob disease (CJD) in human is the same in CWD endemic regions (like Colorado) as in CWD free regions (Mawhinney S, Pape WJ, Forster JE, Anderson CA, Bosque P, Miller MW. Human prion disease and relative risk associated with chronic wasting disease. *Emerg Infect Dis.* 2006;12(10):1527-35).

Criterion 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

- ① We have observed significant reductions in animal health and welfare within some domestic cervid farms where CWD has been detected. The impacts of CWD are often high due factors such as: the relatively high transmission rate within herds, our limited capacity to detect disease in live animals, a lack of therapeutic options, and the slowly progressive, intractable nature of this neurodegenerative disease. Cervids with the disease are not marketable and mortality is inevitable. Since the initial discovery of CWD in Canada approximately two decades ago, the Canadian farmed cervid industry has contracted in size (both the number of farms and the number of animals) by over 50 percent, with the decline largely attributed to the influence of CWD. Additionally, the Canadian provinces considered endemic for CWD have been significantly impacted through trade restrictions imposed both domestically and internationally.
- ② The species barrier for CWD seems to be high between cervids and sheep (Hamir AN, Kunkle RA, Cutlip RC, Miller JM, O'Rourke KI, Williams ES, Miller MW, Stack MJ, Chaplin MJ, Richt JA. Experimental transmission of chronic wasting disease agent from mule deer to cattle by the intracerebral route. *J Vet Diagn Invest* 2005; 17:276-81; PMID:15945388; <http://dx.doi.org/10.1177/104063870501700313>), cattle (Hamir AN, Kunkle RA, Cutlip RC, Miller JM, O'Rourke KI, Williams ES, Miller MW, Stack MJ, Chaplin MJ, Richt JA. Experimental transmission of chronic wasting disease agent from mule deer to cattle by the intracerebral route. *J Vet Diagn Invest* 2005; 17:276-81; PMID:15945388; <http://dx.doi.org/10.1177/104063870501700313>) and pigs (Moore SJ, West Greenlee MH, Kondru N, Manne S, Smith JD, Kunkle RA, Kanthasamy A, Greenlee JJ. *Journal of Virology*. 2017 Sep 12; 91(19): e00926-17), as far as oral inoculation with a large dose of CWD brain material into sheep and cattle is usually not successful in transmitting the infection.

Criterion 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

- ① It has been challenging to fully assess the impact of CWD on wild cervids given the numerous additional confounding influences on these populations, including predation, other diseases, environmental and anthropogenic factors. Several recent studies have investigated wild cervid population dynamics in the presence of CWD, and have found significant evidence for negative impacts on white-tailed deer, mule deer and elk population health (DeVivo *et al.*, 2017; Edmunds *et al.*, 2016; Monello *et al.*, 2014). Annual adult survival rates are significantly lower in CWD-infected cervids when compared to uninfected animals, and over time, the presence of CWD can alter the mean age of a population and gender distributions. The long term effects of this CWD-induced destabilization of population dynamics remain unclear, but several models predict that the sustainability of some wild cervid populations may be significantly compromised in some circumstances (Foley *et al.*, 2016; Almberg *et al.*, 2011; Wasserberg *et al.*, 2009). As the geographical range of CWD continues to expand, additional naïve wild populations will be exposed, and there is particular concern regarding the impact CWD could have on the large migratory caribou herds of northern Canada.
 - Almberg ES, Cross PC, Johnson CJ, Heisey DM, Richards BJ. Modeling routes of chronic wasting disease transmission: environmental prion persistence promotes deer population declines and extinction. *PLoS One*. 2011; 3:e19896.
 - DeVivo MT, Edmunds DR, Kauffman MJ, Schumaker BA, Binfet J, Kreeger TJ, Richards BJ, Schätzl HM, Cornish TE. Endemic chronic wasting disease causes mule deer population decline in Wyoming. *PLoS One*. 2017; 12:e0186512.
 - Edmunds DR, Kauffman MJ, Schumaker BA, Lindzey FG, Cook WE, Kreeger TJ, Grogan RG, Cornish TE. Chronic Wasting Disease Drives Population Decline of White-Tailed Deer. *PLoS One*. 2016; 11:e0161127.
 - Foley AM, Hewitt DG, DeYoung CA, DeYoung RW, Schnupp MJ. Modeled Impacts of Chronic Wasting Disease on White-Tailed Deer in a Semi-Arid Environment. *PLoS One*. 2016; 11:e0163592.

- Monello RJ, Powers JG, Hobbs NT, Spraker TR, Watry MK, Wild MA. Survival and population growth of a free-ranging elk population with a long history of exposure to chronic wasting disease. *J Wildl Manage* 2014; 78:214–223.
- Wasserberg G, Osnas EE, Rolley RE, Samuel MD. Host culling as an adaptive management tool for chronic wasting disease in white-tailed deer: a modelling study. *J Appl Ecol*. 2009; 46:457-466.

- ② It has been reported a decline of cervid population in the CWD regions in Wyoming, in white-tailed deer (Edmunds DR, Kauffman MJ, Schumaker BA, Lindzey FG, Cook WE, Kreeger TJ, et al. (2016) Chronic Wasting Disease Drives Population Decline of White-Tailed Deer. *PLoS ONE* 11(8): e0161127. <https://doi.org/10.1371/journal.pone.0161127>) and in mule deer (DeVivo MT, Edmunds DR, Kauffman MJ, Schumaker BA, Binfet J, Kreeger TJ, et al. (2017) Endemic chronic wasting disease causes mule deer population decline in Wyoming. *PLoS ONE* 12(10): e0186512. <https://doi.org/10.1371/journal.pone.0186512>)

Summary Conclusion:

