WORLD ORGANISATION FOR ANIMAL HEALTH
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REPORT OF THE MEETING

OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 5–9 September 2016

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A meeting of the OIE Scientific Commission for Animal Diseases (the Commission) was held at the OIE Headquarters from 5 to 9 September 2016.

Dr Monique Eloit, Director General of the OIE, welcomed the Commission members and thanked them for their continuous support of the OIE activities. She introduced Dr Matthew Stone, the new Deputy Director General for International Standards and Science, and Dr Ann Backhouse, the new Head of the Standards Department. Dr Eloit also informed the Commission that two new departments had been created as part of the new organisation of the OIE, one dedicated to official disease status recognition and one to science and new technologies.

Dr Eloit indicated that the OIE is committed to enhancing the support to the four Specialist Commissions by harmonising the Secretariat procedures and by building capacity among OIE staff responsible for each of the Secretariats. The OIE is also committed to improving the management of Member Country comments on the circulated *Terrestrial Animal Health Code* chapters by developing fit-for-purpose IT tools.

Dr Eloit reiterated the importance of establishing a transparent and objective procedure for the selection of the members of the Specialist Commissions. She highlighted that, in line with the objectives of the OIE 6th Strategic Plan, the procedure for the selection of the members of the Specialist Commissions and the appointment of experts to Working Groups and *ad hoc* Groups were being reviewed. In preparation for the forthcoming elections in May 2018, the new procedure would be submitted for approval to the OIE Council in September 2016 before being presented to the OIE World Assembly of Delegates in May 2017.

Dr Stone acknowledged the importance of coordination among the Specialist Commissions and expressed his commitment to enhancing and facilitating the communication and coordination among them.

Dr Backhouse also expressed her commitment to strengthening coordination between the Commissions and the OIE Secretariat.

Dr Brückner, President of the Commission, welcomed Dr Stone and Dr Backhouse and offered the Commission's support of their new mandate. He acknowledged with appreciation the support received from Member Countries and the OIE for the work of the Scientific Commission. Finally He summarised the most critical aspects of the proposed agenda and outlined the priority issues and the work plan for the week.

1. Adoption of the agenda and appointment of rapporteur

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

2. Feedback from the 84th General Session

The President briefly outlined the most important outcomes from the 84th General Session related to the work of the Commission.

3. *Terrestrial Animal Health Code*

3.1. Member Country comments received for the Commission's consideration

a) Chapter 1.4. Animal health surveillance

The Code Commission had improved the structure and the wording of Chapter 1.4. on animal health surveillance that had been circulated for Member Country comment after its February 2016 meeting.

The Commission noted that some Member Country comments referred not only to the structure and wording of the chapter but also to the content. Considering the impact of this chapter on all the disease-specific chapters, in particular on those diseases for which the OIE officially recognises Member Country status, the Commission recommended that this chapter be fully reviewed by a dedicated *ad hoc* Group that would also consider the Member Country comments.

b) Chapter 2.X. Draft new chapter on criteria for assessing the safety of commodities

The Commission welcomed the proposed draft chapter and acknowledged that the purpose of this chapter was to list the criteria to be considered by the OIE experts and Specialist Commissions when assessing the safety of commodities to be listed in the disease-specific chapters.

c) Chapter 4.3. Zoning and compartmentalisation

The Commission acknowledged that Chapter 4.3. on zoning and compartmentalisation was circulated for Member Country comment after revision aimed at improving its structure and wording. However, some Member Countries also suggested significant conceptual modifications.

In view of the current work that has already been undertaken on Chapter 8.8. on foot and mouth disease (FMD), which includes the revision of some of these concepts (i.e. compartment with vaccination, larger containment zone), the Commission suggested that the revision of Chapter 8.8. be taken into account when amending this chapter and Chapter 1.4 on animal health surveillance.

d) Chapter 8.X. Infection with *Mycobacterium tuberculosis* complex

A revised version of Chapter 8.X. had been circulated to Member Countries for the second round of comments in February 2016. The Commission addressed the comments, which had been forwarded by the Code Commission.

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

The amended chapter addressing Member Country comments was returned to the Code Commission for further processing.

e) Chapter 11.11. Lumpy skin disease (caused by group III virus, type Neethling)

The chapter was extensively amended and circulated for first-round comment after the February 2016 meetings of the Specialist Commissions. The Commission reviewed and addressed the Member Country comments forwarded by the Code Commission.

The Commission discussed the latest epidemiological events in Europe and concurred that the adoption of this new *Terrestrial Code* chapter, as well as the update of the *Terrestrial Manual* chapter, should be a priority.

The detailed rationale for the Commission's proposed amendments is attached at Annex 4.

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

f) Chapter 15.1. Infection with African swine fever

The revision of this chapter was initiated in 2014, and the draft was circulated twice for Member Country comment.

The Commission referred Member Countries to the rationale for the modifications provided in previous of this Commission's meeting reports, in particular to the Commission report of February 2016.

The Commission stressed that the purpose of this chapter was not only to consider the situation in Europe but also other epidemiological scenarios where the presence of vector is epidemiologically relevant (e.g. African countries).

The detailed rationale for the Commission's proposed amendments is attached at Annex 5.

The amended chapter addressing Member Country comments was forwarded to the Code Commission for further processing.

g) Chapter 15.X. Porcine respiratory reproductive syndrome

The drafting of Chapter 15.X. was initiated in 2013, and it had been circulated twice for Member Country comment.

The Commission addressed the comments received by the OIE after the Code Commission meeting in February 2016.

The detailed rationale for the Commission's proposed amendments is attached at Annex 6.

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

h) Glossary: Zone, free zone, containment zone, protection zone

The Commission reviewed the first-round Member Country comments on the proposed glossary definitions.

The Commission reviewed and agreed with the modifications proposed by the FMD *ad hoc* Group to the definitions of zone and protection zone. It was suggested that these modifications should also be applied to the definition of compartment.

The Commission was of the opinion that the revision of the concepts should be in line with the revision of Chapter 4.3 on zoning and compartment (see Section 3.1.c of this report) and suggested that the opinion of the *ad hoc* Group on FMD be considered when revising these definitions.

The amended definitions were forwarded to the Code Commission for its consideration.

3.2. Other considerations

a) Surveillance articles of Chapter 12.10. Infection with *Burkholderia mallei* (Glanders)

The Commission expressed its concerns on the possibility of confirming freedom from glanders in a *country* or *zone*. Due to the epidemiology of the disease, which when present is most often present at a very low prevalence, the experts considered that to demonstrate freedom, all animals should be tested. In addition, the reduced sensitivity and specificity of the current available tests could result in a significant number of false negative and false positives results. The Commission also noted that in the framework of the high health high performance (HHP) concept, horses must be tested for glanders regardless of the status of their country of origin.

The Commission emphasised that these difficulties should not preclude Member Countries from conducting surveillance as described in the draft articles. However, the Commission challenged the need for and the scientific validity of the concept of a glanders free *country* or *zone*.

The Commission revised and amended the proposed articles on surveillance drafted by the experts from the OIE Reference Laboratories for Glanders with the collaboration of the OIE Headquarters.

The amended draft articles on surveillance were forwarded to the Code Commission for its consideration.

b) Inactivation of foot and mouth disease virus in milk and cream for human consumption

The Commission welcomed the risk assessment provided by a Member Country on FMD virus (FMDV) persistence in commercially manufactured milk powder and butter for human consumption. However, the Commission recommended that the opinion of experts on FMD and relevant OIE Collaborating Centres should be requested to assess the inactivation parameters in relation to the risk assessment.

c) Revision of Chapter 8.13. Infection with rabies virus

The Commission discussed the proposal to include provisions for zonal freedom for rabies in the current chapter of the *Terrestrial Code* (Article 8.13.3).

Such provisions would support Member Countries' efforts to gradually eliminate rabies leading eventually to the total elimination in the whole territory.

The Commission acknowledged that since 2005, the OIE had organised several international conferences on rabies in collaboration with the WHO[1] and FAO[2] (Kiev, Paris, Seoul and Geneva). The outcomes of those conferences provided very important and updated information on the approach to rabies control, especially as it relates to canine rabies.

According to the Commission, this updated information should be considered in the *Terrestrial Code* chapter on rabies. In view of the OIE-WHO-FAO Tripartite Agreement and Resolution No. 26 on rabies adopted during the 84th General Session, the Commission was of the opinion that the current chapter should undergo a full revision.

The Commission recommend that the Director General convene an *ad hoc* Group, under the auspices of the Scientific Commission, to review and update the existing chapter on rabies.

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1 WHO: World Health Organization

2 FAO: Food and Agriculture Organization of the United Nations

4. *Ad hoc* and Working Groups

4.1. Meeting reports for endorsement

a) *Ad hoc* Group on Vaccination, 29–31 March 2016

The Commission reviewed the report of the second meeting of the *ad hoc* Group and made minor changes to the draft *Terrestrial Code* chapter on vaccination that the *ad hoc* Group proposed. The draft chapter included the suggestions made by the three Specialist Commissions at their February meetings. The purpose of this draft chapter was to provide guidance to Member Countries to successfully implement vaccination in support of disease control programmes.

The Commission concurred with the Group that the "transmissibility of live-attenuated vaccine strains", the "purity", "contamination" and "release and spread of extraneous agents" were important criteria for the choice of the vaccine and referred the decision to include these aspects in the draft chapter to the Biological Standard Commission.

The Commission noted that the vaccine selected for use in a vaccination programme should be subjected to the registration procedure of the country, in agreement with the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medical Products (VICH). The Commission referred the endorsement of this requirement to the Biological Standard Commission.

The report of the *ad hoc* Group is attached at Annex 7.

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

b) *Ad hoc* Group on Foot and Mouth Disease (chapter revision), 14–16 June 2016

The Commission considered the report of the *ad hoc* Group that was tasked with developing new concepts related to FMD control and to address the Member Country comments received after the adoption of the amended chapter in May 2015.

The new concepts may affect other disease-specific chapters and include a broader concept of *containment zone*, *compartmentalisation* with vaccination, implementation of emergency preventive vaccination in response to an increased risk of disease incursion, and risk of virus transmission posed by vaccinated animals.

The Commission suggested that the modifications proposed in the amended chapter on FMD (see Section 3.1.c and 3.1.h of this report) be taken into account in the revisions of Chapter 4.3. on zoning and compartmentalisation and of certain terms in the Glossary.

The Commission identified two main principles that should be considered when introducing additional provisions to the *Terrestrial Code*: trade facilitation and disease control. While the essence of the provisions of the *Terrestrial Code* is to facilitate trade, they should not compromise the disease free status of a *country* or *zone* or deteriorate/discourage its efforts to control a disease. The Commission underlined that careful consideration should be taken before adding new provisions to the *Terrestrial Code* to accommodate every scenario between *countries* and *zones* with different status. A certain balance should be established to maintain and encourage the efforts of countries in controlling and eradicating the disease.

The Commission took note of the opinion of the *ad hoc* Group with regard to the risk represented by the use of serotype C for vaccination and vaccine challenge, and agreed that the OIE should formally recommend that those practices be progressively stopped.

The Commission strongly recommended that all Member Countries that suspect the presence of serotype C should send the samples to an OIE Reference Laboratory for confirmation.

The detailed rationale for the Commission's proposed amendments is attached at Annex 8.

The report of the *ad hoc* Group is attached at Annex 9.

The amended chapter addressing Member Country comments and including the draft concepts, and the *ad hoc* Group report were forwarded to the Code Commission for further consideration.

c) *Ad hoc* Group on Equine Trypanosomosis – Surra and Dourine, 14–16 June 2016

The Commission considered the report of the *ad hoc* Group on Equine Trypanosomosis, which was convened to draft a new *Terrestrial Code* chapter on surra and revise the *Terrestrial Code* chapter on dourine.

The Commission concurred with the *ad hoc* Group's decision to draft a separate *Terrestrial Code* chapter on infection with *Trypanosoma evansi* (not including equine surra) and to amend Chapter 12.3. on dourine to broaden its scope to trypanosomosis in equids, thereby encompassing both dourine and equine surra.

The Commission agreed with the scientific content of the draft chapters but was of the opinion that their structure should be revised in accordance with the established format for other disease chapters in the *Terrestrial Code*. It was suggested that this task could be done by the OIE Headquarters in collaboration with the representatives of both Specialist Commissions who attended the *ad hoc* Group meeting.

The Commission agreed with the proposal to use the information available from experimental studies as the base to establish the incubation period.

The Commission also noted that trypanosomosis was not listed in Chapter 4.6. on collection and processing of bovine, small ruminant and porcine semen as a disease that should be tested for, and questioned the need for such a provision in the draft chapters. However, should the provisions be considered necessary, similar provisions should be provided for embryos and oocytes.

The Commission recommended that revision of the *Terrestrial Manual* be put on hold until the Member Countries have expressed their opinion on the approach suggested by the *ad hoc* Group. The Commission concurred with the *ad hoc* Group on the need to conduct further research, in particular with reference to the validation of assays for the detection of *T. evansi* in different host species.

The draft chapters and the *ad hoc* Group report were forwarded to the Code Commission for further consideration.

The report of the *ad hoc* Group is attached at Annex 10.

d) *Ad hoc* Group on Antimicrobial Resistance, 21–23 June 2016

The Commission considered the report of the *ad hoc* Group on Antimicrobial Resistance that was requested to support the further elaboration of the OIE database on the use of antimicrobial agents in animals and to provide advice on a denominator to be used to calculate the use of antimicrobials by kg of animal biomass.

The Commission took note that the forthcoming OIE National Focal Point training for Veterinary Products would provide further opportunities to encourage the participation of Member Countries in the second phase of the data collection.

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

e) *Ad hoc* Group on Classical Swine Fever, 5–7 July 2016

The Commission reviewed the report of the *ad hoc* Group responsible for updating the *Terrestrial Code* chapter based on the recommendations made by previous *ad hoc* Groups and for addressing pending Member Country comments received after the adoption of the chapter in 2013. The Commission acknowledged the efforts made by the experts in harmonising the Classical swine fever (CSF) chapter with chapter 15.1. on African swine fever, which was also under revision.

In response to a Member Country's comment, the Commission clarified that the OIE would not publish self-declarations of freedom from diseases for which the OIE could grant an official country status. For this reason, references to self-declaration of CSF historical freedom should not be included in the chapter.

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

The detailed rationale for the Commission's proposed amendments to the chapter is attached at Annex 12.

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

f) *Ad hoc* Group on Bovine Spongiform Encephalopathy (chapter revision), 23–25 August 2016

The Commission reviewed the report of the *ad hoc* Group responsible for amending Chapter 11.4. of the *Terrestrial Code* on Bovine spongiform encephalopathy (BSE), by drafting a case definition, differentiating atypical from classical BSE, and adapting the surveillance system.

The Commission endorsed the case definition and the revision of the chapter to differentiate atypical from classical BSE.

The Commission also noted that the provisions on risk assessment from Articles 11.4.23. to 11.4.29. were duplicated in the BSE questionnaire for the official recognition of a BSE risk status. The Commission suggested that Articles 11.4.23. to 11.4.29. on risk assessment be removed from Chapter 11.4.

The Commission acknowledged that additional work would be required to further revise the surveillance requirements. Two surveillance models were discussed (including a revised version of the BSurvE model). Both models would require that simulations be conducted to explore the impact these models may have on the Member Countries already recognised as having an official BSE risk status.

The Commission recommended that the OIE Director General convene a new meeting of the *ad hoc* Group to finalise the revision of the surveillance provisions once the two revised models become available. The Commission emphasised that if the surveillance provisions were to be revised, a transition period would be needed for countries to adapt their surveillance strategies.

The Commission extensively discussed the progress made by Member Countries in the management of BSE risk and pointed out that the official recognition of BSE risk status had been initiated at a time when BSE was considered as representing a global threat.

The Commission discussed the current risks represented by the presence of BSE agent in view of recent epidemiological data, and questioned the relevance of maintaining an official risk status recognition by the OIE. It acknowledged that it would be Member Countries' responsibility to decide whether or not the OIE should continue with the official recognition of BSE risk status.

The amended chapter and the *ad hoc* Group report were forwarded to the Code Commission for further consideration. Should the chapter be circulated for Member Country comments, the Commission recommended that it should exclude the provisions for surveillance.

The detailed rationale for the Commission's proposed amendments to the chapter is attached at Annex 14.

The report of the *ad hoc* Group is attached at Annex 15.

4.2. Planned meetings of *ad hoc* Groups and the Working Group on Wildlife

The Commission took note of the dates of the *ad hoc* Group and Working Group meetings scheduled to be held before the next Commission meeting in February 2017.

The Commission reviewed the agenda of the Working Group on Wildlife and suggested minor modifications.

a) *Ad hoc* Group on Foot and Mouth Disease: 17–20 October 2016
b) *Ad hoc* Group on Contagious Bovine Pleuropneumonia: 25–27 October 2016
c) Working Group on Wildlife: 7–10 November 2016
d) *Ad hoc* Group on Classical Swine Fever: 8–9 November 2016
e) *Ad hoc* Group on Bovine Spongiform Encephalopathy: 22–24 November 2016
f) *Ad hoc* Group on African Horse Sickness: 29 November–1 December 2016
g) *Ad hoc* Group on Peste des Petits Ruminants: 6–8 December 2016
h) *Ad hoc* Group to update Chapter 11.12. on Theileriosis (to be decided)
i) *Ad hoc* Group on Antimicrobial Resistance: 23–26 January 2017

5. Official disease status

5.1. Expert missions to Member Countries requested by the Commission

a) FMD Bolivia and Paraguay: 17–26 April 2016

The Commission was updated on the main outcomes of the two missions to assess the maintenance of the FMD free status of Bolivia and Paraguay. The Commission congratulated both countries on the measures applied and the progress made and their commitment to implementing the recommendations made by the mission team.

b) CSF Mexico: 2–5 May 2016

The Commission was updated on the main outcomes of the mission, the main objective of which was to verify the maintenance of the disease status granted in 2015. The mission team highlighted the efforts made by the country in maintaining the CSF free status, in particular with regard to the control measures implemented in the bordering areas and in backyard and semi-technical holdings.

c) Planned missions

- Assessment for recognition of a CSF zonal free status

  Following the postponement of the mission planned for April 2016, the Commission took note of the new dates proposed by a Member Country and discussed the Terms of Reference for the mission.

- Maintenance of official disease status

  The Commission reiterated the importance of conducting field missions to verify the efforts made by Member Countries to maintain their disease status. The Commission reviewed the list of Member Countries that had already been informed of the intention to conduct this type of mission and added two countries to be considered as a priority.

  The Commission considered the proposal made by the OIE Director General to create a pool of experts to conduct country missions related to official disease status recognition. The Commission strongly advised that the selected experts should be formally trained by the OIE to ensure adequate understanding of the OIE procedures and requirements and to harmonise the evaluation criteria.

5.2. Update on official disease status

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

- Venezuela (FMD)

  The Commission acknowledged the difficulties recently faced by Venezuela and the support offered by several of its neighbouring countries. Considering the regional and national willingness to take all the necessary actions to progress along the endorsed official control programme, as well as the OIE country mission planned for November 2016, the Commission agreed to provisionally maintain the endorsement of the official control programme.

- Morocco (FMD)

  The Commission acknowledged with appreciation the information provided by Morocco and highlighted its transparency in responding to the Commission's requests.