- ① Based on the above assessment, Chronic Wasting Disease (CWD) does not currently meet the criteria for inclusion in the OIE List of Diseases, as listed in Chapter 1.2 of the Terrestrial Animal Health Code. There is adequate evidence for the international spread of CWD, and we possess sufficient diagnostic tools to detect and diagnose the disease in cervids. Recent evidence has demonstrated that CWD can have a measureable negative impact on wild cervid populations, and we have observed detrimental effects on domestic cervid production as well. The primary factor precluding the listing of CWD is that no country can currently demonstrate freedom or impending freedom from disease (Question 2). This will be particularly difficult to attain given the nature of CWD, but the recent initiation of surveillance programs in several European countries may eventually facilitate this. Numerous factors contribute to making CWD uniquely challenging to control amongst animal pathogens, and given the difficulty associated with reducing it once established, it seems prudent to continue monitoring the distribution of disease to inform future decisions.
- ② In my opinion, the response to questions 1 (International spread of the pathogenic agent), 2 (at least one country has demonstrated freedom or impending freedom from the disease) and 3 (specific reliable means of detection and diagnosis) are “YES”.
For the responses of the question 4, 4a (human infection) is “NO” in my opinion, rather “No” for 4b (impact on the health of domestic animals), but “YES” for 4c (significant impact on the health of wildlife).
In conclusion, I consider that Chronic Wasting Disease meets the criteria for listing in the *Terrestrial Animal Health Code*.

**SUMMARY OF THE EXPERT ASSESSMENT FOR
THEILERIA LESTOQUARDI, *T. LUWENSHUNI*, *T. UILENBERGI* AND *T. ORIENTALIS***

Three experts participated in these consultations:

- Dr Philip Toye (Member of the AHG on theileriosis, February 2017, Kenya)
- Dr Frans Van Gool (Member of the AHG on theileriosis, February 2017, Belgium)
- Dr Andrew MacFadden (Veterinary epidemiologist/Principal Adviser, New Zealand)

The table below presents the expert assessment against the criteria listed in Chapter 1.2. Although all *Theileria* species were assessed separately, the expert replies were the same for each of them, and are then reported aggregated in the following table.

Experts	Philip Toye ①	Frans Van Gool ②	Andrew MacFadden ③
CRITERION 1 : International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven	Yes	Yes	Yes
CRITERION 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.	Yes	Yes	No
CRITERION 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.	Yes	Yes	Yes
CRITERION 4a : Natural transmission to humans has been proven, and human infection is associated with severe consequences.	No	No	No
CRITERION 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.	Yes	Yes	Yes
CRITERION 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	No	No	No
CONCLUSION Does <i>Theileria lestoquardi</i> , <i>T. luwenshuni</i> , <i>T. uilenbergi</i> and <i>T. orientalis</i> (Ikeda and Chitose) match the listing criteria that are described in the <i>Terrestrial Animal Health Code Chapter 1.2</i>	Yes	Yes	Yes

The experts agreed that *Theileria lestoquardi*, *T. luwenshuni*, *T. uilenbergi* and *T. orientalis* (Ikeda and Chitose) **match** the listing criteria that are described in the *Terrestrial Animal Health Code* Chapter 1.2.

Hereby the scientific rationale underlying the expert assessment for each criterion and for each *Theileria* species; the replies of each expert are presented with a different colour.

THEILERIA LESTOQUARDI

Criterion 1: International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.

- ① *T. lestoquardi* is transmitted by the tick *Hyalomma anatolicum*. There is no obvious reason why the disease could not be spread across international borders by importation of infected animals and/or ticks. For example, the history of the disease as reported by El Imam *et al.* 2015 [1] suggests that the disease has spread from the location of the initial report in Egypt in 1914.
- ② Several scientific evidence based publications confirm the pathogenicity of *T. lestoquardi* in Small Ruminants as Malignant Ovine Theileriosis.
- ③ Spread is by movement of infected animals to places, regions, and countries where a suitable vector exists.

Criterion 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.

- ① The disease appears to be restricted to countries principally around the Mediterranean Sea, the Middle East and western Asia [1,2]. Based on this, it is highly likely that there will be more than one country which can be considered to be historically free of the disease in accordance with 1.4.6 of the Code.
- ② *T. lestoquardi* infections are only described in the Mediterranean basin, North Africa and Asia.
- ③ No (but maintenance of country freedom is possible and the fundamental focus for country status with regards to tick borne disease)
Eradication is not a practical option, but prevention of introduction is feasible (similarly for *T. orientalis* Ikeda and Chitose). Bearing in mind that *Hyalomma* ticks (the vector group) are known to occur in drier biotopes compared to most other tick genera so climate change or global warming might favour *Hyalomma* survival and spread and subsequently potential movement into new areas/zones and countries where suitable controls are not applied (DISCONTTOOLS 2018).

Criterion 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.

- ① The clinical signs for case definition have been documented [1,2]. Several methods exist for the accurate detection and diagnosis of the disease including indirect fluorescent antibody test [3], enzyme-linked immunosorbent assay [4] and reverse line blot [5].
- ② A pan-piroplasm PCR and subsequent sequencing of amplicons.
- ③ Molecular tests are available [Yaghfoori *et al.*, 2017; El Imam *et al.*, 2015]; however, there are complexities around diagnosing the disease vs. diagnosing its presence in an animal (see the discussion under *T. orientalis* Ikeda and Chitose for a more in-depth commentary); as well as false negatives in the non-clinical carrier animal.

- Yaghfoori S, Mohri M, Razmi G. Experimental *Theileria lestoquardi* infection in sheep: Biochemical and hematological changes. *Acta Tropica* 173, 55-61, 2017
- El Imam AH and Taha KM. Malignant Ovine Theileriosis (*Theileria lestoquardi*): A Review, *Jordan Journal of Biological Sciences* 8, 165-174, 2015

Criterion 4a: Natural transmission to humans has been proven, and human infection is associated with severe consequences.

- 2 No natural transmission to humans and no human infection with *T. lestoquardi* was observed in any outbreak.
- 3 No disease in humans has occurred from this species.

Criterion 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

- 1 A detailed assessment of the economic impact of disease caused by *T. lestoquardi* infection appears not to have been undertaken. However, Taha *et al.* [6] reported that 73% of goats died within four days of showing clinical signs due to *T. lestoquardi* infection. Tageldin *et al.* [7] reported high mortality in sheep and goats in Oman due to *T. lestoquardi* infection. Morbidity rates of up to 93% have been recorded in experimentally infected sheep [8]. Taken together, these results suggest that infection with *T. lestoquardi* can have a significant effect on the health of domestic animals.
- 2 Several scientific papers confirm direct production losses and mortality in outbreaks. Morbidity rate can approach 100%, mortality rates between 46 and 100% in highly susceptible breeds.
- 3 *T. lestoquardi* is transmitted by *Hyalomma* ticks and is considered to be the most important *Theileria* species of economic significance infecting small ruminants (Occurring in Africa (Sudan and Tanzania), the Mediterranean basin (Tunisia with PCR evidence and Turkey) and Asia (DISCONTTOOLS 2018) causing "malignant ovine theileriosis". Mortality of the disease in sheep can be between 46-100% and as with all the *Theileria* sp. gives rise to a carrier state. Animals that do recover from the disease are likely to suffer from reduced production (milk, growth rates etc.), [El Imam, 2015]. Mortality has also been reported in goats [Taha, 2012].
 - El Imam AH and Taha KM. Malignant Ovine Theileriosis (*Theileria lestoquardi*): A Review, *Jordan Journal of Biological Sciences* 8, 165-174, 2015
 - Taha M. First confirmed report of outbreak of malignant ovine theileriosis among goats in Sudan. *Parasitol Res.* 109, 2011
 - Yaghfoori S *et al.* An experimental ovine Theileriosis: The effect of *Theileria lestoquardi* infection on cardiovascular system in sheep. *Acta Trop* 161, 2016.

Criterion 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

- 2 It is only described in different deer species in China.
- 3 No (but potential in wild small ruminants). Not reported, but unlikely that significant investigations have been carried out.

Summary Conclusion:

- ① The evidence as detailed above indicates that infection with *T. lestoquardi* matches the OIE listing criteria.
 1. El Imam, A.H. and Taha, K.M. 2015. Malignant ovine theileriosis (*Theileria lestoquardi*): A review. Jordan Journal of Biological Sciences, 8, 165-174.
 2. Lawrence, J.A., Byaruhanga, C., Oosthuizen, M. and Mans, B.J. 2017. Theileriosis of sheep and goats. In Infectious Diseases of Livestock, eds. Coetzer, J.A.W., Thomson, G.R., MacLachlan, N.J. and Penrith, M.L.
 3. Leemans, I., Hooshmand-Rad, P. and Uggla, A., 1997. The indirect fluorescent antibody test based on schizont antigen for study of the sheep parasite *Theileria lestoquardi*. Veterinary Parasitology, 69, 9-18.
 4. Bakheit, M.A., Seitzer, U. and Ahmed, J.S. 2006. A new recombinant protein-based ELISA for the diagnosis of malignant theileriosis of sheep and goats. Parasitology Research, 98, 145-149.
 5. Schnittger, L., Yin, H., Qi, B., Gubbels, M.J., Beyer, D., Niemann, S., Jongejan, F. and Ahmed, J.S., 2004.
 6. Simultaneous detection and differentiation of *Theileria* and *Babesia* parasites infecting small ruminants by reverse line blotting. Parasitology Research, 92, 189-196.
 7. Taha, K.M., Salih, D.A., Ahmed, B.M., Enan, K.A., Ali, A.M. and El Hussein, A.M. 2011. First confirmed report of outbreak of malignant ovine theileriosis among goats in Sudan. Parasitology Research, 109: 1525-1527.
 8. Tageldin, M.H., Fadiya, A.A., Sabra, A.A. and Ismail, S.I. 2005. Theileriosis in sheep and goats in the Sultanate of Oman. Tropical Animal Health and Production, 37: 491-493.
 9. El Imam, A.H., Hassan, S.M., Gameel, A.A., El Hussein, A.M., Taha, K.M. and Salih, D.A. 2015. Variation in susceptibility of three Sudanese sheep ecotypes to natural infection with *Theileria lestoquardi*. Small Ruminant Research, 124: 105-111.
- ② *T. lestoquardi* fulfills all the necessary criteria for the inclusion in the OIE list.
 - N. Abdela, T. Bekele (2016). Bovine Theileriosis and its control: A Review. In Advances in Biological Research 10 (4): 200-212
- ③ *T. lestoquardi* has been considered to be the most significant *Theileria* sp. in terms of impact in small ruminants. As with the other *Theileria* sp. being examined there has not been demonstrated freedom although references are made by countries considering themselves free (presumably from small studies where the agent was not detected).

THEILERIA LUWENSHUNI

Criterion 1: International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.

- ① *T. luwenshuni* was initially described in China, being initially classified as *T. ovis* and then *T. lestoquardi* [1,2]. There is no obvious reason why the disease could not be spread across international borders by importation of infected animals and/or ticks. Recently, there has been confirmation of the infection in other countries such as India and Great Britain [3,4], indicating that international spread of the parasite is possible.
- ② Several scientific publications confirm the pathogenicity of *T. luwenshuni* in Small Ruminants as Oriental Ovine Theileriosis.
- ③ As with other *Theileria* sp. spread through live animals and the tick vectors have been shown to occur.

Criterion 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.

- ① The disease has been reported principally in the Far East and western Europe [1,2, 3, 4]. Based on this, it is highly likely that there will be more than one country which can be considered to be historically free of the disease in accordance with 1.4.6 of the Code.