  The Commission stressed the importance of establishing an FMD vaccine bank for North African countries and encouraged the OIE to support this initiative.

b) Update on countries or zone with suspended disease status

- FMD: Korea (Rep. of) (2014).

  The Commission took note that the FMD free status of Korea (Rep. of) had been suspended for more than 2 years and, according to the requirements of the *Terrestrial Code*, future recovery of FMD status would have to follow the provisions of Articles 8.8.2. or 8.8.3.

- FMD: Mauritius (2016)

  The Commission discussed the recent FMD outbreak in Mauritius and the country's efforts in implementing emergency vaccination. The Commission highlighted the importance of prompt notification as outlined in *Terrestrial Code* chapter 1.1. as a foundation of transparency and trust among all the Member Countries.

5.3. Annual reconfirmations and other official status related issues

a) Review of the status recognition questionnaires

The OIE Headquarters had harmonised the questionnaires for official disease status recognition and endorsement of control programme based on the revised version provided by the Commission and by each *ad hoc* Group responsible for the evaluation of Member Country disease status dossiers. The purpose of the revision was to ensure consistency with the disease-specific chapters and, when appropriate, to harmonise the structure and wording of the different questionnaires.

The Commission addressed specific questions raised by the OIE Headquarters and endorsed the revised questionnaires with minor changes.

b) Selection of countries for comprehensive review of their 2016 annual reconfirmation

The Commission reviewed the list of Member Countries proposed by the OIE Headquarters for a comprehensive review of their 2016 annual reconfirmations, to take place during the Commission's forthcoming meeting in February 2017. The selection was based on a set of criteria already agreed on by the Commission.

c) Tool box for OIE Regional and Sub-Regional Representatives

The Commission welcomed the document prepared by the OIE intended to enhance the support provided by the OIE Regional and Sub-Regional Representatives to Member Countries in the process of submitting their annual reconfirmation.

d) Identification of PVS critical competencies relevant for endorsement of official control programme and official status recognition

While acknowledging that PVS missions were not a prerequisite to the official recognition of disease status, the Commission discussed the value of using this OIE tool to highlight the strengths and possible weaknesses of the Veterinary Services in charge of maintaining a free status or of progressing an official control programme.

The Commission noted that reports of PVS missions conducted less than 5 years before were already available during the evaluation process, provided the Member Country had accepted to share them with OIE partners. This was frequently used as a support and complementary to the information provided by Member Countries in their dossiers.

The Commission supported the proposal of the OIE Headquarters to work closely with PVS experts to identify the critical competences that may be relevant for disease status recognition. The Commission would review the proposal and would continue the discussion at forthcoming Commission meetings.

6. Foot and Mouth Disease and Peste des Petits Ruminants control strategies

6.1. Peste des Petits Ruminants: Global Eradication Strategy

Dr David Sherman from the OIE Regional Activities Department provided a brief update on the current status of the global peste des petits ruminants (PPR) control and eradication programme. He noted that the OIE/FAO PPR Working Group had been disbanded and that the OIE/FAO PPR Secretariat had been established, consisting of a Secretary, a representative from FAO and a representative from the OIE, and located at FAO headquarters in Rome, Italy. The Secretariat is responsible for the day-to-day management of the global programme.

A key activity undertaken by the Secretariat since the last Commission meeting in February 2016 was the preparation of a Global PPR Eradication Programme based on the Global Strategy for the Control and Eradication of PPR (GCES) adopted in Abidjan, Côte d'Ivoire, in April 2015. A Drafting Committee of experts developed the document, which was subsequently reviewed and refined by a Peer-Review Committee meeting in Rome in July 2016. The final version completed in August was being formatted and would be published in six languages. A donor pledging meeting for support of the global PPR eradication programme was planned for early 2017.

Finally he informed the Commission that six regional roadmap meetings have been held for the countries in the various regions designated by the GCES to have their status relative to PPR infection and control activities assessed and to begin developing regional strategies for eradication of the disease. To finalise the first round of regional roadmap meetings, three more meetings would be organised before the end of the year (i.e. SADC[3], North Africa [UMA[4]] and ASEAN[5]).

6.2. Foot and Mouth Disease: Global Control Strategy

Dr Laure Weber-Vintzel, Head of the Status Department, briefly updated the Commission on the last activities conducted in the framework of the Global FMD Control Strategy and under the umbrella of the Global Framework for the progressive control of Transboundary Animal Diseases (GF-TADs). She listed the regions where roadmaps meetings took place or were planned in the coming months and highlighted the progress made in some of them.

She also updated the Commission on the state of play of the FAO/OIE guidelines for post-vaccination monitoring, and indicated that the guidelines should be available shortly.

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3 SADC: Southern African Development Community

4 UMA: Union du Maghreb Arabe (Arab Maghreb Union)

5 ASEAN: Association of Southeast Asian Nations

Finally she informed the Commission that the GF-TADs FMD Working Group had finalised the revision of a template for the risk-based strategic plan that may be used by countries willing to move from Stage 1 to Stage 2. Components 2 and 3 of the Global Strategy, related to the strengthening of the Veterinary Services and to the prevention and control of other major diseases of livestock, were included in the template.

7. OIE Collaborating Centres

7.1. Follow-up on the proposal for an OIE Collaborating Centre for Training of Veterinary Officials, Diagnosis of Infectious Animal Diseases and Zoonoses and the Control of Veterinary Drugs in West and Central Africa

The Commission reviewed the response sent by the candidate Collaborating Centre applicant to the Director General detailing how the current OIE Reference Laboratory could be integrated into the existing Collaborating Centre. The Commission was satisfied with the proposed new organisation of activities and responsibilities, and recommended approval of the application by the OIE Council. The Commission undertook to closely monitor the annual reports of the new Collaborating Centre to verify that the new structure is operating optimally for the benefit of Member Countries in the region.

7.2. Collaborating Centre for Methods Development for Antimicrobial Control in Products of Animal Origin

An application had been received from an OIE Member Country in Europe for an OIE Collaborating Centre for Methods Development for Antimicrobial Control in Products of Animal Origin. The Commission noted that the applicant's main proposed activity was residue testing of bee products in connection with food safety. The Commission agreed that this activity resided better within the remit of the Codex Alimentarius rather than the OIE and proposed that the applicant address their application to Codex.

8. Liaison with other Specialist Commissions

8.1. Terrestrial Animal Heath Standard Commission

a) Revision of the agenda for the joint meeting with the Code Commission

Please refer to the joint meeting between the two Commissions attached at Annex 16.

8.2. Biological Standards Commission

a) Update on the proposal to develop a replacement international standard bovine tuberculin

Dr Elisabeth Erlacher-Vindel, Head of the Science and New Technologies Department, updated the Commission on the progress that had been made with the project to develop a replacement international standard bovine tuberculin. An action plan has been developed and instigated with the target date on proposing the new standard for adoption by the World Assembly in May 2019. The Plan has five milestone steps: donation of bulk material, preparation of candidate tuberculin, preliminary evaluation, international collaborative study, and finally adoption of the New International Standard Bovine Tuberculin. The OIE is soliciting financial support from public and private partnerships to support this important and urgent activity.

b) Feedback on the update of the *Terrestrial Manual* chapter on lumpy skin disease

The Commission was informed that the comments made by the *ad hoc* Group on Lumpy Skin Disease had been reviewed by the OIE Reference Laboratory experts, and the *Terrestrial Manual* chapter had been amended. The Biological Standards Commission had approved the amended chapter to be sent for the first-round of Member Country comments with the view to propose it for adoption in May 2017. Once adopted, the technical disease card would be also updated to include the new information and would be uploaded on the OIE web site.

8.3. Issues common to several Specialist Commissions

a) Update from the World Animal Health Information and Analysis Department: WAHIS renovation process

The Commission was briefed on the progress made towards the WAHIS renovation process, which is divided into three phases: i) setting a timetable and recruiting an assisting company, ii) Project launch and iii) production and delivery of the new WAHIS.

An international call for tenders to recruit the assisting company was launched with a deadline of 5 October 2016. A contract is expected to be signed by 14 November 2016. There are a number of milestones, such as development of a project business case, donor pledging paper, stakeholder consultations and defining the profile and skills required for the Project Manager who is expected to start work early 2017.

The technical specifications and the estimated budget for the project would be prepared based on the feedback provided by OIE Member Countries and stakeholders. An international call for tender would be launched to select the company responsible for the development of the new WAHIS, which is expected to be delivered by June 2019.

The Commission took note with thanks of the progress made by the OIE in continuing to improve and facilitate Member Countries' notifications. It stressed that WAHIS serves not only for disease notification but includes also other important information relevant to antimicrobial resistance.

The Commission commended the report made by Dr Paula Caceres during the 84th General Session that included selected diseases that affected wildlife during the past year and encouraged Member Countries to continue reporting non-OIE listed wildlife diseases to the OIE.

9. Conferences, workshops, meetings, missions

9.1. Lumpy Skin Disease

The Commission was informed of the outcome of the first LSD Standing Expert Group (SEG1) meeting (under the umbrella of the GF-TADs for Europe) where the use of preventive vaccination was extensively discussed. The LSD-SEG2 would be organised back-to-back with the next Regional Conference for Europe, which would take place in Lisbon, Portugal, in September 2016.

The Commission noted that some Member Countries were implementing preventative vaccination in a response to a threat, and therefore the adoption of the amended chapter on lumpy skin disease should be a priority.

9.2. African Swine Fever

The Commission was informed of the outcome of the third meeting of the ASF Standing Expert Group (SEG3) (under the umbrella of the GF-TADs for Europe) and noted that the ASF-SGE4 would be organised in Lithuania. The proposed topics would be the status of implementation of the ASF SGE country mission recommendations, depopulation/stamping out procedures as prevention and control measures, and the practical aspects related to carcass disposal and disinfection of holdings.

9.3. Crisis Management Centre – Animal Health (CMC-AH): follow up of the mission to Angola

The Commission acknowledged the reception of the final report of the CMC-AH mission requested during the Commission's February 2016 meeting.

9.4. 2nd International Symposium on Alternatives to Antibiotics (13–15 December 2016)

The Commission noted the upcoming International Symposium on Alternatives to Antibiotics and requested to be updated during the next Commission meeting.

10. Disease-specific issues

10.1. Foot and Mouth Disease: use of a combination of vaccines (FMD or others)

The Commission took note of the request made by a Member Country and confirmed that the use of a combination of vaccines would not affect the official disease status of the country if it can be demonstrated that the efficacy of the vaccine is not affected.

10.2. Follow up on the *ad hoc* Group on Diseases of Camelids opinion on Middle East Respiratory Syndrome Coronavirus (MERS-CoV) case definition

The Commission considered with thanks the draft version of the MERS-CoV case definition in dromedary camels proposed by Dr Mehdi Elharrak, Chair of the OIE *ad hoc* Group on Diseases of Camelids and of the OIE *ad hoc* Group on MERS-CoV Infection in Animals. The Commission agreed with the proposal and suggested that it be discussed among all members of the two *ad hoc* Groups before finalisation. The Commission observed that the updated case definition would support those Member Countries in the process of notifying MERS-CoV in dromedary camels to the OIE.

10.3. Chronic wasting disease of cervids: inclusion in the OIE list of diseases

The Commission discussed the request of a Member Country to evaluate chronic wasting disease (CWD) of cervids against the criteria in Chapter 1.2 of the *Terrestrial Code*, with the view to include it in the OIE list of diseases.

The Commission took note of the opinion of the *ad hoc* Group on BSE on this subject, and considered with appreciation the opinion of CWD experts who had been contacted by OIE Headquarters.

The Commission suggested including this topic on the agenda of the forthcoming meeting of the Working Group on Wildlife. The Working Group's opinion would be considered at the Commission's February meeting.

10.4. Global Surveillance for Influenza A Viral Diversity in Wild Birds

The Commission was updated on the latest activities of the OFFLU[6] wild bird technical activity group. The OFFLU wild bird group drafted a new concept and discussion paper on *Global Surveillance for Influenza A Viral Diversity in Wild Birds*, which was presented to the Commission for information. The document explained the rationale, objectives, design, operation, organisational structure and governance of a global surveillance programme in wild birds. The main objective of this proposed programme is to effectively and regularly monitor the changing characteristics of genomic diversity of influenza viruses and to secure the benefits of such surveillance information equally for all countries through a single affordable programme for which cost is shared internationally. The surveillance data from the Northern and Southern hemispheres, along with genetic sequences, can then be made available free of charge on a website to all governments, non-government organisations and individuals. The necessary resources for this global surveillance programme need to be identified through a suitable funding mechanism.

11. Matters of Interest for Information

11.1. Update on elimination of rinderpest virus material

a) The FAO-OIE Joint Advisory Committee on Rinderpest

The Commission was informed that the current tenure of the membership of the FAO-OIE Joint Advisory Committee (JAC) on Rinderpest came to an end on 31 August 2016. However, in consideration of continuing post-eradication activities, the JAC would continue with the five original members being re-appointed along with two new members for another 3 years starting 1 September 2016 until 31 August 2019. The Commission was also informed that the next JAC meeting would be held from 8 to 9 November 2016 at the OIE Headquarters.

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6 OFFLU: Joint OIE-FAO Network of Expertise on Animal Influenza

b) Rinderpest Holding Facilities

The Commission was notified that one institute that applied in 2014 to be a rinderpest holding facility (Category A – rinderpest virus containing material, excluding vaccines), was inspected in July 2016. The report and the findings as to its appropriateness as a rinderpest holding facility (Category A) would be discussed during the JAC meeting in November 2016. It was also reported that another facility is ready for its on-site inspection; however, the timing of the inspection is still to be determined. The Commission noted that there were already five rinderpest holding facilities in four countries as per Resolution No. 25 (adopted in May 2015).

c) Definition of rinderpest holding facility

In May 2011, the World Assembly adopted Resolution No. 18 *Declaration of Global Eradication of Rinderpest and Implementation of Follow-up Measures to Maintain World Freedom from Rinderpest*. An Appendix to this Resolution, *Global Rinderpest Eradication: Guidelines for Rinderpest Virus Sequestration*, indicates that all rinderpest holding facilities should be biosafety level 3 (BSL3). The JAC noted that this criterion would create practical problems for manufacturing vaccines as some vaccine manufacturing facilities do not operate at BSL3. The JAC suggested that the guidance be amended, and this proposal was accepted by the Biological Standards Commission during its meeting in September 2013. However, it was not taken into account in an updated Resolution adopted by the Assembly in May 2014. The Commission was thus asked to update the guidance with the view of presenting it for adoption by Resolution at the 85th General Session of the World Assembly in May 2017. At its next meeting, the Commission would review the proposal from the Biological Standards Commission to amend the guidance in Resolution No. 18 (adopted in May 2011).

d) Definition of rinderpest virus containing material

The Commission was informed that there was a request, from at least one rinderpest holding facility, to change the definition of rinderpest virus containing material to exclude heat-inactivated sera. The definition of rinderpest virus containing material given in both Resolution No. 18 (adopted in May 2011) and Chapter 8.15. of the *Terrestrial Code*, was purposefully broad to include all possibilities. The Commission was reluctant to support changes to the definition of such materials given the pronounced desire to keep the world free from rinderpest.

11.2. Update on twinning projects

The Commission was updated on the status of laboratory twinning projects. As of August 2016, 35 projects had been completed and 29 projects were underway. Six of the candidate laboratories that had completed their twinning projects successfully applied to became OIE Reference Centres.

11.3. Update on research projects in which the OIE is involved

The Commission was informed of the involvement of the OIE in An International Research Consortium (IRC) on Animal Health building on the EU-funded STAR-IDAZ Project (Global Strategic Alliances for the Coordination of Research on the Major Infectious Diseases of Animals and Zoonoses). The IRC aims to deliver measurable advances in the control of animal diseases through the alignment of both public and privately funded animal health research around the world. The OIE will host the technical secretariat of this Consortium to strengthen the link between the OIE's mandate on research and the needs of the Member Countries.

The Commission welcomed the initiative and commended the OIE for its involvement. The Commission recommended monitoring how this network would impact on research groups at the national level.

12. Programme and priorities

12.1. Review, update and prioritisation of the work plan

The Commission updated its work plan and prioritised its activities in accordance with the OIE priorities and the Code Commission's programme.

The updated working programme is attached at Annex 17.

13. Adoption of the report

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

The next meeting of the Scientific Commission is scheduled for 13–17 February 2017.

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…/Annexes

Annex 1

MEETING OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 5–9 September 2016

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Agenda

Opening

1. Adoption of the agenda and appointment of rapporteur

2. Feedback from the 84th General Session

3. *Terrestrial Animal Health Code*

3.1. Member Country comments received for the Commission's consideration

a) Chapter 1.4. Animal health surveillance
b) Chapter 2.X. Draft new chapter on criteria for assessing the safety of commodities
c) Chapter 4.3. Zoning and compartmentalisation
d) Chapter 8.X. Infection with *Mycobacterium tuberculosis* complex
e) Chapter 11.11. Lumpy skin disease (caused by group III virus, type Neethling)
f) Chapter 15.1. Infection with African swine fever
g) Chapter 15.X. on Porcine respiratory reproductive syndrome
h) Glossary: Zone, free zone, containment zone, protection zone

3.2. Other considerations

a) Surveillance articles of Chapter 12.10. Infection with *Burkholderia mallei* (Glanders)
b) Inactivation of foot and mouth disease virus in milk and cream for human consumption
c) Revision of Chapter 8.13. Infection with rabies virus

4. *Ad hoc* and Working Groups

4.1. Meeting reports for endorsement

a) *Ad hoc* Group on vaccination, 29–31 March 2016
b) *Ad hoc* Group on Foot and Mouth Disease (chapter revision), 14–16 June 2016
c) *Ad hoc* Group on Equine Trypanosomosis – Surra and Dourine, 14–16 June 2016
d) *Ad hoc* Group on antimicrobial resistance, 21–23 June 2016
e) *Ad hoc* Group on Classical Swine Fever (chapter revision), 5–7 July 2016
f) *Ad hoc* Group on Bovine Spongiform Encephalopathy (chapter revision), 23–25 August 2016

4.2. Planned meetings of *ad hoc* Groups and the Working Group on Wildlife

a) *Ad hoc* Group on Foot and Mouth Disease: 17–20 October 2016
b) *Ad hoc* Group on Contagious Bovine Pleuropneumonia: 25–27 October 2016
c) *Ad hoc* Group on Classical Swine Fever: 8–9 November 2016
d) *Ad hoc* Group on Bovine Spongiform Encephalopathy: 22–24 November 2016
e) *Ad hoc* Group on African Horse Sickness: 29 November–1 December 2016
f) *Ad hoc* Group on Peste des Petits Ruminants: 6–8 December 2016
g) *Ad hoc* Group to update Chapter 11.12. on Theileriosis: (to be decided)
h) *Ad hoc* Group on Antimicrobial Resistance: 23–26 January 2017
i) Working Group on Wildlife: 7–10 November 2016

5. Official disease status

5.1. Expert missions to Member Countries requested by the Commission

a) FMD Bolivia and Paraguay: 17–26 April 2016
b) CSF Mexico: 2–5 May 2016

c) Planed missions:
   - Assesment for recognition of a CSF zonal free satus
   - Maintenance of official disease status

5.2. Update on official disease status

a) Follow-up of some countries having an official endorsed control programme
   - Venezuela (FMD)
   - Morocco (FMD)

b) Update on countries or zone with suspended disease status
   - FMD: Korea (Rep. of) (2014)
   - FMD: Mauritius (2016)

5.3. Annual reconfirmations and other official status related issues

a) Review the status recognition questionnaires
b) Selection of countries for comprehensive review of their 2016 annual reconfirmation
c) Tool box for OIE Regional and Sub-Regional Representatives
d) Identification of PVS critical competencies relevant for endorsement of official control programme and official status recognition.

6. FMD and PPR control strategies

6.1. Peste de Petits Ruminants: Global Eradication Strategy

6.2. Foot and Mouth Disease: Global Control Strategy

7. OIE Collaborating Centres

7.1. Follow up on the proposal for an OIE Collaborating Centre for Training of Veterinary Officials, Diagnosis of Infectious Animal Diseases and Zoonoses and the Control of Veterinary Drugs in West and Central Africa

7.2. Collaborating Centre for Methods Development for Antimicrobial Control in Products of Animal Origin

8. Liaison with other Commissions

8.1. Terrestrial Animal Heath Standard Commission

a) Revision of the agenda for the joint meeting with the Code Commission

8.2. Biological Standards Commission

a) Update on the proposal to develop a replacement international standard bovine tuberculin
b) Feedback on the update of the *Terrestrial Manual* chapter on lumpy skin disease

8.3. Issues common to several Specialist Commissions

a) Update from the World Animal Health Information and Analysis Department: WAHIS renovation process

9. Conferences, workshops, meetings, missions

9.1. Lumpy Skin Disease

9.2. African Swine Fever

9.3. Crisis Management Centre – Animal Health (CMC-AH): follow up of the mission to Angola

9.4. 2nd International Symposium on Alternative to Antibiotics (13–15 December 2016)

10. Disease specific issues

10.1. Foot and Mouth Disease: use of a combination of vaccines

10.2. Follow up on the *ad hoc* Group on Diseases of Camelids opinion on Middle East Respiratory Syndrome Coronavirus (MERS-CoV)case definition

10.3. Chronic wasting disease of cervids: inclusion in the OIE list of diseases

10.4. Global Surveillance for influenza A viral diversity in wild birds

11. Matters of Interest for Information

11.1. Update on elimination of rinderpest virus material

a) The FAO-OIE Joint Advisory Committee on Rinderpest
b) Rinderpest Holding Facilities
c) Definition of rinderpest holding facility
d) Definition of rinderpest virus containing material

11.2. Update on twinning projects

11.3. Update on research projects in which the OIE is involved

12. Programme and priorities

12.1. Review, update and prioritisation of the work plan

13. Adoption of the report

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Annex 2

MEETING OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 5–9 September 2016

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Annex 3

Rationale for the amendments to:

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

Article 8.X.1. General provisions

The inclusion of New World camelids in the list of susceptible species to be considered for the purpose of this Article was discussed. The Commission indicated that it should remain under study as there was not sufficient scientific evidence available to take an informed decision.

While a Member Country suggested including *Mycobacterium avium* complex, the Commission pointed out that the chapter was dedicated to the infection with *Mycobacterium tuberculosis* complex. Thus the Commission did not support the proposal.

Article 8.X.2. Safe commodities

The Commission agreed that pasteurised milk should be considered safe for the trade. This provision was already included in Article 8.X.13. The question on whether pasteurisation should be considered as a risk mitigation measure specifically directed against the *Mycobacterium tuberculosis* complex, was referred to the Code Commission.

In response to another Member Country's comment, the Commission clarified that a disease-specific list of safe commodities was developed for each disease and that meat-and-bone meal should be considered a safe commodity with regard to *M. tuberculosis* complex.

Article 8.X.4. Country or zone free from infection with *M. tuberculosis* complex in bovids

The Commission agreed to amend the provision of point 1b) by requesting a surveillance programme based on regular testing, instead of regular testing of all herds. This would also be consistent with the wording of point 2c).

In addition, the Commission considered a comment on the design prevalence and regretted that the Member Country did not provide any scientifically sound alternative to be considered. The Commission decided to keep the requirement as it was.

The Commission acknowledged that a range of species are susceptible to *M. tuberculosis* complex but, with reference to the case definition, should the infection occur in any species other than those listed in Article 8.X.1. or in feral or wild animals, the disease status of the country should not be modified.

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

In response to a proposal from a Member Country on point 3c), the Commission did not agree to require active surveillance aimed at assessing the risk of infection posed by the wildlife reservoir. This was considered to be an expensive burden that could be misinterpreted.

Article 8.X.7. Recommendations for the importation of bovids or cervids for breeding or rearing

With regard to a Member Country's suggestion to either remove point 2c) or to add the requirement for an ancillary test in addition to the second intradermal tuberculin test, the Commission reminded the Member Country that the *Terrestrial Manual* only considers the intradermal tuberculin test as the standard test.

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

In response to a Member Country's suggestion, the Commission contacted experts from the OIE Reference Laboratories for Tuberculosis to seek their opinion and scientific references on an existing validated test that would confirm that an individual goat is free from tuberculosis.

Considering the lack of scientific evidence, the Commission suggested that the Biological Standard Commission provide its opinion and consider whether or not Chapter 2.4.6. of the *Terrestrial Manual* should be amended. Meanwhile, the Commission advised to put this provision under study.

The Commission agreed with a Member Country that a 6-month waiting period for an infection free goat herd did not provide sufficient evidence of absence of infection. The Commission suggested that the Code Commission delete this requirement.

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

The Commission clarified that the difference in the requirements of Article 8.X.14. and of Article 8.X.13. was due to the fact that there were no specific provisions for infection free herds of goats.

Annex 4

Rationale for the amendments to:

Chapter 11.11. LUMPY SKIN DISEASE (caused by group III virus, type Neethling) provided by the Scientific Commission

Article 11.11.1. General provisions

The Commission noted that wild ruminants are less susceptible to lumpy skin disease (LSD) than cattle and water buffaloes and they do not seem to play a significant role in the epidemiology of the disease. While acknowledging the limited understanding of LSD in wild animals, the Commission proposed to maintain the current wording.

Article 11.11.2. Safe commodities

The Commission pointed out that *ante-* and *post-mortem* inspections were a prerequisite for all commodities, including for those considered safe. For this reason, clinically infected animals would be detected and removed from the food chain. The Commission did not support one Member Country's proposal to include *ante-* and *post-mortem* inspections in this Article.

The Commission acknowledged that limited information was available on the risk of virus transmission posed by trade of some commodities. The Commission noted that it is accepted that skeletal muscle is safe but this consideration could not be extended to the heart and liver.

Article 11.11.4.*bis*: Recovery of free status

The Commission drafted a new Article to allow countries or zones that were previously free from LSD to recover their free status. The draft was circulated to the experts on the *ad hoc* Group on LSD for their consideration and opinion.

Two different waiting periods were proposed depending on the type of surveillance implemented. Where clinical, virological and serological surveillance were implemented, the Commission suggested establishing a waiting period of two vector seasons and to add two additional months for security, for a total of 14 months. If only clinical surveillance was implemented, the waiting period was extended to 26 months following a similar approach to that in Article 11.11.3.

The Commission also considered the specific situation when a Member Country may implement preventive vaccination in response to a risk of LSD virus (LSDV) introduction. In this scenario, the Member Country would lose its free status but the waiting period to recover could be reduced to one vector season (to which 2 months should be added for safety).

Article 11.11.5. Recommendations for importation from countries or zones not free from LSD

The Commission acknowledged that there were no commercially available serological tests for LSD and agreed that meeting this requirement would require a laboratory that is able to develop in-house tests.

The Commission took note of the efforts made by several research groups to develop and validate an enzyme-linked immunosorbent assay (ELISA) to support LSD serological surveillance. The Commission recommended to follow up on this development as it could influence the recommendations of this chapter.

Article 11.11.10: Recommendations for the importation of milk and milk products

The Commission discussed the risk of virus transmission through the importation of milk and milk products. The Commission noted that pasteurised milk was mainly intended for human consumption and not as animal feed. In addition, infected animals usually show a decrease in milk yield as well as mastitis. It is therefore unlikely that infected milk would reach the milk collection centre, and if it did, it would be highly diluted in the milk tank with a low risk of being infective.

In addition, the Commission consulted the experts from the OIE Reference Laboratories for LSD and the members of the OIE *ad hoc* Group on LSD who provided references[1,2] confirming the inactivation of LSD virus in milk by pasteurisation.

Article 11.11.11. Recommendations for importation of products of animal origin from cattle and water buffaloes intended for agricultural or industrial use

The Commission was of the opinion that this Article was vague and did not provide any information to the Member Countries. The Commission suggested the deletion of this Article for consistency with other chapters of the *Terrestrial Code* (i.e. African swine fever, classical swine fever, foot and mouth disease).

Article 11.11.13. Recommendations for importation of hides of cattle and water buffaloes

In response to a Member Country's suggestion to detail the process allowing inactivation of the LSDV in hides, the Commission agreed that a more detailed description of the procedure would be necessary. The Commission considered the proposal made by a Member Country and consulted the experts from the OIE Reference Laboratories for LSD and the members of the OIE *ad hoc* Group on LSD. They confirmed that salting, as proposed, would inactivate the virus. However, the Commission could not support the suggestion of including air drying of hides. More scientific evidence would be necessary to make sure that this procedure inactivates the virus in the scabs.

The Commission considered that there was not sufficient justification to reduce the period during which the animal should be kept in a country or zone free from LSD to 28 days, as proposed by a Member Country.

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1 http://www.milkfacts.info/Milk%20Processing/Heat%20Treatments%20and%20Pasteurization.htm

2 Al-Salihi K.A.,2014. Lumpy Skin disease: Review of literature. *MRSVA*. **3**(3), 6-23

Annex 5

Rationale for the amendments to:

Chapter 1.5.1. INFECTION WITH AFRICAN SWINE FEVER provided by the Scientific Commission

Article 15.1.1. General provisions

The Commission reiterated that the distinction between the different types of susceptible animals was based on livestock management systems. This was consistent with other swine disease chapters of the *Terrestrial Code*.

The Commission discussed the incubation period for African swine fever (ASF) and noted that according to the *Terrestrial Manual*, the maximum incubation period is 19 days. However, this would not justify increasing it to 21 days as requested by a Member Country. The Commission indicated that for the purpose of the *Terrestrial Code* chapter, the 15-day incubation period was endorsed by the *ad hoc* Group and adopted by the Member Countries.

However, the Commission suggested a revision of this point by the Biological Standard Commission.

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

The Commission concurred with a Member Country's opinion on the responsibility of the Veterinary Authority to have up-to-date knowledge of the species of African wild suids present in the country or zone, in addition to other wild and feral pigs. However, the Commission questioned the need to distinguish three categories in the chapter, as African wild pigs should be included under the term "wild pigs".

The Commission also considered a proposal that each time *Ornithodoros* ticks are mentioned the chapter in, it should specify that "unless surveillance has been undertaken to demonstrate that there is no evidence of tick involvement in the epidemiology of the infection", and recommended adding the words "where relevant" to include areas where tick surveillance demonstrated no evidence of the presence of *Ornithodoros* in the area or where ticks are known not to play a role in the disease transmission.

The Commission noted the contradictory comments made by several Member Countries with regard to the safety of commodities from domestic pigs to be traded from countries or zones where ASF virus (ASFV) is present in wild or feral pigs. The Commission confirmed its previous opinion on the safety of those commodities should they be traded in accordance with the provisions of the chapter.

Article 15.1.3. Country or zone free from ASF

The Commission agreed with a Member Country's comment on the need to consider the specific situation where the absence of *Ornithodoros* was demonstrated in the past, but not recently.

The Commission also clarified that once a feral pig is farmed, it should not be considered feral. The Commission did not support a Member Country's comment and did not propose any further change in this the Article.

Article 15.1.3.*bis* Compartment free from ASF

The Commission discussed the opinion of a Member Country that challenged the establishment of a compartment based on fencing. The Commission stressed that for the establishment of a compartment, it is necessary to evaluate the local epidemiological situation and geographical factors that influence the spread of the disease and to adopt adequate measures to ensure separation of the compartment from the adjacent animal population with different health status. Those measures may differ in areas where ticks play a role from those areas where ticks are not involved in the epidemiology of ASF.

The Commission also pointed out that it would not be adequate to compare *Ornithodoros* with flying vectors, as ticks have a low mobility[1],[2] and can be effectively controlled. *Stomoxys* or other flying vectors have not been demonstrated to play an epidemiological role in the spread of ASF, besides the experimental study quoted for *Stomoxys*. With reference to the Mellor's study[3], the Commission emphasised that experimental conditions may not always represent the real field conditions.

In addition, in some European countries, fencing had proven to be efficient in controlling ASF[4]. Double-fencing and tick control had been used successfully for years in several southern African countries[5].

The Commission concluded that, in contrary to other vector-borne diseases, ASF could be successfully prevented in compartments due to the low mobility of *Ornithodoros*. The Commission did not propose any change in this draft Article.

Article 15.1.4: Recovery of free status

In response to a Member Country's request for clarification as to why compartments had been removed from the first paragraph, the Commission clarified that should ASF occur in a compartment, this would indicate a breach in the biosecurity and therefore the compartment would have to go through the requirements of Article 15.1.3.bis to demonstrate freedom.

The Commission supported the proposal made by a Member Country to specify that the use of sentinel pigs would only be appropriate in regions where ticks are involved in the epidemiology of the disease. However, the Commission reiterated that acaricide treatment was ineffective and referred to the ASF *ad hoc* Group report of June 2014. The Commission amended the text accordingly.

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

The Commission did not support the proposal to keep the animals for export separated from newly introduced animals. Those new introductions should follow the requirements of the *Terrestrial Code* and therefore, they should be considered safe having the same status as those animals that were already on the premises.

Article 15.1.9: Recommendations for importation from countries or zones not free from ASF – for semen of domestic and captive wild pigs

In response to the references provided on the experimental infection of a female boar with ASF using frozen sperm, the Commission referred to the rationale given at its previous meeting in February 2016.

Article 15.1.10: Recommendations for importation from ASF free countries, zones or compartments – for *in vivo* derived embryos of domestic pigs

In accordance with the recommendations of the *ad hoc* Group on Classical Swine Fever (CSF), the Commission agreed to amend this article for consistency with other chapters of the *Terrestrial Code*.

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1 Oleaga *et al.*, (1990). Relationships between the defensive systems if Iberian-breed swine and the European vector of African swine fever, *Ornithodoros erraticus*, *J. Parasitol*., **76**, 874–880. – describes that these ticks were relatively immobile and are likely to starve before locating alternative hosts.

2 *EFSA Journal* (2015). **13**(7), 4163.

3 Mellor *et al*., (1987). *Res. Vet. Sci.*, **43**, 109–112.

4 Arias *et al.*, (2002). African swine fever eradication: the Spanish model. *In*: Trends in Emerging Viral Infections of Swine, Morrila A., Jin K. & Zimmerman J., eds, 133–139. Iowa State University Press, Iowa – describes where the disease was controlled in Spain by fencing the infected premises.

5 Penrith M.-L., Thomson G.R. & Bastos A.D.S. (2004a). African swine fever. *In* Infectious Diseases of Livestock, J.A.W. Coetzer & R.C. Tustin, eds. Oxford University Press, Cape Town.

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

The Commission did not support the proposal to conduct *ante-mortem* inspections in addition to *post-mortem* inspections of wild and feral pigs as such inspections were considered impractical.

In response to a Member Country's request to re-introduce the paragraph on the requirement for testing of meat from wild pigs, the Commission agreed and suggested reverting to the original text.

Article 15.1.17. Recommendations for the importation of litter and manure from pigs

The Commission considered the opinion of a Member Country with regard to the trade in litter and manure.

The Commission considered that the trade of these commodities was frequent and it posed a risk for transmission of ASF.

The Commission agreed that the trade of these commodities poses a high risk, but disagreed with the Member Country's opinion that having specific provisions for safe trade could be seen as promoting their international trade. In fact it should be seen as a promotion of safe trade and therefore in line with good international practice.

In addition it was noted that this Article was also included in the adopted Chapter 15.2. on CSF.

Article 15.1.17bis. Recommendations for the importation of skins and trophies from suids

The Commission did not support a Member Country's proposal to only keep provisions for the importation of skins and trophies from countries historically free or with freedom in all suid populations. The Commission indicated that trade of skins and trophies was frequently practised in Africa and should be considered in the Chapter.

Article 15.1.23

The Commission agreed with a Member Country's comment and highlighted that surveillance aimed at detecting disease and infection should include all suid populations within the country or zone.

Rationale for the amendments to:

Chapter 15.X. PORCINE REPRODUCTIVE AND RESPIRATORY SYNDROME provided by the Scientific Commission

Article 15.X 1. General provisions

In response to a Member Country that expressed its disagreement with the exclusion of porcine reproductive and respiratory syndrome virus (PRRSV) infection in wild and feral pigs from the provisions of this chapter, the Commission referred to a scientific article[1] where it is stated that: "PRRSV transmission would be favoured within dense wild boar populations, but the lack of infection in many of these animal groups suggests that the initial transmission from wild boar to domestic swine does not occur, or occurs very sporadically. The transmission of PRRSV from domestic swine to wild boar is considered more likely than vice-versa. Current knowledge offers no evidence that the wild boars can act as PRRSV reservoir."

The Commission reiterated that the distinction of susceptible animals for the purpose of the chapter was based on their management system and it was consistent with other pig disease chapters (i.e. African swine fever, classical swine fever).

In response to a Member Country's comments, the Commission pointed out that modified live vaccines, which can potentially spread the disease, were only used in the event of an outbreak with the aim of controlling the outbreak. Hence, they should not be included in the definition of an infection with PRRSV. Similarly, the replacement of sows is normally carried out in the acclimatisation of an infected holding. The Commission stressed that this section was aimed at defining an infection with PRRSV and not at listing the control measures that could be applied to manage an outbreak.

With regard to the infective period, the Commission noted that this information was usually included in the *Terrestrial Manual* and not in the *Terrestrial Code* and suggested deleting it from the *Terrestrial Code* chapter for consistency.

Article 15.X.3. Country, zone or compartment free from PRRS

With reference to a Member Country's proposal to specify that the disease should be notifiable for at least 12 months, the Commission considered that it was never requested in other chapters of the *Terrestrial Code* and therefore did not support this suggestion.

In response to a Member Country's proposal to include a provision for the recognition of historical freedom from PRRS, the Commission highlighted that one of the requirements to declare a country or a zone free from disease or infection without pathogen-specific surveillance was that "*the disease agents to which these provisions apply, are likely to produce identifiable clinical signs in susceptible animals*" (Point 1 of Article 1.4.6. of the *Terrestrial Code*). Hence, considering the clinical manifestation of PPRS, it would not qualify for historical freedom.

With reference to a suggestion to have a similar waiting period after the use of inactivated and modified live vaccine, the Commission pointed out that the modified live vaccine has the potential to spread the disease and was only used for outbreak control purposes. The Commission considered that 2 years should elapse since the last vaccination with modified live vaccines before being eligible for PRRS freedom.

[1] Ruiz-Fons F. (2008). A review of viral diseases of the European wild boar: Effects of population dynamics and reservoir role. *Vet. J.*, **176**, 158–169.