- ② *T. luwenshuni* has been identified as a severe disease in sheep in China. Recently also in sheep in England and also as a severe disease in goats in India. The presence of *T. luwenshuni* is also confirmed in sheep in Northern Spain.
- ③ No (but maintenance of country freedom is possible and the fundamental focus for country status with regards to tick borne disease).
Eradication is not a practical option, but prevent of introduction is (similarly for *T. orientalis* Ikeda and Chitose). It is unlikely that country level surveys have been carried out for these *Theileria* sp. given that they have been relatively recent detections.

Criterion 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.

- ① The clinical and post mortem signs for case definition have been documented [1,2,4]. Serological and molecular methods exist for the detection and diagnosis of the infection. Serological methods such as IFAT and ELISA are sensitive but suffer from lack of specificity, with crossreactions particularly with *T. uilenbergi* and *T. ovis* [5,6]. Molecular methods have been developed and remain the principal methodology to differentiate *T. luwenshuni*, *T. ovis* and *T. uilenbergi*. These methods include conventional PCR using species-specific primers [7], RLB [8] and multiplex PCR [9].
- ② Amplification of PCR; sequencing analysis.
- ③ Suitable molecular techniques have been developed as per other *Theileria* sp. However, the issues outlined for *T. orientalis* (Ikeda and Chitose) apply, both in terms of association of the agent with disease and with false negative test animals in the non-clinical carrier state [Hin et al., 2008 ; Mans, 2015].
- Yin H *et al.* Detection and Differentiation of *Theileria luwenshuni* and *T. uilenbergi* Infection in Small Ruminants by PCR. Transboundary and Emerging Diseases 55, 2008
 - Mans BJ. A review of *Theileria* diagnostics and epidemiology. Int J Parasitol Parasites Wildl 4, 2015

Criterion 4a: Natural transmission to humans has been proven, and human infection is associated with severe consequences.

- ② No natural transmission to humans and no human infection with *T. luwenshuni* was observed in any outbreak.
- ③ No disease in humans has occurred from this species.

Criterion 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

- ① In an initial report [2], it was observed that mortality rates with *T. luwenshuni*/*T. uilenbergi* ranged between 17.8% and 75.4 % depending on the area, with morbidity rates of between 18.8 and 65%. Mamatha *et al.* [3] reported mortality rates of 20%-60% in sheep and goat herds in India. High mortalities were also reported in an outbreak of *T. luwenshuni* infection in Great Britain in 2005, although this was associated with heavy tick infestation [4].
- ② Several scientific papers confirm direct production losses and mortality in small ruminants in outbreaks with *T. luwenshuni*

- ③ *Theileria uilenbergi* and *Theileria luwenshuni* are pathogenic ovine piroplasms described in northwestern China and other parts of Asia (including Myanmar in SE Asia and India), but similar (by sequence comparison) *Theileria* parasites have been found in sheep in Northern Spain and Turkey, with apparently low pathogenicity. Thus, the significance both in terms of impact, species variation and epidemiology need further work [references below].

- Phipps LP *et al.* Detection of *Theileria luwenshuni* in sheep from Great Britain. *Parasites and vectors* 9, 2016
- Yin H *et al.* Transmission of an unidentified *Theileria* species to small ruminants by *Haemaphysalis qinghaiensis* ticks collected in the field. *Parasitology Research* 88, 2002
- Bawm S *et al.* First molecular detection of *Theileria luwenshuni* from goats in Myanmar, *Parasitology Research* 117, 2018
- Li Y. Report of *Theileria luwenshuni* and *Theileria* sp. RSR from cervids in Gansu, China, *Parasitology Research* 114, 2015
- Luo J, Yin H. Theileriosis of sheep and goats in China. *Trop Anim Health Prod* 29. 1997
- Yin H *et al.* Detection and Differentiation of *Theileria luwenshuni* and *T. uilenbergi* Infection in Small Ruminants by PCR. *Transboundary and Emerging Diseases* 55, 2008
- Mans BJ. A review of *Theileria* diagnostics and epidemiology. *Int J Parasitol Parasites Wildl* 4, 2015
- Begam R *et al.* Emergence of *Theileria luwenshuni* infection in goats of Assam, India. *Journal of Entomology and Zoology Studies* 6, 2018

Criterion 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

- ② No indications in literature that *T. luwenshuni* has an impact on the health of wildlife.
- ③ *T. luwenshuni* has been recently detected in wild deer; however, its significance in determining what impact it is having is too early to say [Li, 2015].
- Li Y. Report of *Theileria luwenshuni* and *Theileria* sp. RSR from cervids in Gansu, China, *Parasitology Research* 114, 2015

Summary Conclusion:

- ① The evidence as detailed above indicates that infection with *T. luwenshuni* matches the OIE listing criteria.
1. Lawrence, J.A., Byaruhanga, C., Oosthuizen, M. and Mans, B.J. 2017. Theileriosis of sheep and goats. In *Infectious Diseases of Livestock*, eds. Coetzer, J.A.W., Thomson, G.R., MacLachlan, N.J. and Penrith, M.L.
 2. Yin, H., Schnittger, L., Luo, J., Seitzer, U. and Ahmed, J. 2007. Ovine theileriosis in China: a new look at an old story. *Parasitology Research*, 101 (Suppl 2), S191-S195.
 3. Mamatha, G.S., Shruthi, R., Chandranaik, B.M., D'Souza, P.E., Thimmareddy, P.M., Shivashankar, B.P. and Puttalakshamma, G.C. 2017. Molecular epidemiology and phylogenetic characterisation of *Theileria luwenshuni* in India: A first report. *Small Ruminant Research*, 154, 52-57.
 4. Phipps, L.P., Hernandez-Triana, L.M., Goharriz, H., Welchman, D. and Johnson, N., 2016. Detection of *Theileria luwenshuni* in sheep from Great Britain. *Parasites & Vectors*, 9, 203-206.
 5. Liu, Z., Li, Y., Salih, D.E., Luo, J., Ahmed, J.S., Seitzer, U. and Yin, H., 2014. Validation of a recombinant protein indirect ELISA for the detection of specific antibodies against *Theileria uilenbergi* and *Theileria luwenshuni* in small ruminants. *Veterinary Parasitology*, 204, 139-145.
 6. He, H., Li, Y., Liu, J., Liu, Z., Yang, J., Liu, A., Chen, Z., Ren, Q., Guan, G., Liu, G., Luo, J. & Yin, H., 2016. An indirect ELISA for detection of *Theileria* spp. antibodies using a recombinant protein (rTISP) from *Theileria luwenshuni*. *Experimental Parasitology*, 166, 89-93.
 7. Yin, H., Liu, Z., Guan, G., Liu, A., Ma, M., Ren, Q. and Luo, J., 2008. Detection and differentiation of *Theileria luwenshuni* and *T. uilenbergi* infection in small ruminants by PCR. *Transboundary and Emerging Diseases*, 55, 233-237.
 8. Niu, Q., Luo, J., Guan, G., Ma, M., Liu, Z., Liu, A., Dang, Z., Gao, J., Ren, Q., Li, Y., Liu, J. and Yin, H. 2009. Detection and differentiation of ovine *Theileria* and *Babesia* by reverse line blotting in China. *Parasitology Research* 104, 1417-1423.