Article 15.X.6. Recommendations for importation from countries or zones not free from PRRS – For domestic and captive wild pigs for breeding or rearing

In response to a Member Country's comment, the Commission was of the opinion that isolation in a *quarantine station* should not replace the requirements of point 1) of this Article.

The Commission was of the opinion that conducting a serological test within 10 days prior to shipment would provide sufficient guarantees. Therefore, it would not be necessary to use the RT-PCR test. This rationale is valid also in other articles for which a similar comment was received.

Article 15.X.7. Recommendations for importation from countries or zones not free from PRRS – For domestic and captive wild pigs for slaughter

In response to a Member Country's comment, the Commission emphasised that foot and mouth disease and CSF requirements could not be used as a template for all diseases. PRRS has a different epidemiology and a different impact. The provisions of the PRRS chapter were tailored to the specificities of the disease.

Article 15.X.9. Recommendations for importation from countries or zones not free from PRRS – For semen of domestic and captive wild pigs

The Commission considered that a serological test prior to and 21 days after entry into the pre-entry isolation facility would provide enough assurance that the semen was safe. Therefore, it did not recommend to undertake a virological test.

The Commission discussed in-depth the provision to ensure the safety of semen and referred back to the rationale and text proposed during its September 2015 meeting. The Commission noted that polymerase chain reaction has higher sensitivity for the detection of PRRSV in the donor serum than in semen. The Commission therefore maintained the deletion of the previous point ii).

Article 15.X.12. Recommendations for importation of fresh meat of domestic and captive wild pigs

The Commission would consider fresh meat as a safe commodity and suggested the deletion of this Article.

Annex 7

Original: English
March 2016

MEETING OF THE OIE *AD HOC* GROUP ON VACCINATION

Paris, 29-31 March 2016

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A meeting of the OIE *ad hoc* Group on vaccination (hereafter the Group) was held at the OIE Headquarters from 29-31 March 2016.

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

On behalf of Dr Monique Eloit, OIE Director General, Dr Elisabeth Erlacher-Vindel, Deputy Head of the Scientific and Technical Department, welcomed the Group. She highlighted the importance of this draft chapter that was expected by OIE Member Countries. She emphasised that the participation of representatives from the three Specialist Commissions would bring different angles to the discussions to ensure consistency with what was already covered in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)* and in the *Terrestrial Animal Health Code (Terrestrial Code)*.

The Group was chaired by Dr Cristobal Zepeda. Dr Francisco Reviriego acted as rapporteur with the support of the OIE Secretariat. The Group endorsed the proposed agenda. The agenda and list of participants are presented as Appendices I and II, respectively.

2. Revision of previous draft chapter

The Group considered the recommendations made by the Specialist Commissions during their February 2016 meeting and reviewed the articles drafted during the Group's November 2015 meeting. The draft chapter was restructured and split in more articles to be aligned with established format of the *Terrestrial Code*. Other revisions were proposed as follows:

Article 4.X.1. Introduction and objectives

The Group clarified that vaccine should induce immunity, not only to prevent the occurrence of clinical signs, but also to reduce multiplication and shedding of pathogenic agent.

After further consideration of the definition of 'vaccination' in the Glossary of the *Terrestrial Code*, the Group revised the definition of 'vaccination coverage' to specify that it refers to animals to which the vaccine has been administered rather than animals effectively immunised.

The Group also modified the definition of 'emergency vaccination' to include the use of vaccination in response to a change in the risk of introduction or emergence of a disease.

Article 4.X.3. Vaccination programmes

Following the recommendation of the Terrestrial Animal Health Standard Commission, this draft article was split in three articles for ease of reference. The articles on vaccination programme, launching a vaccination programme and vaccination strategies were created.

The Group included a reference to the importance of the harmonisation of regional vaccination harmonisation among neighbouring countries.

Article 4.X.4. Launching a vaccination programme

The criteria to be considered when deciding whether or not to initiate vaccination, were revised and completed. The Group agreed to have a list as exhaustive as possible of those critical elements and reshuffled the whole set of criteria for better coherence. Some elements such as the risk of introduction or emergence of a disease, the probability and consequences of exposure to diseases of specific subpopulation of susceptible animals, the suitability of vaccination as an alternative to or to complement other disease control measures and the impact on trade were included in the list.

Article 4.X.6. Critical elements of a vaccination programme

The Group adjusted the critical elements of a vaccination programme identified in its previous meeting.

- Target animals, retitled as target population

The Group made clear that the target population should be estimated and updated regularly.

In addition, the Group agreed that the target population could include wildlife when relevant.

- Vaccination coverage

Considering the importance to define in advance the minimum vaccination coverage necessary to reach the objectives of the programme, the Group developed a dedicated section.

- Stakeholder involvement

The Group identified the acceptance of the use of vaccines by the stakeholders as a critical element for the success of the vaccination programme. While acknowledging that private sector veterinarians, non-governmental organisations and para-professionals were covered by the definition of Veterinary Services, the Group proposed to specifically clarify that they should be involved in the vaccination programme.

- Auditing of the vaccination campaigns

The Group clarified that this section, previously titled "Quality assurance", was referring to the vaccination campaigns and not to the vaccine production quality assurance which was already covered in the *Terrestrial Manual*.

The Group listed the most relevant performance indicators to be considered when auditing a vaccination campaign.

- Exit strategy

The Group agreed that the provisions for the exit strategy, initially included in this article, justify a single article, placed after the article related to the evaluation and monitoring of the vaccination strategy.

Article 4.X.7. Choice of vaccine:

This section initially under the critical elements was moved to a dedicated article.

The Group emphasised that the selected vaccine should be compliant with the *Terrestrial Manual*, and that the countries should consider the criteria listed in this article to select the most appropriate one among all eligible vaccines.

The Group considered the transmissibility of live-attenuated vaccine strains as important criteria for the choice of the vaccine. However, the Group was unclear if this issue should be included in this chapter or if it was already sufficiently covered in the *Terrestrial Manual.* The same considerations were made for aspects related to the "purity", "contamination" and "release and spread of extraneous agents". The Group referred the decision to include these aspects in the draft chapter to the Biological Standard Commission.

3. Finalising drafting the chapter on vaccination based on the outline validated by the Specialist Commissions

The Group continued with the elaboration of the provisions to be considered when designing and implementing a vaccination programme based on the modified chapter outline.

Article 4.X.8. Logistics of vaccination

The Group highlighted the importance to plan a vaccination campaign in advance and mentioned that the specificities of emergency vaccination should be part of the national disease contingency plan. When drafting this section, the Group made reference to a number of existing documents, in particular to the OIE *Guidelines for animal disease control*[1], and its section 7 on Emergency Preparedness and Contingency Planning, to the OIE *Communication Handbook for Veterinary Services*[2] and to the possible establishment of vaccine banks in compliance with Chapter 1.1.10. of the *Terrestrial Manual*.

The Group listed the logistical elements that should be considered in a given vaccination programme, including procurement of vaccine, implementation of the vaccination programme, human resources, public awareness and communication, animal identification, record keeping and vaccination certificates, and additional animal health-related activities.

Article 4.X.9. Evaluation and monitoring of a vaccination programme

The Group agreed that any given vaccination programme should have an evaluation and monitoring component and drafted a specific article for it. This section would include the evaluation and monitoring of key aspects of the vaccination programme, including post-vaccination monitoring.

The Group noted that FAO and the OIE were about to jointly publish Guidelines on post-vaccination monitoring.

Article 4.X.10. Exit strategy of a vaccination programme

While acknowledging that it may not concern all vaccination programmes (Anthrax may be an example of a permanent one), the Group stated that the majority of the vaccination programmes may need to include a plan for cessation of vaccination and listed the possible reasons to cease vaccination. In addition to the achievement of the objectives of the programme, the Group considered that vaccination may need to be ceased in case the programme is unable to meet the desired objectives due to the failure of the programme itself in such a way that would not allow its re-design, lack of resources or adverse public reaction.

The Group stressed that the cessation of vaccination should be compulsory when the achievement of disease freedom without vaccination is expected. The Group discussed the importance of dealing with remaining vaccine stocks in the country.

Finally, the Group emphasised the need of a thorough revision of the biosecurity plan and the surveillance strategies for early disease detection before ceasing vaccination.

Article 4.X.11. Impact on disease status and management of vaccinated animals

The Group took into account some elements from the OIE Global Conference on Vaccination (Buenos Aires 2004).

Recognising the possible impact of vaccination on the detection of infection, surveillance, movement control and trade, the Group drafted this article to emphasise the need for countries implementing a vaccination programme to consider the management of vaccinated animals. The Group was aware that the Scientific Commission and the *ad hoc* Group on FMD were working on these topics and that this article may need to be revised in the future. Reference was made to disease-specific chapters of the *Terrestrial Code*.

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1 Guidelines for animal disease control, [30/03/2016]: http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/A_Guidelines_for_Animal_Disease_Control_final.pdf

2 Communication Handbook for Veterinary Services, developed for hands-on trainings, [30/03/2016] www.oie.int/communication_handbook

In addition, the Group was of the opinion that, unless specified in disease-specific chapters, the use of systematic or emergency vaccination in response to a threat should not affect the disease status or disrupt trade. The Group also recalled that Member Countries having an OIE officially recognised disease free status should inform the OIE of any change in the vaccination policy.

4. Adoption of the report

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

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…/Appendices

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON VACCINATION

Paris, 29-31 March 2016

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Agenda

1. Opening, adoption of agenda and appointment of chairperson and rapporteur
2. Revision of previous draft chapter
3. Finalising drafting the chapter on vaccination based on the outline validated by the Specialist Commissions
4. Adoption of the report

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Appendix II

MEETING OF THE OIE AD HOC GROUP ON VACCINATION

Paris, 29-31 March 2016

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List of participants

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Annex 8

Rationale for the amendments to:

Chapter 8.8. INFECTION WITH FOOT AND MOUTH DISEASE provided by the Scientific Commission

Article 8.8.2.: Country or zone free from FMD where vaccination is not practised

The Commission welcomed the modifications that took into consideration the consequences of a small group of potentially infected wild African buffaloes entering a country or zone free from foot and mouth disease (FMD). The Commission further modified the text proposed by the *ad hoc* Group to clarify that, in practise, not all stray African buffaloes could be isolated or removed and tested. However, it pointed out that should the African buffaloes be captured or killed, they should be appropriately tested.

Article 8.8.4.bis.: Compartment free from FMD where vaccination is practised

The Commission supported the proposed Article and noted that its inclusion in the chapter would require adjustments in the Articles throughout the chapter on the recommendations for importation of animals and commodities.

Article 8.8.6.: Establishment of a containment zone within a FMD free country or zone free from FMD

The Commission supported the new concept of an additional larger containment zone where outbreaks continue to occur. This new containment zone would be an additional possibility to the current concept of a containment zone. The Commission was of the opinion that both types of containment zones should be available to fit Member Countries' needs. The Commission amended the Article accordingly and suggested two different timelines for the validity of the containment zone.

Article 8.8.6.bis.: Establishment of a temporary preventive zone within a country or zone free from FMD

The Commission acknowledged the proposal from the *ad hoc* Group to allow an FMD free country or zone facing an identified and increased risk of FMD incursion to establish a temporary preventive zone in which additional control measures would be applied (which may also include vaccination) and would allow the rest of the country or zone to maintain its free status in case of FMD virus (FMDV) incursion in the temporary preventive zone.

The Commission clarified that the Veterinary Authority should submit an application to the OIE to be considered for approval by the Commission, similarly to the procedure for the establishment of a containment zone.

With regard to the status of the new temporary zone, the Commission was of the opinion that if vaccination was not part of the enhanced control measures, the temporary preventive zone would retain its free status. However, the FMD free status without vaccination of the zone would be suspended should vaccination be implemented. In this scenario, the temporary preventive zone could only gain the status of free where vaccination is practised 6 months after the implementation of the vaccination following the new provisions of Article 8.8.7. (Point 5), provided that surveillance is applied in accordance with Article 8.8.40 to 8.8.42.

The Commission extensively discussed the consequences of the implementation of the temporary preventive zone and agreed that it should be considered as a temporary measure. Therefore, it should be lifted within 12 months of its approval. Should the Member Country want to maintain the temporary preventive zone as a separate zone, an application for an FMD free zone would have to be sent to the OIE in accordance with Articles 8.8.2 or 8.8.3.

The Commission recommended that should the concepts be adopted, a specific Resolution should be presented to the World Assembly of Delegates to expand the Commission's mandate to recognise the establishment of the temporary preventive zone.

Article 8.8.7.: Recovery of free status

The Commission recommended that an *ad hoc* Group be convened to explore and develop other tools that may allow the introduction of more flexibility in the waiting period for recovery of free status.

This Article was amended to provide recommendations for the recovery of free status where vaccination is practised in the case of the creation of a temporary preventive zone.

Article 8.8.11.: Recommendations for importation from countries or zones free from FMD where vaccination is practised

The Commission restructured the Article to accommodate the different requirements for animals vaccinated or non-vaccinated destined for a country or zone with or without vaccination with relevant requirements for each.

Article 8.8.22.bis.: Recommendations for importation from countries or zones infected with FMDV, where an official control programme exists

The Commission did not extend the species considered under this Article to sheep and goats as absence of FMD in these animals cannot be demonstrated solely based on clinical inspection.

Article 8.8.42.: The use and interpretation of serological tests

The Commission recommended that the Biological Standard Commission consider the inclusion of Figure 3 *Schematic representation of laboratory tests for determining evidence of infection with FMDV by means of serological surveys* in the *Terrestrial Manual*.

Annex 9

Original: English
June 2016

MEETING OF THE OIE AD HOC GROUP ON FOOT AND MOUTH DISEASE

Paris, 14-16 June 2016

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A meeting of the OIE *ad hoc* Group on Foot and Mouth Disease (FMD) (hereafter the Group) was held at the OIE Headquarters from 14 to 16 June 2016.

1. Opening

On behalf of Dr Monique Eloit, Director General of the OIE, Dr Brian Evans, the Deputy Director General for Animal Health, Veterinary Public Health, International Standards, welcomed and thanked the Group for its commitment and its extensive support towards the OIE in fulfilling the mandates given by Member Countries. He extended his appreciation to the institutions that kindly allowed the experts to participate in the meeting.

Dr Evans highlighted that the OIE 6th Strategic Plan underpinned the importance of maintaining scientific excellence as the foundation of the OIE international standards setting procedure to preserve international credibility. He reminded the link between OIE standards and the World Trade Organization (WTO). He emphasised that until now the procedure and quality of the standards have been reinforced by WTO but that this should not preclude the OIE to continuously adapt its international standards to the new scientific findings.

Dr Evans reminded the experts that they had been selected based on their scientific expertise and were not representing their own countries or institutions. All experts were also asked to identify any potential conflict of interest that could influence their opinion. He clarified that the Group would work under Chatham House rule, hence, the opinion would be attributed to the Group and not to the individual expert. He also indicated that the OIE would continue to append the reports of the *ad hoc* Groups to the Specialist Commission report but would also provide a direct access to ease reference and communication.

Finally Dr Evans announced that a representative of the Scientific Commission for Animal Diseases and of the Terrestrial Animal Health Standards Commission would also participate in the meeting to support the Group discussion and to guide the experts in the completion of the term of references.

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

The Group was chaired by Dr Alf Füssel. Dr Ben Du Plessis acted as rapporteur, with the support of the OIE Secretariat. The Group endorsed the proposed agenda.

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

3. Review of the comments received from Member Countries on Chapter 8.8. on foot and mouth disease of the *Terrestrial Animal Health Code*

The Groups was reminded that Chapter 8.8. had been last adopted after revision in May 2015, with the commitment that the OIE would address the remaining comments. In addition, the draft article offering provisions for FMD free compartment where vaccination is practised (Article 8.8.4. bis) was specifically circulated for Member Countries' comments in February 2016. The Group was tasked to address the scientific comments received.

Article 8.8.1.:

In response to a Member Country's comments on the case definition, the Group acknowledged that other species are also susceptible to FMDV but considered the very low probability that FMDV be isolated from one of those species without or before being identified in one of the species listed in Point 2 of Article 8.8.1. The Group pointed out that in the hypothetical case of finding evidence of FMDV infection in species other than those included in the case definition, it would only be notifiable to the OIE on a voluntary basis. However, that finding should be appropriately investigated to rule out infection in the species included in Point 2 of Article 8.8.1. With reference to the possible epidemiological significance of infection in different species under different circumstances, the Group noted that, unlike the possible rare occurrence of FMD in animals of very low susceptibility, carriers were a common outcome of infection of ruminants and that such animals are kept in close contact with other susceptible animals justifying their different consideration in the chapter.

Article 8.8.4. bis: Compartment free from FMD where vaccination is practised

The Group considered Member Countries' comments on the proposed article 8.8.4.bis which included provisions for surveillance and biosecurity measures to ensure early detection of FMDV incursion or to demonstrate absence of infection in a compartment where vaccination is practised.

The Group pointed out that the concept of allowing vaccination in a compartment followed a similar scientific rationale as the concept of a country or zone free with vaccination. In both cases, the strategy of vaccination was intended to contribute to Member Countries' efforts in controlling the disease whilst minimising the impact on trade.

The Group reiterated that the establishment of compartments was not included in the OIE procedure for official status recognition and that a compartment should be considered as a self-declaration that would support bilateral trade agreements and allow access to regional/international markets.

The early detection of FMDV incursion in a compartment with vaccination was considered to be feasible with the surveillance strategies already described in the chapter. The Group noted that several Member Countries proposed to use sentinel animals in the compartment, and pointed out that this possibility was already covered by the *Terrestrial Code*. In addition, the Group highlighted that the diagnostic techniques conducted prior to moving animals out of the compartment, as described in Article 8.8.11., would strengthen surveillance and provide additional assurance that the animals did not harbour FMDV and therefore, were safe for trade.

In addition, the Group recommended extending the scope of all the articles of this chapter referring to importation of animals and animal products from a country or zone free with vaccination, to include provisions for the importation of animals and animal products from a compartment free from FMD where vaccination is practised.

With regard to some Member Countries' comments concerning the requirement of absence of FMD outbreaks within a ten-kilometre distance from the compartment, the Group emphasised that, this distance is the minimum that would be required to minimise the risk of FMDV incursion into the compartment. The Group took into account peer-reviewed literature[1] and concurred that, under certain conditions, the distance may be reduced. However, the Group suggested maintaining the ten-kilometre provision as an appropriate risk mitigation measure to ensure the practicability of its implementation.

The Group agreed with the proposal of one Member Country to clarify that the absence of cases of FMD within a ten-kilometre radius of the compartment not only refers to the first approval of the compartment but also to the reinstatement in case of status suspension. The Group amended the draft article and Article 8.8.4. accordingly.

[1] J.W. Wilesmith, M.A. Stevenson, C.B. King, R.S. Morris, (2003). Spatio-temporal epidemiology of foot-and-mouth disease in two counties of Great Britain in 2001, *Preventive Veterinary Medicine*, **61**, 157–170.

Article 8.8.7.: Recovery of free status

The Group considered the proposal made by a Member Country to add a third path in the recovery of status for a country or zone previously free with vaccination by proposing a three-month waiting period in the absence of emergency vaccination. The Group pointed out that the six-month waiting period was established to ensure that appropriate surveillance was conducted to detect the presence of virus circulation in a vaccinated population and referred to Section 4.5 of this report where the recovery period was extensively discussed. The Group admitted that a three-month waiting period might be acceptable if all vaccinated ruminants, including those vaccinated during the routine vaccination, were adequately tested. However, the Group concluded that this approach was not practical.