9. Zhang, X., Liu, Z., Yang, J., Chen, Z., Guan, G., Ren, Q., Liu, A., Luo, J., Yin, H. and Li, Y. 2014. Multiplex PCR for diagnosis of *Theileria uilenbergi*, *Theileria luwenshuni*, and *Theileria ovis* in small ruminants. *Parasitology Research*, 113, 527–531.

- ② *T. luwenshuni* fulfills all the necessary criteria for the inclusion in the OIE List.
 - H.Yin *et al.* (2008). *Transboundary and Emerging Diseases*. Vol. 55; n° 5/6 p 233-237
 - R. Begam *et al.* (2018) Emergence of *Theileria luwenshuni* infection in goats of Assam, India. *Journal of Entomology and Zoology Studies*. 6 (5): 57-60
 - L P Phipps *et al.* (2016). Detection of *Theileria luwenshuni* in sheep from Great Britain. *Parasites & Vectors* 9: 203
- ③ Despite some of the details around impact being somewhat vague there is sufficient evidence that recognition of the risks of potential impact from movement of small ruminants/vectors across borders is necessary through their inclusion to the OIE disease list.

THEILERIA UILENBERGI

Criterion 1: International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.

- ① *T. uilenbergi* was initially described in China, being initially classified as *T. ovis* and then *T. lestoquard* [1,2]. A report of *T. uilenbergi* infection in Turkey, based on PCR and RLB detection suggests international spread of the parasite [3]. There is no obvious reason why the disease could not be spread across international borders by importation of infected animals and/or ticks.
- ② Several scientific publications confirm the pathogenicity of *T. uilenbergi* in Small Ruminants as Oriental Ovine Theileriosis and clinical outbreaks.
- ③ A suitable vector exists for these agents where *T. luwenshuni* and *T. uilenbergi* are known not to occur.

Criterion 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.

- ① The disease has been reported principally in the Far East and Turkey [1,2, 3]. Based on this, it is highly likely that there will be more than one country which can be considered to be historically free of the disease in accordance with 1.4.6 of the Code.
- ② *T. uilenbergi* has been identified as a severe disease in sheep in China.
- ③ No (but maintenance of country freedom is possible and the fundamental focus for country status with regards to tick borne disease).
Eradication is not a practical option, but prevention of introduction is possible for zones and countries currently free (similarly for *T. orientalis Ikeda and Chitose*). Given that these pathogens have only been recognised reasonably recently it would be an unreasonable expectation that countries have carried out surveys to demonstrate either its presence or its freedom. In addition, it has not been a listed disease and consequently there is little motivation by country staff to carry out such surveillance work.

Criterion 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.

- ① The clinical and post mortem signs for case definition have been documented [1,2]. Serological and molecular methods exist for the detection and diagnosis of the infection. Serological methods such as IFAT and ELISA are sensitive but do suffer from lack of specificity, with crossreactions particularly with *T. luwenshuni* and *T. ovis* [4, 5]. Molecular methods have been developed and remain the principal methodology to differentiate *T. uilenbergi*, *T. ovis* and *T. luwenshuni*. These methods include the use of species-specific primers in conventional PCR [6], RLB [7] and multiplex PCR [8].
- ② Amplification of PCR; sequencing analysis.
- ③ See discussion for *T. luwenshuni* and *T. orientalis* Ikeda and Chitose.

Criterion 4a: Natural transmission to humans has been proven, and human infection is associated with severe consequences.

- ② No natural transmission to humans and no human infection with *T. uilenbergi* was observed in any outbreak.
- ③ No disease in humans has occurred from this species.

Criterion 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

- ① In an initial report [2], it was observed that mortality rates with *T. luwenshuni*/*T. uilenbergi* ranged between 17.8% and 75.4 % depending on the area, with morbidity rates of between 18.8 and 65%. Although separate attributions of pathology were not done, it is reasonable to suggest that both species contribute to the theileriosis disease complex seen in small ruminants in China. Both species have been described as being 'highly pathogenic for sheep and goats in China' [6].
- ② Several scientific papers confirm direct production losses and mortality in small ruminants in outbreaks with *T. uilenbergi*.
- ③ The agent along with *T. luwenshuni* have been reported to be highly pathogenic in sheep and goats in China, although details of both intra and inter-farm impact are vague.

Criterion 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

- ② No indications in literature that *T. uilenbergi* has an impact on the health of wildlife
- ③ No (but potential in wild small ruminants). Not reported, but unlikely that significant investigations have been carried out.