Article 8.8.12.: Recommendations for importation from countries or zones infected with FMDV, where an official control programme exists

The Group disagreed with the proposal of modifying the time and the testing regime for the importation of ruminants and pigs from infected countries or zones where an official control programme exists. Considering the incubation period, the Group pointed out that 14 days after isolation may not be sufficient time for the development of antibodies in those animals isolated at the beginning of an incubation period that can itself be up to 14 days. Considering that the seroconversion measured in NSP tests in vaccinated animals can sometimes be delayed, the Group confirmed that retaining the provision for a 28-day period, associated with virological and serological tests, would ensure that the animals are not infected.

In addition, the Group reminded that a virological test was routinely required to ensure detection of FMDV early infection in animals that have not yet seroconverted. It was also reminded that virological tests are very important if a small group of animals is imported, as the NSP test at animal level may not be sensitive enough to detect infection.

Article 8.8.15. and Article 8.8.19.: Recommendations for importation of frozen semen and embryos from countries or zones free from FMD where vaccination is practised

The Group disagreed with the proposal of reducing the time before sampling the donors for importation of semen and *in vitro* produced embryos of cattle from countries or zones free from FMD where vaccination is practised. The Group emphasised that these animals were coming from a free country or zone and were subjected to increased surveillance. Following the same rationale than above for Article 8.8.12., the Group considered that 21 days (7 days for seroconversion after the end of the incubation period) as the earliest point in time after the collection of the germinal products would allow detection of antibodies to structural proteins (since this option provides for unvaccinated donors) in case of virus circulation.

Article 8.8.26.: Recommendations for importation from countries infected with FMDV

The Group concurred with a Member Country's suggestion to amend Article 8.8.26. by including a specific provision to ensure that necessary precautions were taken after processing blood-meal and meat-meal from FMD susceptible animals to avoid contact of the products with any potential source of FMDV. The Group amended the text accordingly.

Article 8.8.42.: The use and interpretation of serological tests

The Group reviewed the modification proposed by a Member Country on Article 8.8.42. with regard to the procedure to follow in case of positive test results and emphasised that the animals tested during the follow-up investigations must remain on the farm to ensure that the appropriate measures could be taken in case of confirmation.

The Group also discussed the flow-chart published by Paton et al (2014)[2] which included other factors that can influence the interpretation of the laboratory results such as the size of the outbreaks, sample size, clustering, etc. It recommended the Biological Standard Commission to consider this flow-chart when revising the *Terrestrial Manual* chapter on FMD.

[2] Paton D., Füssel A., Vosloo W., Dekkerd A., De Clercq K., (2014). The use of serosurveys following emergency vaccination, to recover the status of "foot-and-mouth disease free where vaccination is not practised". *Vaccine*, **32**, 7050–7056

4. Considerations regarding different concepts of *Terrestrial Animal Health Code* Chapter 8.8. on FMD

4.1. Revision of the containment zone concept

Following-up the discussion of another *ad hoc* Group in charge of FMD status recognition engaged at its December 2015 meeting, the Group reviewed the proposal made by some Member Countries to extend the concept of the containment zone. The amended concept would cover circumstances where outbreaks continue to occur within an infected zone as long as a protection zone, in which no outbreaks occurred, is established within and along the perimeters of a larger containment zone. However, the Group referred to the Scientific Commission and the Code Commission the decision to keep both concepts (small containment zone with no outbreaks anymore, and larger containment zone with outbreaks still occurring) included in the article or to modify the current by the proposed one.

The Group drafted the provisions that would be needed to establish a containment zone with outbreaks and emphasised the importance of implementing, on confirmation of the first detected case, control on movements of animals and commodities on a large enough scale to include an area at least as large as the eventual future containment zone.

The provisions described in the amended article should be implemented for at least 28 days to allow that supportive evidence be provided when requesting the OIE to approve the containment zone. Upon approval, the free status of the rest of the country or zone would be reinstated. While outbreaks could still occur in the infected area of the containment zone, should an outbreak occur in the protection zone, the status of the country or zone would be suspended.

The Group discussed the maximum time during which the containment zone should be allowed. While some experts reminded that this period had been fixed to 12 months for the current concept of a containment zone, some others considered that this may not be enough for the new concept of containment zone. The Group decided to harmonise the time limit for both alternatives of the containment zone and, in line with Article 8.8.7., proposed that 24 months since the initial suspension (day of the declaration of the first outbreak) be the maximum period that a containment zone could be in place, otherwise the status of the zone or country would be withdrawn.

The Group emphasised that the revised concept of containment zone would allow a country or zone to regain the status in part of its territory in a shorter period of time and would therefore limit the trade impact.

4.2. Condition for an FMD free country or zone without vaccination to conduct emergency vaccination in response to an increased risk of FMDV

The Group continued the discussion begun in December 2015 on the provisions for an FMD free country or zone without vaccination to conduct emergency vaccination in response to an increased risk of FMDV, based on a zoning approach. The current procedure, timing and consequences were discussed. Based on the current procedure, a country or zone recognised as free from FMD without vaccination would not be able to conduct vaccination, without losing its free status. In addition, dividing the country or zone to have a smaller vaccinated zone would require the submission of a new dossier to the OIE and further adoption by the OIE World Assembly of Delegates. Meanwhile, in case of an outbreak, the whole country or zone would lose its official disease status.

The Group concluded that a new concept of "preventive emergency zoning" should consider dividing an already recognised FMD free country or zone into two or more smaller zones with the aim of implementing enhanced control measures in at least one of them, to protect the status of the rest of the country or zone in response to an increased risk of virus incursion. While the mandate of the Group was specifically to discuss the situation of an FMD free country or zone without vaccination willing to conduct emergency vaccination in response to an increased risk of FMDV, the Group finally agreed that this concept should be extended to FMD free countries or zones, where vaccination is practised and that the enhanced control measures may or may not include vaccination. This strategy may also be applicable to other diseases and not only to FMD.

The Group considered existing concepts to define this new one and specifically considered the protection zone, the containment zone and the recovery of suspended status.

The Group acknowledged that a protection zone could be established at any moment by the country. However, for a free country or if the threat is adjacent to the free zone, the protection zone will have to be included in the country or in the free zone. Therefore, implementing emergency vaccination or having FMDV incursion in the protection zone would lead to the suspension of the status of the whole previously free country or zone.

The Group noted that the current concept of a containment zone could be adapted to the creation of such a 'temporary preventive zone' in an already free country or zone. The Group also considered the current mandate of the Scientific Commission to approve the establishment of a containment zone and the recovery of status of the rest of the country or zone, without further consultation of the World Assembly. However the Group did not agree that the suspension period (of at least two-incubation period) before the establishment of a containment zone should apply to the establishment of a 'temporary preventive zone', as no outbreaks would have occurred.

The Group agreed that, on the condition that the Scientific Commission is given the mandate to evaluate and endorse this procedure, a 'temporary preventive zone' could be established provided that:

- prompt actions have been taken in response to a new risk of FMD introduction into a country or zone.

- the country has provided the OIE with a precise description of the boundaries of the 'temporary preventive zone' with documented evidence to demonstrate the effective separation between the two subpopulations.

- the application also provides a description of the enhanced control measures conducted and to be conducted, the surveillance strategy to substantiate absence of infection or transmission, and when appropriate, a detailed description of the vaccination strategy and of the mechanism in place which allows to take prompt actions on any suspicion of FMD.

While agreeing that the FMD free status of the rest of the country or zone would be maintained, the Group explored the following different scenarios regarding the status of the 'temporary preventive zone':

a) If there is no change in the vaccination status, the 'temporary preventive zone' could retain its previous free status (with or without vaccination).

b) If vaccination is introduced in the 'temporary preventive zone' (that was previously part of a country or zone recognised as free from FMD without vaccination), the 'temporary preventive zone' could be considered as having a free status with vaccination after an appropriate period of suspension covering the time elapsed to develop immunity in the target vaccinated population (to meet the conditions described in point 3(c) and (d) of Article 8.8.3).

c) Alternatively, the status of the 'temporary preventive zone' would be suspended, whether vaccination is practised or not.

In all scenarios, the status of the free country or zone with the exclusion of the temporary preventive zone would be maintained whether outbreaks occurred or not in the temporary preventive zone. However, in the event of FMD occurrence (infection / transmission depending on the previous free status) in the free zone outside the 'temporary preventive zone', the approval of the 'temporary preventive zone' would be withdrawn and the FMD status of the whole country or zone would be suspended.

The 'temporary preventive zone' would need to be considered as a temporary measure in all scenarios. Should the country wish to have a permanent zoning, it should follow the usual procedure of zonal status recognition by submitting a dossier based on the provisions of Article 1.6.6. within 12 months of the approval in accordance with either Article 8.8.2 or with Article 8.8.3. Alternatively, the country could also request the OIE to lift the 'temporary preventive zone' and merge it back with the rest of the country or zone by providing documented evidence to demonstrate compliance with Point 3 of Article 8.8.7. In this case, the Scientific Commission would evaluate the dossier and, if favourable, the whole country or zone would recover the free status.

The Group extensively discussed the epidemiological grounds and the trade implications of the new concept and whether or not the official status of the 'temporary preventive zone' should be maintained or re-granted (Scenarios a) and b) above). Maintaining or re-granting a free status as long as no outbreaks occur in the 'temporary preventive zone' would imply allowing trade in accordance with the provisions of an FMD free zone. The Group emphasised that the 'temporary preventive zone' may never report outbreaks. However, the Group acknowledged that currently, only the World Assembly had the mandate to recognise official status in countries or zones. The Group also considered the link between official status recognition and the World Trade Organization.

Considering that the Scientific Commission currently has the mandate to approve containment zones, the Group concluded that it should also be given the authority to approve the temporary preventive zone if its status is suspended (scenario c). The Group drafted Article 8.8.X. considering the scenario when the status of the 'temporary preventive zone' would be suspended (scenario c).

However, the Group requested the OIE to explore the possibility to expand the Scientific Commission's mandate to further recognise the free status of the 'temporary preventive zone' (scenarios a and b) and its legal implications for the dispute settlement mechanism of the WTO.

The Group finally discussed whether one or more 'temporary preventive zones' could be established and recognised that a large country may face different threats that would justify the establishment of 'several temporary preventive zones'.

4.3. Condition for an FMD free country or zone without vaccination to conduct routine vaccination and revert to a status free with vaccination

The Group discussed the epidemiological implications of initiating vaccination in a country or zone free without vaccination. The Group agreed that this should be a possibility but the status should be reverted only when approved by the OIE. The Group emphasised that should the vaccination start before approval of the new status, the status would be suspended and could be regained in accordance with Point 2 of Article 8.8.7.

The Group considered that a Member Country willing to request the modification of its status should provide a plan following the structure of the Questionnaire of Chapter 1.6. for freedom with vaccination, for assessment by the Scientific Commission and official recognition by the World Assembly.

After official recognition, vaccination could begin in the country or zone and the country would be given 6 months to prove that the country or zone fully complies with Article 8.8.3. (this would coincide with the time by which the annual reconfirmation of official status is due). If the country or zone would not comply with those requirements, the status would be withdrawn.

The Group amended Article 8.8.3. accordingly.

4.4. Risk of introducing vaccinated animals into a FMD free country or zone without vaccination, including for direct slaughter

The Group acknowledged that movement of vaccinated animals was a request frequently made by Member Countries having zones with different status as regards the use of vaccines to allow movement within the country. Those requests have partly be motivated by the accepted presence of a large number of vaccinated animals in case a country or zone makes the transition from a vaccination regime to the status of free without vaccination.

The Group agreed that the risk of FMDV transmission through vaccinated animals from a free zone or country with vaccination was very low and could be mitigated by appropriate provisions. However, the Group also considered that having a vaccinated population in a free country without vaccination would influence the surveillance strategy to be conducted to substantiate absence of disease.

Recognising the low risk of FMDV transmission of vaccinated animals, the Group amended Article 8.8.2. to allow the importation of vaccinated animals to a free country or zone where vaccination is not practised without jeopardising their disease status provided that these imports are compliant with the revised provisions of the chapter, as follows:

- Article 8.8.11 was amended to include recommendations for importing vaccinated animals from an FMD free country or zone where vaccination is practised to FMD free countries where vaccination is not practised. The Group concluded that including provisions for isolation, testing and identification of vaccinated animals would guarantee that subclinically infected animals would not be imported. In addition, identification of vaccinated animals would ease future FMD surveillance.

- The Group also acknowledged the need of drafting provisions for international trade in vaccinated animals for direct slaughter into a free country or zone. Article 8.8.9.bis and Article 8.8.9.ter were drafted, including the requirements for producing an international veterinary certificate and the fate of the heads, pharynxes, tongues and associated lymph nodes of vaccinated ruminants. The Group was unsure of the structure and denomination to be used in these two new articles, and whether they should follow the template of Article 8.8.8. or of Article 8.8.10. The Group suggested that, when revising the chapter, the Code Commission consider this question taking into account that the concept was to allow international trade, as well as national movement between zones of different status,

4.5. Conditions for the movement of vaccinated animals for slaughter into a country or zone free without vaccination

See Section 4.4. of this report

4.6. Recovery of a previously recognised FMD free status without vaccination, after 3 months, using vaccination-to-live as eradication strategy

The Group discussed the difficulties of establishing a specific waiting period for recovery that fits all scenarios and in particular when vaccination-to-live was used as part of the eradication strategy.

The Group highlighted the challenges to demonstrate absence of subclinical infection in a vaccinated population, even when adequate high potency vaccines were used. The 6-month waiting period had been established to increase the sensitivity of the surveillance system to detect the presence of subclinical infection or carriers.

Ensuring safe trade of already vaccinated animals was considered even more relevant after the proposal to modify Article 8.8.2. to allow the introduction of vaccinated animals into a free country or zone without vaccination.

The Group amended point 1 c) of Article 8.8.7. accordingly.

The Group agreed that, under certain circumstances, with a robust surveillance system including a serological survey (in all vaccinated herds and all vaccinated ruminants and their non-vaccinated offspring, and a representative number of animals of other species), as well as adequate follow up of NSP-positive animals demonstrating effective vaccination, a shorter waiting period to recover the FMD free status without vaccination would be scientifically justified.

The Group recognised that the waiting period proposed on Article 8.8.7. would not fit to all scenarios and could probably be reduced in some specific situations where other tools such as risk-based surveillance, or other methodologies to quantify the probability of freedom may justify a shorter waiting-period. The Group suggested that the OIE convene a specific *ad hoc* Group to explore and develop those tools that may allow introducing flexibility in the waiting period for recovery.

4.7. Provisions for imports of fresh pig meat from infected countries or zones

The Group pointed out that pigs do not act as carriers and subclinical infection in pigs was not epidemiologically relevant. However, fresh meat from viraemic pigs or from pigs in the incubation period may pose a risk for FMDV transmission. Therefore, fresh pig meat should not be considered a safe commodity.

The Group also pointed out that the risk mitigation measures of maturation, deboning and removal of the lymph nodes in beef was not applicable to pork.

However, the Group agreed that meat from pigs that would comply with Article 8.8.12. (import of live pigs from an infected country or zone) would be safe for trade provided specific transport and slaughter conditions have been respected. The Group listed the specific sanitary conditions for the slaughter in previously approved slaughterhouses. The carcasses from those pigs would be considered safe for trade after a sufficient waiting period has elapsed to allow the Veterinary Authority to confirm that FMD was not incubating when the animals were moved out of the establishment of origin. The waiting period would not be necessary for pigs kept in a quarantine station.

The Group drafted Article 8.8.22.bis accordingly to provide recommendations for importation of fresh meat of pigs from countries or zones infected with FMD, where official control programme exists.

4.8. The wildlife-livestock interface (e.g. impact of finding infected buffalo in an FMD free country/zone with no transmission to domestic animals)

The Group considered other diseases for which, in compliance with the *Terrestrial Code*, the occurrence of outbreaks in wildlife would not affect the free status of the country. The Group clarified that this approach would not be appropriate for FMD, considering the airborne virus transmission, the difficulties to maintain effective separation between wildlife and domestic populations and the range of susceptible population that is farmed outdoors.

However, the Group discussed the specific role of African buffaloes in the epidemiology of FMD. Despite the low risk of virus transmission posed by a carrier African buffalo, according Article 8.8.1., the isolation of FMDV in an African buffalo should be considered as a case.

The Group did not feel that free countries or zones neighbouring areas with infected African buffaloes should be penalised in case of escape of a small group of potentially infected African buffaloes that would not readily transmit FMD to domestic population, provided that the Veterinary Authority takes appropriate measures to prevent the spread of the disease and provides documented evidence that a comprehensive investigation was conducted to rule out virus transmission.

The Group amended Articles 8.8.2. and 8.8.3. to include the conditions that a Member Country should maintain its FMD free status when detecting a small group of potentially infected wild African buffaloes in a free country or zone.

The Group recommended the revision of the structure/numbering of the last section of Articles 8.8.2. and 8.8.3. for ease of reference to the specific provisions.

5. Discussion about the differences in terminology of zones (zone/region, containment zone, free zone and infected zone) between the Glossary and its application for FMD zonal status (zones differentiating sub-populations of distinct health status)

Noting the term “distinct” health status in the Glossary definition of a zone, the Scientific Commission had asked this Group to consider whether this wording could be adapted to better fit with the practical application of the zoning concept.

The Group agreed on the fact that two distinct zones could have similar health status but they should have, at least, functional separation of the subpopulations between the zones. Similar reasoning should be applied to a compartment. The Group proposed a modification of the draft definition of zone and compartment.

The Group also amended the definition of a protection zone to clarify that a protection zone could be established within or outside a free zone or within a free country.

The Group suggested that Chapter 4.3. be revised to ensure alignment with the proposed definitions.

6. Current situation of FMDV serotype C, role of the OIE

The Group discussed the report[3] of the last meeting of the network of FAO/OIE Reference Laboratories for FMD and its conclusion related to FMDV serotype C, as well as Resolution III[4] of the 43rd Ordinary Meeting of the South American Commission for FMD Control (Comisión Sudamericana para la Lucha contra la Fiebre Aftosa - COSALFA).

The Group acknowledged the following:

- FMDV serotype C was last isolated in Kenya and Brazil in 2004. In Kenya, the strain was closely related (99.84%; 1 nt difference) to the Kenyan vaccine strain [5, 6];
- vaccination against serotype C is still ongoing in many countries;
- vaccine manufacturers and laboratories still have live FMDV serotype C;
- vaccine challenges, and other experiments, are often conducted with serotype C;
- some OIE Member Countries still report regularly the occurrence of serotype C in their countries to the OIE[7] but samples are not sent to an OIE/FAO Reference Laboratory for FMD for confirmation.

The Group noted that the network of FAO/OIE Reference Laboratories for FMD considered that the use of serotype C for vaccination and vaccine challenge represents a risk of virus escape and that recommendations should be made for these practices to be progressively stopped.

In addition, the Group encouraged the OIE to invite all Member Countries reporting the presence of serotype C to send their samples to an FAO/OIE Reference Laboratory for confirmation, which should make the relevant information available to the OIE/FAO FMD Reference Laboratory Network and possibly to the public. It was highlighted that budget should be found to support this initiative. The Group also mentioned the current twinning between the World Reference Laboratory for FMD (Pirbright, UK) and The National Animal Health Diagnostic and Investigation Center (NAHDIC) in Ethiopia that has been established to improve surveillance in East Africa.