Summary Conclusion:

- ① The evidence as detailed above indicates that infection with *T. uilenbergi* matches the OIE listing criteria.
 1. Lawrence, J.A., Byaruhanga, C., Oosthuizen, M. and Mans, B.J. 2017. Theileriosis of sheep and goats. In Infectious Diseases of Livestock, eds. Coetzer, J.A.W., Thomson, G.R., MacLachlan, N.J. and Penrith, M.L
 2. Yin, H., Schnittger, L., Luo, J., Seitzer, U. and Ahmed, J. 2007. Ovine theileriosis in China: a new look at an old story. *Parasitology Research*, 101 (Suppl 2):S191-S195.
 3. Bilgic, H.B., Bakirci, S., Kose, O., Unlu, A.H., Hacıarlıoglu, S., Eren, H., Weir, W. and Karagenc, Y. 2017. Prevalence of tick-borne haemoparasites in small ruminants in Turkey and diagnostic sensitivity of single-PCR and RLB. *Parasites & Vectors*, 10, 211-223.
 4. Liu, Z., Li, Y., Salih, D.E., Luo, J., Ahmed, J.S., Seitzer, U. and Yin, H., 2014. Validation of a recombinant protein indirect ELISA for the detection of specific antibodies against *Theileria uilenbergi* and *Theileria luwenshuni* in small ruminants. *Veterinary Parasitology*, 204, 139-145.
 5. He, H., Li, Y., Liu, J., Liu, Z., Yang, J., Liu, A., Chen, Z., Ren, Q., Guan, G., Liu, G., Luo, J. and Yin, H., 2016. An indirect ELISA for detection of *Theileria* spp. antibodies using a recombinant protein (rTISP) from *Theileria luwenshuni*. *Experimental Parasitology*, 166, 89-93.
 6. Yin, H., Liu, Z., Guan, G., Liu, A., Ma, M., Ren, Q. and Luo, J., 2008. Detection and differentiation of *Theileria luwenshuni* and *T. uilenbergi* infection in small ruminants by PCR. *Transboundary and Emerging Diseases*, 55, 233-237.
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- ② *T. uilenbergi* fulfills all the necessary criteria for the inclusion in the OIE list.
 - H.Yin *et al.* (2008). *Transboundary and Emerging Diseases*. Vol. 55; n° 5/6 p 233-237
 - R. Begam *et al.* (2018) Emergence of *Theileria luwenshuni* infection in goats of Assam, India. *Journal of Entomology and Zoology Studies*. 6 (5): 57-60
 - L P Phipps *et al.* (2016). Detection of *Theileria luwenshuni* in sheep from Great Britain. *Parasites & Vectors* 9: 203
- ③ Despite some of the details around impact being somewhat vague there is sufficient evidence that recognition of risks of the potential impact from movement of small ruminants/vectors across borders is necessary through their inclusion of this agent to the OIE disease list.
 - Yin H *et al.* Detection and Differentiation of *Theileria luwenshuni* and *T. uilenbergi* Infection in Small Ruminants by PCR. *Transboundary and Emerging Diseases* 55, 2008
 - Li Y *et al.* Experimental transmission of *Theileria uilenbergi* infective for small ruminants by *Haemaphysalis longicornis* and *Haemaphysalis qinghaiensis*. *Parasitology Research* 104, 2009
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THEILERIA ORIENTALIS (IKEDA AND CHITOSE)

Criterion 1: International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.

- ① Although parasites of the *T. orientalis/buffeli* group are widespread, the severely pathogenic forms of the infections appear to be currently limited to eastern Asia and Australasia [1,2]. International spread of the agent has been confirmed by at least one report showing that cattle imported from Australia into Vietnam caused outbreaks of both the Ikeda and Chitose strains [3]. It should also be noted in support that spread of both the Ikeda and Chitose strains between the two main islands of New Zealand has been reported [4,5]. Thus there is evidence to show that international spread of both Chitose and Ikeda strains is possible.
- ② Several scientific and evidence based publications confirm the pathogenicity of *T.orientalis* Ikeda and *T. orientalis* Chitose in cattle and clinical outbreaks.

- ③ Live animals and tick vectors are known to transmit both *T. orientalis* (Ikeda) and *T. orientalis* (Chitose). If the agent is transported by cattle (associated with cells in the blood) for outbreaks to ensue, a suitable tick vector is required at the country destination. Live cattle movements explain the spread through countries in the Asia Pacific region (including NZ), [ref 1, 6-8, 14, 20]. Cattle movement has also shown to be the cause of spread within a country when first introduced [ref 1, 6-8, 14, 20].

Criterion 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.

- ① The severely pathogenic form of *T. orientalis* infection has been reported principally in the eastern Asia and Australasia [1,2]. Based on this, it is highly likely that there will be more than one country which can be considered to be historically free of the disease in accordance with 1.4.6 of the Code.
- ② *Theileria orientalis* Ikeda and *T. orientalis* Chitose have been identified as causing clinical disease in cattle in Australia, New Zealand and Japan.
- ③ No (but maintenance of country freedom is possible and the fundamental focus for country status with regards to tick borne disease)
Eradication of this disease has not been attempted; however, the significance of infection with *T. orientalis* (Chitose) and *T. orientalis* (Ikeda) has only recently become apparent, for instance in Australia and New Zealand (but known for some time in countries such as Japan). In an island nation that does not import cattle, maintenance of freedom is a reasonable and rationale possibility. Eradication is more problematic due to the maintenance of the disease in the tick population. To eradicate would require removal of tick vectors from tick habitat areas which would be both impractical, of dubious feasibility and certainly uneconomic. Thus, prevention of maintenance is critical.

Criterion 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.