7. Adoption of report

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

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…/Appendices

3 Summary report from the 10th OIE/FAO FMD Laboratory Network Meeting , Brussels, Belgium: 24th – 26th November 2015.

4 Resolución III DE LA 43ª Reunión Ordinaria de la Comisión Sudamericana para la Lucha contra la Fiebre Aftosa, Punta del Este, Uruguay, 7 y 8 de abril de 2016, Virus de Fiebre Aftosa serotipo "C".

5 Phylogenetic tree available at http://www.wrlfmd.org/fmd_genotyping/2005/WRLFMD-2005-00004-Kenya-C.pdf consulted on 16/06/2016

6 Report on the phylogenetic origins of FMDV isolates received by the FAO WRLFMD from Kenya in February 2005, Jean-Francois Valarcher, Nick Knowles, Nigel Ferris and David Paton, FAO World Reference Laboratory for FMD, IAH Pirbright, Woking, GU24 0NF, Surrey, UK.

7 World animal Health Information Database, WAHID, http://www.oie.int/wahis_2/public/wahid.php/Wahidhome/Home

Appendix I

MEETING OF THE OIE AD HOC GROUP ON FOOT AND MOUTH DISEASE

Paris, 14-16 June 2016

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Agenda

1. Opening
2. Adoption of the agenda and appointment of chairperson and rapporteur
3. Review of the comments received from Member Countries on Chapter 8.8. on foot and mouth disease of the *Terrestrial Animal Health Code*
4. Considerations regarding different concepts of *Terrestrial Animal Health Code* Chapter 8.8. on FMD
   a. possible revision of the containment zone concept
   b. condition for an FMD free country or zone without vaccination to conduct emergency vaccination in response to an increased risk of FMDV,
   c. condition for an FMD free country or zone without vaccination to conduct routine vaccination and revert to a status free with vaccination
   d. risk of introducing vaccinated animals in an FMD free country or zone without vaccination, including for direct slaughter
   e. recovery of a previously recognised FMD free status without vaccination, after 3 months, using vaccination-to-live as eradication strategy
   f. provisions for imports of pig meat from infected countries or zones
   g. the wildlife-livestock interface (e.g. impact of finding infected buffalo in an FMD free country/zone with no transmission to domestic animals)
5. Discussion about the differences in terminology of of zones (*zone/region*, *containment zone*, *free zone and infected zone*) between the Glossary and its application for FMD zonal status (zones differentiating sub-population of different health status)
6. Current situation of FMDV serotype C, role of the OIE
7. Adoption of report

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Appendix II

MEETING OF THE OIE AD HOC GROUP ON FOOT AND MOUTH DISEASE

Paris, 14-16 June 2016

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List of participants

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Annex 10

Original: English
June 2015

MEETING OF THE OIE *AD HOC* GROUP ON EQUINE TRYPANOSOMOSES

Paris, 14-16 June 2016

A meeting of the OIE *ad hoc* Group on (non-tsetse transmitted) equine trypanosomoses (hereafter the Group) was held at the OIE Headquarters from 14 to 16 June 2016.

1. Opening

On behalf of Dr Monique Eloit, Director General of the OIE, Dr Brian Evans, Deputy Director General and Head of the Scientific and Technical Department, welcomed and thanked the Group for its efforts in reviewing the *Terrestrial Animal Health Code* (hereafter the *Code*) chapter on dourine and draft *Code* chapter on surra.

Dr Evans reminded the Group that dourine and surra were both OIE listed diseases, however recommendations for trade in live susceptible animals and their products, were currently only provided in the *Code* for dourine. He informed the Group that OIE Member Countries had expressed their need for trade standards applicable to surra as well, especially in the context of the OIE initiative with the International Equestrian Federation (FEI) and the International Federation of Horseracing Authorities (IFHA) for the facilitation of international movement of competition horses.

Dr Evans informed the Group that a previous OIE *ad hoc* Group on equine trypanosomoses had been conveyed in 2015 to draft a *Code* Chapter on surra and revise the *Code* Chapter on dourine. The report of this *ad hoc* Group was not endorsed by the *Scientific Commission for Animal Diseases* (hereafter the Scientific Commission) nor discussed by the *Terrestrial Animal Health Standards Commission* (hereafter the Code Commission); a new *ad hoc* Group has therefore been conveyed to finalise this task.

Dr Evans emphasized that the proposed standards should be pragmatic, based on risk mitigating approaches and on the best available science. Lastly, Dr Evans insisted on the importance of a detailed meeting report highlighting the scientific justifications of the proposed texts, as meeting reports are the main channel to communicate the rationale of the proposed standards to the Scientific and Code Commissions and to OIE Member Countries.

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

In the absence of a member of the Group volunteering to chair the Group, Dr Baptiste Dungu, representative of the Scientific Commission, was exceptionally appointed as a Chair. Dr Charles E. Lewis acted as rapporteur. The Group adopted the proposed agenda.

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

3. Presentation of the comments of members of the Scientific Commission and Code Commission on the report of the previous *ad hoc* Group

Dr Dungu clarified that the work of the *ad hoc* Group on equine trypanosomoses that met in 2015 could be utilized by the Group as the reference document for discussion. He emphasised the need to further elaborate on it to fully meet Member Countries' expectations to resolve trade issues associated with equine trypanosomoses.

Dr Etienne Bonbon, President of the Code Commission, advised the Group to specifically concentrate on providing practical and science based guidance to Member Countries to manage surra and dourine, especially in the context of international trade.

4. Revision of the scope of the *Code* chapters

The Group extensively discussed the infections caused by trypanosomes in equids.

The Group reviewed the following article: Carnes J. *et al.* (2015) "Genome and phylogenetic analyses of Trypanosoma evansi revealed extensive similarity to *T. brucei* and multiple independent origins for dyskinetoplasty." *PLoS Negl Trop Dis.,* **9**(1): e3404 that describes that three out of the four known groups within the Trypanozoon subgenus cause the disease dourine. Unpublished data support that the Italian dourine outbreak was actually caused by a trypanosome very similar to *T. brucei* and *T. evansi* type B rather than *T. equiperdum*.

The group also reviewed the following articles: Claes Buscher *et al.* (2005) "*Trypanosoma equiperdum*: master of disguise or historical mistake?" *Trends in Parasitology*, **21**(7): 316-321 (a review with the proposal of a new definition for Dourine) and Zablotskij V.T., *et al*. (2003) "The current challenges of dourine: difficulties in differentiating *Trypanosoma equiperdum* within the subgenus Trypanozoon." *Rev. sci. tech. Off. int. epiz.,* **22**(3), 1087-1096.

Data from an unpublished project conducted by the United States Department of Agriculture (USDA) was also shared with the Group and discussed (unpublished report on the comparison of three reference isolates of *Trypanosoma equiperdum* in ponies).

The Group concluded that these studies converged in indicating that: (i) there is little genetic distinction between *T. evansi, T. equiperdum,* and *T. brucei,* (ii) clinical distinction of individual cases into surra or dourine is not possible, (iii) differential laboratory diagnostics of the infections are complex.

The Group therefore recommended combining the infection of equids with parasites of the subgenus Trypanozoon (*T. evansi, T. equiperdum, or T. brucei*) into a specific *Code* chapter. For consistency, the Group also noted that equids should be excluded from the draft *Code* chapter on infection with *T. evansi* (draft chapter 8.X). Under those provisions, Member Countries would report any infection with trypanosome in equids as an "infection with Trypanozoon in equids".

In brief, the Group determined that the best course of action was:

- To revise the current *Code* Chapter 12.3. on dourine to encompass all infections with Trypanozoon in equids;
- To dedicate the draft *Code* Chapter 8.X. to the infection of susceptible species other than horses with *T. evansi* (non-equine surra).

In drafting Chapter 8.X and revising Chapter 12.3, the Group routinely referred to the report from the *Meeting of the OIE Ad hoc Group on Equine Trypanosomoses – Paris, 21-23 July2015*.

5. Draft Chapter 8.X. (Infection with *Trypanosoma evansi* – non equine surra)

Discussions on individual articles were as follows:

– In **Article 8.X.1 (General Provisions),** the *Code* chapter drafted in 2015 mentioned that "*few human cases have been described*". The Group clarified that the rare occurrence of cases of human infection with *T. evansi* was associated with the lack of serum factors that would normally have destroyed the parasite in the serum (ApoL1 lytic factor). The Group agreed that the General Provisions should concentrate on the facts and evidence supporting the recommendations to mitigate the risk of spread of infection in animals, including thorough management of outbreaks and safe trade in live susceptible animals and their products. Therefore, while acknowledging that the possible occurrence of cases of human infection was relevant in a public health perspective, the Group decided not to mention it in Article 8.X.1, since measures to prevent human cases of that infection were out of the scope of the chapter.

The Group debated the incubation period for infection with *T. evansi*. Due to the wide range of susceptible hosts, the incubation period is highly variable. The Group eventually determined that the best course of action was to utilise the maximum timeframe of six months.

The *Code* chapter drafted in 2015 stated that *T. evansi* can survive for one to two days in stomoxes and 72 hours in infected meat. Based on scientific evidence[1], the Group recommended revising the duration of survival of the parasite in stomoxes to 72 hours. Regarding infected meat, the Group was unable to find specific references in regard to the survival of the parasite for up to 72 hours. However, it was decided to leave this statement as the Group could not justify its removal without further clarification. In addition, considering that carnivores can be contaminated through the contact of the oral mucosa with the parasite contained in ingested fresh meat from infected animals (cases of stray dogs scavenging on slaughterhouse waste), the Group recommended that standard processing practices should be complied with in order to mitigate the risk of transmission through this route -including the prevention of contact between animal by-products and carnivores-.

– The Group established the list of safe commodities in **Article 8.X.2 (Safe Commodities)** on the basis of current knowledge[2].

– **Article 8.X.3 (Country or *zone* free from infection with *T. evansi* in one or more animal species)** was reviewed and the Group decided to include the possibility for a country to claim freedom in specific animal species.

Regarding the conditions for freedom recognition, the Group discussed referencing the point a of Article 1.4.6.1 that specifically addresses historical freedom (i.e. last occurrence of the infection more than 25 years ago) or the whole Article 1.4.6.1 (i.e. including point b that provides requirements to be complied with for at least 10 years to declare a country or a zone free from disease or infection if cases have occurred within the last 25 years). The Group decided that reference should be made to the whole Article 1.4.6.1 since the provisions for historical freedom alone would not suffice.

Point 2 of Article 8.X.3 requires that a free country or zone, adjacent to an infected one, should conduct adequate surveillance in an area of appropriate distance from the bordering infected country or zone in order to detect any case of infection with *T. evansi*. The Group discussed what should constitute an "appropriate distance" and agreed that it should be deemed appropriate in regard to the specific location of the concerned countries or zones, taking into consideration numerous factors such as the vector ecology, the epidemiological situation, the geographic isolation, etc. The Group therefore recommended that this distance should be defined by the Member Country based on an assessment of the relevant local parameters.

– **Article 8.X.4 (Recovery of free status)** was extensively discussed and reformatted. This article gives the possibility to handle an outbreak situation either by applying a stamping out policy or by treating infected or serologically positive animals. The Group insisted that alternatively, if these conditions could not be complied with, the recovery of the free status may also be based on the conditions provided in Article 8.X.3.

The Group discussed the feasibility of a stamping out policy in the light of the definition approved by the Word Assembly during the 84th General Session in May 2016. This definition includes *"the cleansing and disinfection of establishments"*, however, it was unclear to the Group if the definition also includes disinsection/disinfestation as part of a stamping out policy. If the newly adopted definition does not account for this, the Group recommended that it should be incorporated.

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1 Baldacchino F. *et al. (2013)*.- Transmission of pathogens by Stomoxys flies (Diptera, Muscidae): a review. *Parasite*, **20**: 26.

2 Desquesnes M. *et al*. (2013).- *Trypanosoma evansi* and surra: a review and perspectives on transmission, epidemiology and control, impact, and zoonotic aspects. *BioMed research international*.
Campigotto G. *et al*. (2015).- Experimental infection by *Trypanosoma evansi* in sheep: Occurrence of transplacental transmission and mice infection by parasite present in the colostrum and milk of infected ewes. *Veterinary parasitology*, **212**(3): 123-129.

There was detailed discussion regarding the conditions for a country or a zone to claim freedom after an outbreak of infection with *T. evansi*, especially when the control of the outbreak is based on the treatment of infected or serologically positive animals (Point 2.a.ii of Article 8.X.4). Indeed, trypanocide treatment may not always be curative, therefore, the Group recommended that parasitological screening and clinical observation of treated animals should be conducted monthly for at least 6 months to identify any persistence or relapse.

The proposed timelines and conditions for the recovery of a free status when the control of the outbreak is based on stamping out policy as described in Point 2.a.i of Article 8.X.4 are represented in Figure 1. Those described in Point 2.a.ii of Article 8.X.4 for a control based on a trypanocide treatments are represented in Figure 2.

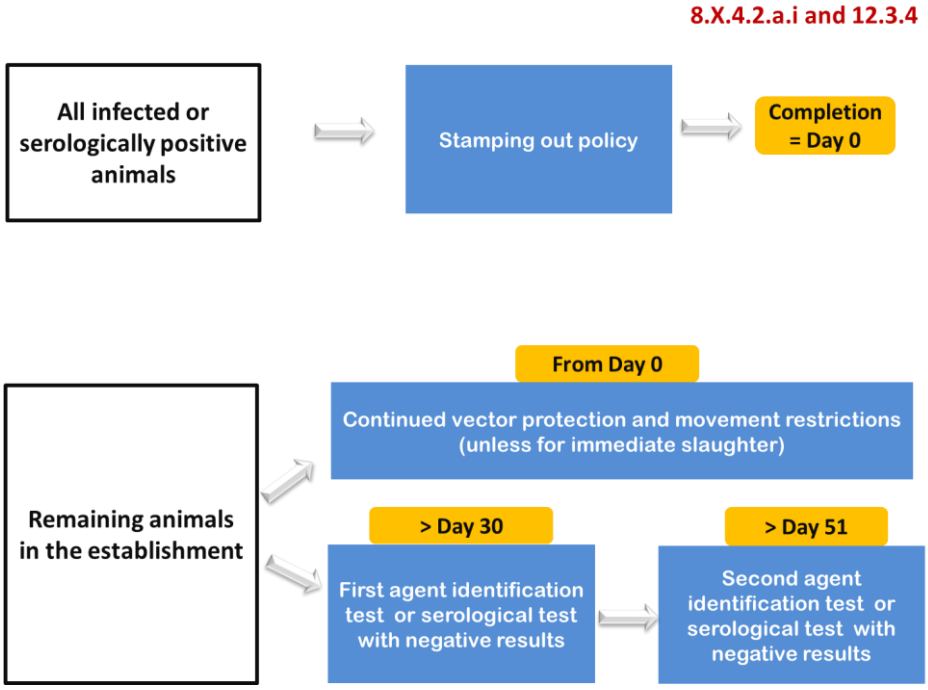

Figure 1. Recovery of a free status – Stamping out policy (Articles 8.X.4.2.a.i and 12.3.4)

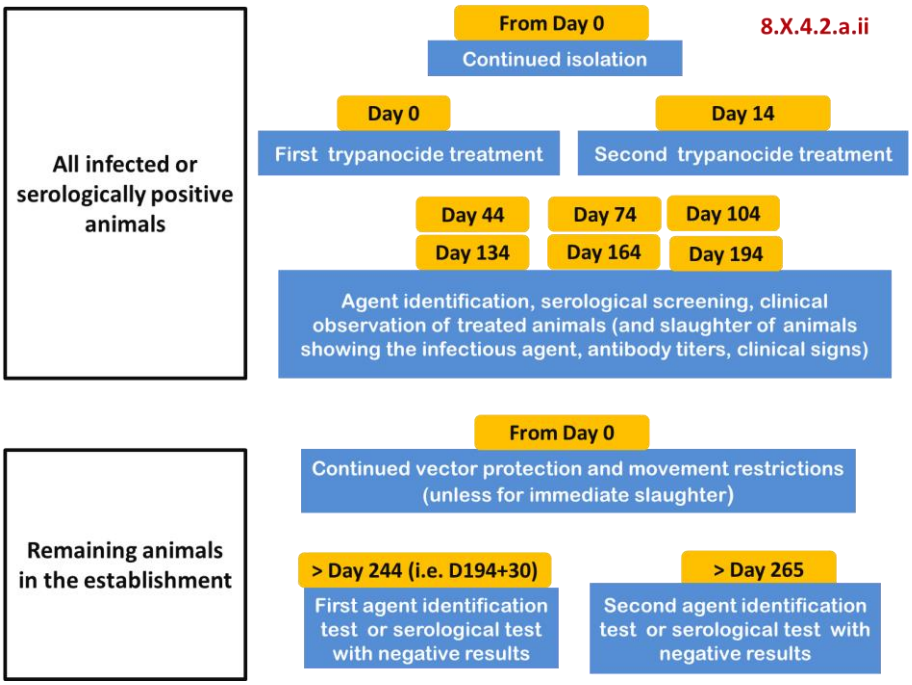

Figure 2. Recovery of a free status – Trypanocide treatment (Article 8.X.4.2.a.ii)

The Group agreed that after completion of the stamping out policy or the trypanocide treatment strategy, a specific surveillance for *T. evansi* should be conducted during a certain time period before the recovery of a free status can be declared (Point 3 of Article 8.X.4). The Group debated the duration of this surveillance period. The Group that met in 2015 recommended that it should be implemented for 2 years before the recovery of a free status (as stated in the *Meeting of the OIE Ad hoc Group on Equine Trypanosomoses – Paris, 21-23 July 2015)* or one year (as stated in the draft *Code* chapter annexed to this meeting report). Taking into consideration that the surveillance period would come in addition to the period during which the stamping out policy or the treatment strategy are applied (which would already take several months (i.e. about 2 months for a stamping out strategy and more than 8 months for a treatment strategy) and provide strong guarantees as to the status of the animal populations with regard to the infection with *T. evansi*) the Group determined that a surveillance period of six months would be acceptable for the purpose of this article.

- Since the Group had decided to include the possibility for a country or zone to claim freedom in specific animal species (see Article 8.X.3), **Article 8.X.5 (Recommendations for importation of camelids, carnivores, bovidae, pigs, cervids, elephants, lagomorphs, rodents and vampire bats)** was reorganized to include two sections: one for countries or zones free from infection in all host species (Point 2.a of Article 8.X.5) and one for countries or zones free in the imported species (Point 2.b of Article 8.X.5). To mitigate the risk of interspecific transmission, the Group agreed that animals imported from countries free in the imported species, but not in all other species should be isolated, protected against vectors and subjected to a diagnostic test prior to shipment. Animals imported from countries or zones not free in that specific species should be subjected to an additional test (two tests in total) (Point 2.c of Article 8.X.5).

- In regard to **Article 8.X.6 (Recommendations for importation of camelids, bovidae, pigs from an infected country or zone for direct slaughter**), the Group insisted on the notion of direct slaughter to mitigate the risk of transmission. The Group specified that the animals should be transported directly from the establishment of origin to the approved slaughterhouse/abattoir in a vector protected vehicle without coming into contact with other susceptible animals.