- ① The clinical and post mortem signs for case definition have been documented [1]. Serological methods are available to distinguish infections with members of the larger *T. orientalis/buffeli* group [6,7]. However, these may not distinguish different strains within this group [8]. Molecular methods have also been developed and remain the principal methodology to differentiate *T. orientalis* strains, such as PCR using allele-specific primers [9]. Multiplex PCR and qPCR methods have been developed on for use with pathogenic Australasian strains [10,11]. As it is not clear whether these are sufficiently specific to distinguish pathogenic from non-pathogenic strains, these should be used in conjunction with clinical and pathological signs of disease.
- ② Molecular techniques targeting MPSP antigens.
- ③ The case definition for disease caused by *T. orientalis* (Ikeda) or *T. orientalis* (Chitose) (rather than detection of its presence) will depend on the specific circumstances in the country of interest. For instance, in New Zealand the initial diagnosis of theileriosis (caused by *T. orientalis* (Ikeda) and similarly for *T. orientalis* (Chitose)) was based on exclusion of other causes of regenerative anaemia). Once confirmed as the cause of outbreaks of anaemia a simplistic case definition was established; however, it did not preclude the possibility of “false positives” occurring (*T. orientalis* (Ikeda/Chitose) present; but not necessarily the cause of the anaemia observed). In other countries where other pathogens exist, for instance *Anaplasma* sp., *Babesia* sp., haemoplasmas etc. A case definition would need to include exclusion of these pathogens (as well as other causes of regenerative anaemias). Given the expense, and timeliness of this testing regime is unlikely that all possible causes of regenerative anaemia could be excluded for every case. However, a working case definition will be possible in some country situations (as it was for both New Zealand and Australia). Explanations of how this was achieved is provided in the reference literature references provided [ref 3, 5, 9, 10, 20].

Detection of the agent itself in cattle is relatively simple with the molecular tests available; the sensitivity of which being dependant on the limits of detection of these techniques [ref 5, 9, 10]. That said, false negatives can occur in the non-clinical carrier animal and risk-based methods would need to be developed that define a negative animal status (these might include non-laboratory methods/results, as well as laboratory test result data to make that assessment), [ref 22].

Criterion 4a: Natural transmission to humans has been proven, and human infection is associated with severe consequences.

- ② No natural transmission to humans and no human infection with *Theileria orientalis* Ikeda and *T. orientalis* Chitose was observed in any outbreak.
- ③ There is no indication that either *T. orientalis* (Ikeda) or *T. orientalis* (Chitose) can cause human illness.

Criterion 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

- ① Recent outbreaks of the disease in Australasia caused by both *T. orientalis* Ikeda and *T. orientalis* Chitose have resulted in significant rates of mortality and morbidity [2,3,4,5,10].
- ② *Theileria orientalis* Ikeda and *T. orientalis* Chitose are economically important parasites in cattle, due to direct production losses and mortality.
- ③ There have been sporadic cases of significant mortality in herds where *T. orientalis* (Ikeda) has been recently introduced (Recent implies exposure over several tick seasons *i.e.* not necessarily at the point immediately following first introduction into a herd. This relates to the epidemiology of building up infection in resident tick populations eventually resulting in significant exposure to cattle within the herd), [ref 1-4, 6-8, 12, 13, 15-19, 21].
 Anaemia in many cases is a subtle clinical sign. Exposure in a naïve herd may not necessarily result in high mortality; yet the prevalence of anaemia in the herd may be very high *i.e.* 60-80%. Despite a high prevalence of anaemia in a cattle herd, signs may not necessarily be detected and may go unnoticed (unless a small prevalence study is undertaken by the attending veterinarian). Anaemic cattle will still continue to occur in the herd, perhaps in perpetuity. The period that animals remain anaemic is likely to depend on a number of factors and will be variable. This will include factors relating to the animals' immune system, but also the degree of continuing infection pressure *e.g.* due to suitability of environment as a tick vector habitat [ref 1-4, 6-8, 12, 13, 15-19, 21].
 Quantification of the impacts of anaemia on production (meat and milk), and reproduction has not been determined to any satisfactory level. In part this is because of the complexities of any study carried out and because of the diversity in the levels of impact. Over and above undefined factors (including factors resulting in animal stress) this could relate to the level of exposure determined by tick ecology (*i.e.* proportion of the herd exposed over time determining whether there is a dramatic high prevalence exposure or drip feed in exposure of cattle over time resulting in a relatively low incidence of new infection over time) *i.e.* endemic stability. This tends to reduce awareness of impact in a disease that only produces overt signs *i.e.* mortality in a small percentage of an infected herd. Thus, there may not necessarily be agreement on the size of impact in affected farms/cattle herds (ranging from extreme to subtle) where studies have been carried out.
 For *T. orientalis* (Chitose) the impacts appear to be less. This most likely relates to the pathogenicity of the agent; but could also relate to (for Australia and New Zealand) its endemicity prior to introduction of Ikeda. It has however, been shown to cause anaemia in naïve cattle [ref 11].

Criterion 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

- ② No indications in literature that *Theileria orientalis* Ikeda and *T. orientalis* Chitose have an impact on the health of wildlife
- ③ The disease is restricted to cattle i.e. absent in wildlife species. Whilst it has been detected in other species e.g. ovine this is likely to relate to traces of *Theileria* DNA being present as a result of mechanical inoculation from the tick vector rather than true infection.

Summary Conclusion:

- ① The evidence as detailed above indicates that infection with *T. orientalis* Ikeda and Chitose matches the OIE listing criteria.
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- ② *Theileria orientalis* Ikeda fulfills all the necessary criteria for the inclusion in the OIE list.
 - G. Bailey (2011). Bovine anaemia caused by *Theileria orientalis* group. New South Wales Government, Primary Industries. Factsheet.
 - J G Watts *et al.* (2016). *Theileria orientalis*: a review. *New Zealand Veterinary Journal* 64(1), 3-9.
- ③ *Theileria orientalis* (Ikeda) is believed to have greater pathogenicity than *T. orientalis* (Chitose) and while Chitose is still known to cause anaemia with low levels of mortality impacts do not appear to be as significant as Ikeda. Thus, an argument could be made for distinguishing the two subspecies on this basis; however, it is likely that introduction of Chitose into a country naïve for the agent would have a significant impact. The most important impact of *T. orientalis* (Ikeda) (and Chitose) is anaemia with clinical signs often being subtle and requiring careful investigation to both detect and define. Thus, observations of disease often go unnoticed; however, this feature of disease does not diminish its importance to animal production both in the short and long term.