- **Article 8.X.7 (Recommendations for importation of semen)** was proposed as a novel article that the Group determined was necessary as there are reports of *T. evansi* present in the semen in rams.

  Again, since the Group had decided to include the possibility for a country or zone to claim freedom in specific animal species (see Article 8.X.3), Article 8.X.7 was modelled in different sections covering: freedom in all animal species (Point 2.a of Article 8.X.7); freedom in the relevant animal species (Point 2.b of Article 8.X.7); absence of freedom in the relevant animal species (Point 2.c of Article 8.X.7). Taking into consideration the risk of interspecies transmission, the Group recommended that the donor from a country or a zone free in the relevant species but not free in all species should be tested prior to entry in a semen collection facility. The Group recommended that in countries or zones not free in the relevant species, the donor males should be isolated and protected against vectors and should be tested twice prior to entry in a semen collection facility.

  The Group discussed the available assays to detect infection in semen and determined that microscopic evaluation would be unreliable and that, at this time, molecular assays (PCR) would be the most reliable assays. The Group recommended that testing of semen, including by molecular methods, should be further described in the *Terrestrial Manual*.

  The Group considered that there was not enough scientific evidence to support concerns about embryos specific to *T. evansi.* The Group therefore determined not to include specific recommendations for embryos in the draft chapter 8.X. Member Countries should refer to the provisions of the *Code* chapter 4.7. (Collection and processing of *in vivo* derived embryos from livestock and equids) in that regard.

6. Revised Chapter 12.3 (Infection with Trypanozoon in equids (dourine, equine surra))

Discussions on individual articles were as follows:

– The Group formatted **Article 12.3.1 (General Provisions)** similarly to Article 8.X.1 of the draft *Code* chapter 8.X. Importantly, a statement was added to justify the unification of *T. evansi*, *T. equiperdum*, and *T. brucei* infections in equids in a single chapter.

A statement was also added to indicate that the transmission of Trypanozoon can be mechanical, venereal, or tse-tse transmitted (*T. brucei*).

The Group noted the lack of data concerning the survival time for *T. brucei* and *T. equiperdum* in contaminated meat, and defined the duration of survival of Trypanozoon in contaminated meat listed in the General Provisions (72 hours) in reference to *T. evansi.*

A case definition was modelled after the one produced for the chapter 8.X. The Group discussed the timelines and what constitutes a confirmed case. It determined that, for the purposes of this *Code* chapter, a serologically positive equid showing clinical signs of infection with Trypanozoon or epidemiologically linked to a case should be considered infected.

The Group discussed the incubation period of infection with Trypanozoon in equids. Subclinical infections are possible, so the Group considered it difficult to set an incubation period. It was noted that it could take 60 days for a horse to seroconvert and become antibody positive. In theory, the incubation period could be as high as two years according to field data collected during the Italian dourine outbreak. This period and the consequences of this timeframe were discussed. The previous *Code* chapter indicated an incubation period of six months for dourine. The Group consensus was that it would be best to define the incubation period as 30 days as this represents the timeframe noted for experimental infections.

– In regard to **Article 12.3.2 (Safe Commodities)**, the Group discussed the similarities between the needs of this chapter and chapter 8.X. It was determined that wool, fibers and claws should be removed as this Chapter only references equids.

– The provisions of **Article 12.3.3 (Country or zone free from infection with Trypanozoon in equids)** were developed consistently with Article 8.X.3 (Country or zone free from infection with *T. evansi* in one or more animal species).

– **Article 12.3.4** (**Recovery of free status in equids)** was referenced from Article 8.X.4 (Recovery of a free status), however considering that treatment would only work for *T. evansi* and *T. equiperdum* if the parasite has not spread to the central nervous system, the option of treating infected or serologically positive equids was not included in Article 12.3.4. Consequently, only the option of applying a stamping out policy was left for a swift recovery of a free status from infection with Trypanozoon in equids. Alternatively, the recovery of the free status may also follow the path described in Article 12.3.3.

Considering the potential for subclinical cases of infections, the Group recommended that a disease-specific surveillance system should be conducted for at least 6 months after completion of the stamping out policy. The Group also highlighted the importance of compliance with the *Code* chapter 4.1 (General principles on identification and traceability of live animals) to ensure an adequate surveillance.

The proposed timelines and conditions for the recovery of a free status described in the Points 3 and 4 of Article 12.3.4 are illustrated in Figure 1.

– The Group modelled the recommendations of **Article 12.3.5** (**Recommendations for importation of equids**) after those defined in Article 8.X.5 (Recommendations for importation of camelids, carnivores, bovidae, pigs, cervids, elephants, lagomorphs, rodents and vampire bats).

– With regard to **Article 12.3.6 (Recommendations for the temporary importation of horses for competition purposes**), the Group harmonised the conditions applicable to horses imported from a country or a zone free from infection with Trypanozoon in equids and not free from infection with *T. evansi* in all other species and those applicable to horses imported from a country or a zone not free from infection with Trypanozoon in equids. The rationale for that harmonisation is a presumed lower likelihood of transmission of the infection by horses imported on a temporary basis for competition purposes due to: (i) the shorter duration of the stay in the importing country, and (ii) the limited contacts with the local animal populations. However, the Group insisted that importing countries should consider the expected inherent risk associated with the horses imported under these conditions from a country or a zone not free from infection with Trypanozoon in equids and should keep them separated from the domestic population.

– The Group modelled the recommendations of **Article 12.3.7 (Recommendations for importation of equids from a country or zone not free from infection with Trypanozoon in equids for direct *slaughter***) after those defined in Article 8.X.6 (Recommendations for importation of camelids, bovidae, pigs from an infected country or zone for direct slaughter), and the recommendations of Article 12.3.8 (Recommendations for importation of semen) after those defined in Article 8.X.7 (Recommendations for importation of semen). The Group consulted Chapters 4.5 and 4.6 for recommendations regarding semen collection and processing and noted that Chapter 4.6 does not address equids, but only references bovine, porcine, and small ruminant and it should therefore not be cross-referenced in Chapter 12.3.

7. Recommendations for the revision of the *Manual* Chapters

The Group expressed the need for revising the chapters 2.1.21. (*Trypanosoma evansi* infections (including surra)) and 2.5.3. (Dourine) of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereafter the *Manua*l).

The Group was of the opinion that the *Manual* chapters should be aligned with the proposed scope of the *Code* chapters. Therefore the Group suggested the Scientific Commission to refer to the Biological Standards Commission consideration's on whether a *Manual* chapter on infections with Trypanozoon in equids should replace the current *Manual* chapter 2.5.3. on Dourine -on the model of the *Manual* chapter 2.1.4. [Brucellosis (*Brucella abortus, B. melitensis* and *B. suis*)]-.

The Group reviewed the following recommendations for revisions to the OIE *Manual* listed in the report from the *Meeting of the OIE Ad Hoc Group on Equine Trypanosomoses – Paris, 21-23 July2015*:

- "The Surra *Manua*l chapter should specify that in case of detection of *T. evansi* the agent identification test should include a PCR in order to exclude as a first step *T. brucei*;
- The Surra *Manual* chapter should contain also a "fit for purpose test" table, as already included in the Dourine chapter;
- The Dourine *Manual* chapter should be aligned to the *Code* chapter regarding the use of the term "breeding animals";
- Include in the *Manual* a statement that treatment is possible for both diseases, but only for the bloodstream form, not once the parasite has crossed the cerebrospinal fluid barrier".

The Group disagreed with the statement suggesting that "the Surra *Manual* Chapter should specify that in case of detection of *T. evansi* the agent identification test should include a PCR in order to exclude as a first step *T. brucei*" on the basis that such a distinction is not systematically necessary: (i) if an animal is found with trypanosomosis in a non-tsetse endemic country, *T. brucei* would not be included on the differential diagnosis list; (ii) the treatment of the animal would be the same if it is infected by *T. evansi* or by *T. brucei*. The Group therefore concluded that this recommendation would be irrelevant outside of the African continent where tsetse flies are endemic. The Group recommended that a battery or panel of PCR assays should be conducted to distinguish *T. evansi*, *T. equiperdum*, and *T. brucei*.

The Group unanimously supported the statement that "The Surra *Manual* Chapter should contain also a "fit for purpose test" table, as already included in the Dourine chapter".

In addition, the Group listed a number of other issues that would need to be addressed in the *Manual* chapters and recommended to forward them to the *Biological Standards Commission*:

- the occurrence of human cases of infection with *T. evansi* (as evocated in the section 5 of this report, Article 8.X.1);
- the pathogenicity of *T. evansi* in the different host species;
- the reasons why more than one test might be required to establish an individual health status (Articles 8.X.4, 8.X5, 8.X.7, 12.3.4, 12.3.5, 12.3.8);
- the efficacy of trypanocide treatments (including the penetration of drugs into tissues and the central nervous system and the use of serology to monitor efficacy of treatment's);
- criteria for the genetic characterization of the trypanosome species;
- molecular methods for testing semen.

In addition, the Group expressed needs for:

- the validation of assays for the detection of *T. evansi* in the different host species;
- the characteristics of the PCR assays (sensitivity, specificity);
- the definition of reference strains;
- the definition of diagnostic pathways.

8. Adoption of the report

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

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…/Appendices

Appendix I

OIE AD HOC GROUP ON EQUINE TRYPANOSOMOSES

Paris, 14-16 June 2016

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Terms of Reference

On the basis of the preliminary work conducted by the OIE ad hoc Group on equine trypanosomoses conveyed in Paris in July 2015, further develop a *Code* Chapter on Surra and revise the *Code* Chapter on Dourine.

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Agenda

1. Opening
2. Adoption of the agenda and appointment of chairperson and rapporteur
3. Presentation of the comments of members of the Scientific Commission and Code Commission on the report of the previous ad hoc Group
4. Revision of the scope of the *Code* chapters
5. Chapter 8.X. (Infection with Trypanosoma evansi – non equine surra)
6. Chapter 12.3 (Infection with Trypanozoon in equids (dourine, equine surra))
7. Recommendations for the revision of the *Manual* Chapters

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Appendix II

OIE AD HOC GROUP ON EQUINE TRYPANOSOMOSES

Paris, 14-16 June 2016

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Annex 11

Original: English
June 2016

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON ANTIMICROBIAL RESISTANCE

Paris, 21 – 23 June 2016

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1. Opening and background information

The OIE *ad hoc* Group on Antimicrobial Resistance (hereafter referred to as 'the Group') met from 21 to 23 June 2016 at the OIE Headquarters in Paris, France.

Dr Elisabeth Erlacher-Vindel, Deputy Head of the Scientific and Technical Department, welcomed the participants and reiterated the importance of antimicrobial resistance (AMR) in the current working programme of the OIE. She informed the Group that Resolution No. 36 on "Combating Antimicrobial Resistance through a One Health Approach: Actions and OIE Strategy" had been adopted at the last OIE General Session in May 2016, and that the Technical Item 1 of the next General Session (May 2017) will be on antimicrobial resistance and based on the analysis of a questionnaire that will be sent to all OIE Delegates. She also informed the Group that a Scientific Symposium on alternatives to antimicrobial agents will be organised by the USDA (United States Department of Agriculture) with the support of the OIE in December 2016 at OIE Headquarters, and that a Second Global Conference on the Responsible and Prudent Use of Antimicrobial Agents for Animals will be organised in 2017. She thanked the Group for its continued support of the OIE's activities related to the use of antimicrobial agents, and stressed the ongoing need of the Group's expertise and support in the collection of data and reporting by OIE Member Countries on their use of antimicrobial agents in animals.

Dr Erlacher-Vindel thanked the representatives of the World Health Organization (WHO) and of the Food and Agriculture Organization of the United Nations (FAO) who attended the meeting and highlighted their productive collaboration and the development of joint activities for the reduction of antimicrobial resistance. Dr Awa Aidara-Kane gave an update on AMR activities by the WHO. These included organisation of regional workshops to support the development of "One Health" National Action Plans to combat AMR, with Tripartite participation; the proposal for new work on AMR to be considered in June 2016 by Codex Alimentarius, and the upcoming United Nations General Assembly High Level Meeting in September 2016 that would further endorse the great progress that has been made through resolutions at the WHO, FAO and OIE annual meetings and through the agreement of the Global Action Plan on Antimicrobial Resistance (GAP). Dr Sylvia Kreindel informed the participants that AMR will be also on the agenda of important forthcoming meetings of the FAO.

Finally, Dr Erlacher-Vindel explained that the meeting of the Group would be focused mainly on the OIE Database on the use of antimicrobial agents in animals and on the adoption of a provisional calculation of the denominator to estimate the animal biomass. The main objectives of the meeting would be a presentation of the first phase of data collection from OIE Member Countries on the use of antimicrobial agents in animals as presented during the OIE General Session, to adopt a provisional calculation of the denominator estimating animal biomass in the short- and long-term, given future improvements to WAHIS (World Animal Health Information System), and to validate improvements to the data collection template and guidance.

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

The meeting was chaired by Dr Herbert Schneider, and Dr Carolee Carson acted as rapporteur.

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

3. Presentation of the data collected by the OIE on the use of antimicrobial agents in animals in 2015, and of the proposed draft report

Dr Delfy Gochez presented an overview of the data on the use of antimicrobial agents collected from 130 participating OIE Member Countries. This overview consisted of a presentation of the final results of the first phase of data collection, including what was presented at the OIE General Session in May 2016 to the World Assembly of Delegates, as well as additional analyses performed.

The Group recognised the value of the contributions of OIE Member Countries and the efforts of the OIE National Focal Points for Veterinary Products in providing these data.

Dr Gochez also presented an outline of the draft report providing a summary of the global and regional results of the first phase of data collection. The Group agreed on the proposed outline and made some comments to improve the draft report. The Group was informed that the aim would be to publish the final report on the OIE website before the end of the year.

4. Review of the proposed updates to the template and guidance documents to be sent at the end of 2016 to all the OIE Member Countries for the collection of data on the use of antimicrobial agents in animals (2nd phase)

As a result of the experience of the first phase of data collection, and to improve the template to clarify and to simplify the guidance for Member Countries, an updated version of the template and guidance document were presented to the Group for their consideration.

The following improvements to the template were proposed to the Group. The outcomes of the Group's discussion of these points are described below:

Template - Baseline Information

- Reporting year of data
  - A proposal was made to modify from a free text field to check boxes, thereby reducing the number of choices possible, with the expectation of reducing data error and misinterpretation. In addition, a line requesting 2014 data in the template was inserted, with an information box indicating that 2014, 2015 or 2016 data would be accepted for the second phase. In the future, data from a single year will be requested from all Member Countries. Additional information on the time period covered by the data, with an example given (1 January – 31 December), was included.
- Data source
  - A proposal was made to re-group the current 23 data sources into eight categories: imports, marketing authorisation holders, manufacturers, feed manufacturers, wholesalers and retailers, veterinarians, pharmacy, farmers and other users.
  - Although the Group noted the complexity of the number of categories, the Group proposed to keep the original categories for the second phase of data collection with the exception of "Sales data – Veterinarians" as it was a duplicate category and of "Veterinary prescription data – Dispensing" as it was covered by other categories.
- Animal groups covered by the data
  - The Group agreed on the proposed changes to this field, with text modification for additional clarity to assist in the selection of the correct Reporting Option.
- Table to assist Member Countries in choosing the most appropriate Reporting Option
  - The Group agreed on the improvement of the original table, in which the excel spreadsheet would automatically select the most appropriate Reporting Option, based on the replies of the Member Countries to the Baseline Information sheet.

Template - Reporting Options 2 and 3

- The Group agreed to add a "Companion animals" column to Reporting Options 2 and 3, to accommodate reporting of this information.

Guidance document

- The Group accepted the proposed modifications of the Guidance document, such as colour coding of sections and the grouping of all information by Reporting Option. No changes were made to the Annex.

5. Discussion and adoption of a provisional calculation of the denominator estimating animal biomass

Dr Neo Mapitse, Deputy Head of the World Animal Health Information and Analysis Department (WAHIAD), and Dr Lina Awada, Veterinary Epidemiologist in WAHIAD, attended this part of the meeting.

Dr Mapitse informed the Group that some Member Countries have started to submit animal population information by the sub-categories of birds and pigs that were developed in the previous year. He said WAHIAD was committed to reminding the countries of the importance of the categories and verification of their data. He also mentioned that WAHIAD will continue to make improvements and adapt the 'Guidelines to Member Countries' as far as possible at this stage to take into account the needs of accurate animal population data for reporting quantities of antimicrobial agents intended for use in animals. However, he pointed out that a project for a new version of the WAHIS has recently been initiated and that WAHIAD is accepting suggestions from stakeholders on their needs. The Group therefore decided to refine its previous suggestions and modified the list of animal categories or animal species suggested to be included in WAHIS + (see Appendix III) in order to submit it to WAHIAD for their official consideration for the new version of WAHIS.

Dr Gérard Moulin presented short- and long-term proposals for both the provisional calculation of the denominator to estimate the animal biomass (hereafter 'the model') and its future refinement, with contributions made by Dr Carolee Carson and Dr Jordi Torren. The model takes into account key parameters such as OIE animal point in time census data, number of production cycles in a year, and average weights. The Group compared the estimated biomass from the model with available published biomass data of the EU and Canada. There appeared to be good agreement between the model estimates and the national estimates. The Group appreciated the merit of this approach and recommended that additional countries, including low- and middle-income countries, be included to further validate the model. Based on the results, the model may need to be adapted.

The Group discussed the proposals made by Dr Moulin and agreed with the pragmatic, short- and long-term approach.

1. Short-term proposal: Estimate for each country the annual biomass of animals, based on the point-in-time census data currently provided to WAHIS. The following detailed actions were proposed:

    a) To verify whether data in WAHIS are production or point-in-time census data for the countries that will be included in the development of the model.

    b) To include information from additional countries to refine the estimate of the number of production cycles in a year and weights, which may vary by country/region, for animal categories as defined by WAHIS.

2. Long-term plan: Proposal for additional animal species/production categories to be included in WAHIS + that will enable better estimation of the biomass.

    The Group recognised that while WAHIS provides the data on terrestrial and aquatic animals, additional information may be needed in order to construct the denominator in the long-term. In particular, the total number of animals produced in one year is critical to put into context the total amount of antimicrobial agents used in one year. As such, the Group noted limitations with point-in-time census data, which

affects animals with production cycles of less than one year, such as birds and pigs. For these animals, point-in-time census data will underestimate the number of terrestrial animals produced in a calendar year, which may lead to an apparent overestimate in the use of antimicrobial agents. The Group agreed, therefore, that a production cycle factor will be needed.

The Group recognised that there is variability in production cycles and weights around the world and that comprehensive data are not available. The Group agreed that future refinement would reduce uncertainty and facilitate detection of trends. Depending on the differences observed, it might be necessary to adapt regional/subregional estimates of production cycles and weights for short-lived species.

6. Future perspectives and next steps

The Group considered the robust content of the draft report invaluable and acknowledged it as a major milestone in the global effort to contain antimicrobial resistance. The Group encouraged further active participation of all Member Countries in the data collection on the use of antimicrobial agents in animals.

Forthcoming OIE National Focal Point trainings for Veterinary Products will provide further opportunities encouraging participation of countries that have not engaged so far in the second phase of the data collection.