Eradication for all practical purposes is not possible; however, prevention of introduction into a country/zone is relatively easy. Requiring restriction of live cattle imports or alternatively (carrying some risk through test and exclusion/treatment for ticks) multiple testing of livestock in a tick free area prior to shipment. Thus, whilst countries have not necessarily demonstrated freedom, this is not precluded in the future and could be a possibility (depending on their history of live cattle imports from endemic countries). Testing using molecular techniques has high levels of sensitivity. For the purposes of detecting the agent (rather than diagnosing disease) available molecular tests are more than satisfactory for the purposes of defining country/zone status.

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**WORK PROGRAMME FOR
THE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES (FEB 2019)**

Issue and priority order (1-3; 1 being highest priority)		Status and action
Update of OIE standards		
1	Glossary	Not applicable
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
3	Ch 4.Y. Official control of listed and emerging diseases	Proposed amendments and sent to TAHSC.
3	Ch.8.8. Infection with foot and mouth disease	Not applicable
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	Received chapter updated by OIE HQ under the coordination of JAC. Chapter to be amended by the expert Group.
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. Considered the assessment against the criteria described in Chapter 1.2. of the <i>Terrestrial Code</i> , and recommended amending Chapter 1.3. accordingly. Recommended convening and <i>ad hoc</i> Group to finalise the drafting of the <i>Terrestrial Code</i> chapters on dourine and surra
1	Ch. 8.Y. Animal African Trypanosomoses	Considered the opinion of the <i>ad hoc</i> Group on animal African trypanosomoses. Considered the assessment against the criteria described in Chapter 1.2. of the <i>Terrestrial Code</i> , and recommended amending Chapter 1.3. accordingly. Revised chapter and endorsed <i>ad hoc</i> Groups sent to TAHSC.
1	Ch.10.4. Infection with avian influenza virus	Not applicable
1	Ch. 11.4. Bovine spongiform encephalopathy	<i>Ad hoc</i> Group reports on BSE surveillance and risk assessment (2nd meeting) and draft chapter considered. Work ongoing by an <i>ad hoc</i> Group on BSE risk assessment and surveillance.
3	Ch. 11.9. Infection with lumpy skin disease virus	Not applicable.
3	Ch. 11.12. infection with <i>T. anulata</i> , <i>T. orientalis</i> , <i>T. parva</i>	Considered the assessment against the criteria described in Chapter 1.2. of the <i>Terrestrial Code</i> , and recommended amending Chapter 1.3. accordingly
3	Ch. 12.3. Infections with Trypanozoon in equids	Considered the opinion of the <i>ad hoc</i> Group on animal African trypanosomoses. Considered the assessment against the criteria described in Chapter 1.2. of the <i>Terrestrial Code</i> , and recommended amending Chapter 1.3. accordingly.
2	Ch. 12.6. Infection with equine influenza virus	Proposed amendments and sent to TAHSC.
3	Ch. 14.X. infection with <i>T. lestoquardi</i> , <i>T. luwenshuni</i> , <i>T. uilenbergi</i>	Considered the assessment against the criteria described in Chapter 1.2. of the <i>Terrestrial Code</i> , and recommended amending Chapter 1.3. accordingly.
1	Ch 15.1. African Swine Fever	Considered some Member comments and sent to TAHSC.
1	Ch 15.2. Classical Swine Fever	Proposed amendments and sent to TAHSC.

Official disease status recognition		
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 February meeting] SCAD evaluated the annual reconfirmations of selected countries' disease status and endorsed official control programmes [Each September meeting] SCAD selected 10% of countries' disease status for comprehensive review at its meeting in February 2019.
1	Harmonisation of the requirements in the <i>Terrestrial Code</i> Chapters for official disease freedom	SCAD considered the harmonised provisions in Chapter 1.6. and Articles 14.7.3. and 14.7.34. (PPR) used as a model and sent to TAHSC. SCAD recommended to review other articles including Recovery of free status.
2	Official status of non-contiguous territories	SCAD noted the clarified situation of non-contiguous territories as part of countries' already officially recognised status, to be included in the Resolutions proposed for adoption in May 2019.
Disease control issues		
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	Considered the AHG on MERS-CoV. and its assessment of MERS-CoV against the criteria described in Chapter 1.2. of the <i>Terrestrial Code</i> , and recommended amending Chapter 1.3. accordingly. Reviewed the case definition and the Q&A.
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"> - Evaluation if Porcine Epidemic Diarrhoea matches the OIE listing criteria of <i>Terrestrial Code</i> Chapter 1.2.; - Evaluation if Chronic Wasting Disease matches the OIE listing criteria of <i>Terrestrial Code</i> Chapter 1.2.; - Prion disease in dromedary camels in Algeria; - Update on the foot-and-mouth disease reference laboratory network and disease global situation; - Zoonotic potential of hepatitis B in gibbons; - Risk of LSD vaccine-like strain transmission; - Update on the project on replacement of International Standard Bovine Tuberculin.
1	Define a procedure for the evaluation of diseases against the listing criteria of Chapter 1.2.	Discussion document on the establishment of an SOP and guidance document to the application of the listing criteria 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	Report reviewed.
AMR		
1	Assess and endorse AMR related <i>ad hoc</i> Groups reports	Report endorsed.

Other activities that could impact SCAD work programme		
1	Evaluation of applications for OIE Collaborating Centre status	Opinion provided on the principle of the OIE to consider addressing the issue of traditional veterinary medicine. Considered the 5-year workplan provided for the proposed OIE CC on Risk analysis and modelling Collaborating Centre application.
	Updated on the main conclusion/recommendations of meeting relevant for the work of the Commission	The Commission was updated on the outcomes of the most relevant meetings organised since September 2018
	Any other business	

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