The excel spreadsheet containing the current model will be improved as described above and then circulated with the Group, with the aim of providing more data for refinement of the estimated production cycles and weights.

The final report of the first phase of data collection will be published on the OIE website before the end of the year. For the second phase of data collection, the aim would be to include quantitative information at the global and regional levels using the provisional calculation of the denominator.

7. Other business

Dr Jordi Torren gave a presentation on “Future plans of the European Surveillance of Veterinary Antimicrobial Consumption project”.

Dr Moulin gave a presentation on “Evolution of the French system for the surveillance of Antimicrobials used in animals”.

The Group thanked the speakers and noted the information provided. The Group intends to keep abreast of surveillance initiatives to inform the future direction of collection of data on the use of antimicrobial agents in animals.

The Group reviewed the letter to Delegates (which accompanied the first data collection template on the use of antimicrobial agents in animals sent in 2015) with the aim of updating it for the second phase. The Group agreed that the background information on the collection of data on the use of antimicrobial agents should be highlighted in one paragraph, as some receivers of the letter may not be the same people as the previous year. The Group also suggested that the letter not exceed one page.

8. Next meeting

The Group proposed the following dates for the next meeting: between 23 and 26 January 2017.

9. Adoption of report

The Group adopted the report.

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…/Appendices

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON ANTIMICROBIAL RESISTANCE

Paris, 21 – 23 June 2016

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Agenda

1. Opening and background information
2. Appointment of chairperson and rapporteur, and adoption of agenda
3. Presentation of the data collected by the OIE on the use of antimicrobial agents in animals in 2015, and of the proposed draft report
4. Review of the proposed updates to the template and guidance documents to be sent end of 2016 to all the OIE Member Countries for the collection of data on the use of antimicrobial agents in animals (2nd phase)
5. Discussion and adoption of a provisional calculation of the denominator estimating animal biomass
6. Future perspectives and next steps
7. Other business
8. Next meeting
9. Adoption of report

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Appendix II

MEETING OF THE OIE *AD HOC* GROUP ON ANTIMICROBIAL RESISTANCE

Paris, 21 – 23 June 2016

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Appendix III

List of animal categories or animal species suggested to be included in WAHIS

ANIMAL CATEGORY
Cattle
Beef cattle
Dairy cattle
Heifers
Steers and Bulls
Veal calves
Buffaloes
Cervidae
Pigs
Adult pigs
Fatteners
Piglets
Backyard pigs
Birds
Poultry
Broilers
Layers
Turkeys
Backyard poultry
Other birds
Small ruminants
Sheep and goats
Sheep
Goats
Lambs and kids
Equidae
Horses
Donkeys
Camelidae
Hares and Rabbits
Hares
Rabbits
Cats and Dogs
Cats
Dogs
Fish (farmed)
Molluscs
Crustaceans
Amphibians
Reptiles

Rationale for the amendments to:

Chapter 15.2. INFECTION WITH CLASSICAL SWINE FEVER VIRUS provided by the Scientific Commission

Article 15.2.3. Country or zone free from CSF

The Commission discussed the current DIVA[1] vaccine situation and whether Chapter 15.2. should maintain provisions for freedom from classical swine fever (CSF) where vaccination with DIVA vaccines is practised by specifying that the Section was under study or if it should be deleted until the inclusion of the DIVA vaccine test in the *Terrestrial Manual*. Considering that this test could be included in the Terrestrial Manual in the near future, the Commission decided to maintain the provisions under study in the *Terrestrial Code* chapter and to further discuss the issue with the Biological Standard Commission.

Article15.2.6.*bis*. Direct transfer of pigs from an infected zone for slaughter in a free zone within a country

The Commission welcomed the draft Article 15.2.6.*bis*. allowing the direct transfer of pigs from an infected zone for slaughter into a free zone within a country, that would address the request of a Member Country to be consistent with other chapters of the *Terrestrial Code* (i.e. foot and mouth disease [FMD]). The Commission emphasised the following points that would make this concept possible:

- It is national trade from an infected to a free zone within a country;
- Surveillance 30 days prior to slaughter would guarantee that none of the slaughtered pigs was recently and acutely infected, although it may have been infected in the past;
- The pigs should not come from an *establishment* with continuous pig movements and therefore it should be required that the pigs to be slaughtered were kept for at least 3 months in the *establishment*;
- The meat would be treated to inactivate CSF virus (CSFV).

Article 15.2.14. *bis* Recommendations for the importation from countries or zones not free from CSFV, where an official control programme exists – fresh meat of domestic pigs

The Commission considered the proposal made by the *ad hoc* Group on CSF and on FMD and endorsed the proposed requirements for importation of fresh meat of domestic pigs from an infected country or zone.

Article 15.2.25. *bis*. Procedures for the inactivation of CSFV in bristles

The Commission reviewed the scientific literature[2] compiled by the OIE Headquarters and concluded that boiling was currently the only method with enough scientific justification that would inactivate CSFV in bristles.

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1 DIVA: differentiating infected from vaccinated animals

2 http://onlinelibrary.wiley.com/store/10.2903/sp.efsa.2009.EN-6/asset/supinfo/6eax1-sup-0001.pdf?v=1&s=f06b8df44c0858ed66421cb264335bbcc9bb462a

Diagrams on the use and interpretation of diagnostic tests in surveillance

The Commission acknowledged that the diagrams on the use and interpretation of diagnostic tests in surveillance created more confusion than clarification and therefore recommended to delete them from the *Terrestrial Code* chapter. However, it was recommended that the Biological Standard Commission considers whether they should be revised and included in the *Terrestrial Manual* chapter.

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Annex 13

Original: English
July 2016

MEETING OF THE OIE AD HOC GROUP ON CLASSICAL SWINE FEVER

Paris, 5-6 July 2016

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A meeting of the OIE *ad hoc* Group on classical swine fever (CSF) (hereafter the Group) was held at the OIE Headquarters from 5 to 6 July 2016.

1. Opening

Dr Monique Eloit, Director General of the OIE, welcomed and thanked the Group for its commitment and its extensive support of the OIE in fulfilling the mandates given by Member Countries.

Dr Eloit highlighted that one of the mandates of the OIE was maintaining scientific excellence as part of the foundation of the OIE international standards setting procedure in order to preserve international credibility. She explained that the OIE remained committed to maintaining transparent and robust procedures for the selection of experts for the *ad hoc* Groups, Working Groups and Specialist Commissions, and to further expand the international scientific expertise of the OIE. She mentioned that more training tools would be made available to the OIE staff in order to further improve the implementation of the OIE 6th Strategic Plan.

Dr Gregorio Torres, Chargé de mission of the Sciences and New Technologies Department, reminded the experts that they had been selected based on their scientific expertise and that they were not representing their own countries or institutions. Prior to the meeting all experts signed a confidentiality agreement and a declaration of interests. Dr Torres emphasised that the discussions captured in the report would be attributed to the Group and not to the individual expert.

Finally, he announced that a representative of the Scientific Commission for Animal Diseases and of the Terrestrial Animal Health Standards Commission would also participate in the meeting to support the Group discussion and to guide the experts in the completion of the term of references.

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

Dr Trevor Drew acted as chair of the Group. Dr Cristobal Zepeda acted as rapporteur, with the support of the OIE Secretariat. The Group endorsed the proposed agenda.

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

3. Review of Chapter 15.2. on CSF of the *Terrestrial Animal Health Code*

The Group was reminded that Chapter 15.2. had been last adopted after revision in May 2013, when the procedure for official recognition was expanded to include CSF. The Group was tasked to address the scientific comments received since the last adoption, and to update the Chapter based on the recommendations made by the prior CSF ad hoc Group, but also on the African swine fever (ASF), and FMD *ad hoc* Groups for further harmonisation.

Article 15.2.1.: General provisions

The Group noted a comment made by the *ad hoc* Group on the evaluation of CSF status of Member Countries in November 2015, with regard to the case definition. The Group clarified the text to indicate that the detection of viral antigen or nucleic acid specific to a classical swine fever virus (CSFV) in a sample with the presence of clinical signs from a suspected pig would also be included in the definition of infection with CSFV. The Group emphasised that the case definition based on demonstration of CSFV nucleic acid was not only limited to detection by reverse-transcriptase polymerase chain reaction (RT-PCR), but also included virus characterisation by sequencing and comparative analysis, which would be recommended particularly for first detection in CSF-free countries. The amended definition was more in line with the case definition in the FMD Chapter of the *Terrestrial Animal Health Code* (*Terrestrial Code*).

In response to a Member Country's comment, the Group explained that a definition of a suspected case of CSF is based on clinical signs, pathological lesions, epidemiological links or other suspects following exposure to the pathogens. The Group made note that this was a generally accepted principle that would not require specific definitions and that applied to all disease-specific chapters of the *Terrestrial Code*. Concerning the specific proposal to include virus isolation within point 2 and 3 of the case definition, the Group felt that the inclusion was not appropriate as points 2 and 3 are provided as alternatives when virus isolation is not feasible.

The Group considered the definition of the incubation period in the glossary of the OIE *Terrestrial Code* and agreed that an incubation period of 14 days would be appropriate for the purposes of the *Terrestrial Code*. (Karsten *et al.* 2005)[1]

The Group discussed the use of the term suid versus pigs. Considering the susceptible species, the Group agreed that the term pig was more appropriate for the purposes of the CSF Chapter while suid was more appropriate for the ASF Chapter.

The Group noted that not all CSFV-infected pigs show clinical signs. The Group considered it appropriate to add the possibility of finding pathological lesions suggestive of CSF in the case definition.

The Group clarified the provision that a trade ban in commodities of domestic and captive wild pigs should not be imposed when CSFV existed in wild and feral pigs provided the commodities are traded according to the recommendation of this chapter.

Article 15.2.2.: General criteria for the determination of the classical swine fever status of a country, zone or compartment

The Group highlighted that all pigs showing clinical signs or pathological lesions suggestive of CSF should be subjected to appropriate field investigation, whilst depending on the epidemiological circumstances and findings of the field investigation, laboratory investigation may not always be necessary.

Article 15.2.4.: Classical swine fever free compartment

The Group harmonised the CSF article with the updated FMD Chapter.

The Group discussed if historical freedom could be considered for CSF, noting that the current chapter does not mention the concept, while other chapters for other diseases for which the OIE recognised an official status did. The Group recommended harmonising the disease chapters for which the OIE recognises official disease status in relation to historical freedom.

[1] Karsten S., Rave G., Krieter J. (2005). Monte Carlo simulation of classical swine fever epidemics and control. II. Validation of the model. *Veterinary Microbiology*, **108**, 199-205.

The Group noted that historical freedom complying with Article 1.4.6.1. a) of the *Terrestrial Code* provided an additional level of assurance that a country was free of CSF. However, countries were expected to submit a full dossier in compliance with Article 15.2.3. when applying for official status recognition.

Article 15.2.5.: Establishment of a containment zone within a classical swine fever free country or zone

Consistent with the approach followed by the other disease chapters for official recognition of disease status, the Group added that, in the event of the recurrence of CSF in the containment zone, the approval of the containment zone would be withdrawn and the CSF-free status of the country or zone would be suspended until the relevant requirements of Article 15.2.6. were fulfilled.

The Group provided a time limit of 12 months after establishment of a containment zone for the recovery of the CSF-free status of the containment zone following the provisions of Article 15.2.6. of the *Terrestrial Code*. If freedom was not regained within 12 months, Member Countries would be required to re-apply for CSF-free status in compliance with Article 15.2.3.

The Group considered the extended concept of the containment zone that was discussed by the *ad hoc* Group for FMD in June 2016. The extended concept would cover circumstances where outbreaks continue to occur within an infected zone as long as a protection zone, in which no outbreaks have occurred, is established within and along the perimeters of a larger containment zone (please refer to the report of the *ad hoc* Group on FMD of June 2016). The Group agreed that the proposed concept would also be applicable to CSF and recommended that the Scientific Commission take a harmonised approach.

Article 15.2.6.: Recovery of free status

With regard to the surveillance provisions, the Group decided to refer only to Article 15.2.30. on surveillance, as the article is specific to additional measures associated with the recovery of free status. Nevertheless, this article does also make reference to other general surveillance provisions that need to be taken into consideration.

The Group added a point, in line with the FMD chapter, referring to the provision for recovery in case an outbreak occurs in a CSF-free compartment. The Group created point 5 to clarify when the recovery of free status should be requested. The Group added a 24-month time limit for Member Countries applying for recovery, in line with the equivalent Article in the FMD Chapter. Otherwise, Article 15.2.3. would apply.

Article 15.2.6.bis.: Direct transfer of pigs from an infected zone for slaughter in a free zone

The Group noted that, at the last meeting of the *ad hoc* Group on the evaluation of CSF status of Member Countries in November 2015, an article was drafted in response to a Member Country comment.

The Group discussed the draft article in-depth and aligned the CSF article with the FMD article requiring the pigs to have been kept in the establishment of origin for 3 months prior to movement instead of the proposed 30 days.

The Group highlighted that this article was intended for movements between zones in a country rather than movements between countries.

Article 15.2.6.ter.: Direct transfer of pigs from a containment zone for slaughter in a free zone

The Group noted that, at the last meeting of the *ad hoc* Group on the evaluation of CSF status of Member Countries in November 2015, an article was drafted in line with the FMD chapter and recommended that this draft be considered by the Specialist Commissions.

Article 15.2.8.: Recommendations for importation from countries or zones considered infected with classical swine fever virus

The Group agreed to add a provision for pigs to be quarantined for 28 days (two incubation periods) prior to shipment and subjected to a virological and serological test at least 21 days after entry into the quarantine station.

Article 15.2.9.: Recommendations for the importation of wild and feral pigs

The members of the Group discussed possible scenarios of importation of wild and feral pigs. Whilst the Group agreed that importation of wild and feral pigs was not commonly practised it was concluded that the provisions under Article 15.2.9.do provide the necessary guarantees.

The Group harmonised the isolation of 28 days in a quarantine station in line with Article 15.2.8.

Article 15.2.11.: Recommendations for importation from countries, zones or compartments infected with classical swine fever

For semen of domestic and captive wild pigs

The Group considered the draft article in the ASF chapter. Since transmission of CSFV via semen is scientifically proven, whereas transmission of ASFV via semen of domestic and captive wild pigs is much less supported by scientific evidence, the Group felt that the requirements for CSFV should be more stringent than those for ASFV.

The Group indicated that the 40-day waiting period was inpractical for importation of fresh semen and would be an unnecessary measure for risk mitigation. The provision related to a CSF-free compartment was deleted, as this scenario was covered by Article 15.2.10. Instead, a provision was made for an establishment with the addition of a surveillance requirement of at least 12 months as described in Articles 15.2.26 to 15.2.32. In addition, the Group recommended three conditions to be met: Negative results for i) virological test regardless of the vaccination status; ii) serological test at least 21 days after collection with demonstration that any antibodies are due to the vaccine, if vaccinated; and iii) serological test at least 21 days after collection, if not vaccinated.

Article 15.2.12.: Recommendations for importation from countries, zones or compartments free from classical swine fever

For in vivo *derived embryos of domestic pigs*

The Group aligned the requirement for donor females in accordance with provisions in the amended draft chapter on ASF and FMD chapter and added a requirement for fertilisation. The Group recommended that this requirement be also included in the corresponding article in the ASF chapter (article 15.1.10.).

Article 15.2.13.: Recommendations for importation from countries, zones infected with classical swine fever

The Group amended the article based on the modifications made on Article 15.2.11.

Article 15.2.14.bis: Recommendations for importation from countries or zones infected with CSFV

For fresh meat of domestic and captive wild pigs

The Group noted that the current Chapter did not have provisions for importation of fresh meat of domestic and captive wild pigs.

The members of the Group had differing opinions on whether provisions were needed for fresh meat of domestic and captive wild pigs from infected countries. The Group felt that the concept of CSF-free compartments allowed trade of fresh meat from infected countries, while compartmentalisation would not be applicable for the importation of fresh meat from wild and feral pig from infected countries. Nevertheless, the

Group drafted an article for the importation of fresh meat from domestic and captive wild pigs from infected countries based on the draft articles 8.8.22.bis. of the FMD chapter and 15.1.12.bis. of the ASF chapter, while referring the decision for inclusion to the Specialist Commissions.

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

In response to a Member Country's comment, the Group acknowledged the difficulty in taking serological samples from carcasses of wild pigs that have been refrigerated for the purposes of trade. However, the Group felt that the serological status of wild pigs was an important part of assurance of freedom from CSF for export.

Articles 15.2.16. to 15.2.21.: Recommendations for the importation of different pig products

According to the ASF *ad hoc* Group, specifying the intended use of meat products was irrelevant since the objective was to mitigate the risk posed by the products regardless of their intended use.

The Group aligned the terminology by replacing 'establishment' with 'facility' to avoid confusion with the glossary definition of an establishment.

Article 15.2.16.: Recommendations for the importation of meat and meat products of pigs

The Group included references to the Articles 15.2.14., 15.2.14.bis. and 15.2.15. under both point 1) a) and 1) b) ii), as they refer to the importation of fresh meat.

Article 15.2.21.: Recommendations for the importation of skins and trophies

In response to a Member Country's request to incorporate recommendations on importation of skins and trophies of wild and feral pigs, the Group indicated that provision under point 2) applies.

Article 15.2.23.: Procedures for the inactivation of the classical swine fever virus in meat

Based on a scientific article by Cowan et al. (2015)[2], the Group added a requirement, under point 1. b) for 30 minutes of heat treatment at a minimum temperature of 70°C.

Article 15.2.24.: Procedures for the inactivation of the classical swine fever virus in casings of pigs

The Group considered an EFSA report[3] and concluded that there was limited information on the effect of dry salt in the inactivation of CSFV. The Group concurred with the EFSA report and other studies[4, 5] that the effectiveness of phosphate supplemented dry salt was superior to dry salt alone.

Article 15.2.25.: Procedures for the inactivation of the classical swine fever virus in skins and trophies

The Group did not find scientific evidence on the effectiveness of formalin or formaldehyde for the inactivation of CSFV in skins and trophies and decided not to include these methods in the article.

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2 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. *Vet. Microbiol*., **176**, 1–9

3 EFSA AHAW Panel (EFSA Panel on Animal Health and Welfare), (2012). Scientific Opinion on animal health risk mitigation treatments as regards imports of animal casings. EFSA Journal 2012; 10(7):2820, 32 pp. doi:10.2903/j.efsa.2012.2820

4 Wijnker J.J., Depner K.R., Berends B.R. (2008). Inactivation of classical swine fever virus in porcine casing preserved in salt. *International journal of food microbiology*, **128**, 411-413

5 Wieringa-Jelsma T., Wijnker J.J., Zijlstra-Willems E.M., Dekker A., Stockhofe-Zurwieden N., Maas R., Wisselink H.J., (2011). Virus inactivation by salt (NaCl) and phosphate supplemented salt in a 3D collagen matrix model for natural sausage casings. *International journal of food microbiology*, **148**, 128-134.

Article 15.2.25.bis.: Procedures for the inactivation of CSFV in bristles

The Group agreed that boiling bristles in water for at least 30 minutes would inactivate CSFV. The Group did not find the scientific evidence related to other effective inactivation treatments such as the use of 0.5% formalin as suggested by some Member Countries.

Article 15.2.25.ter.: Procedures for the inactivation of CSFV in litter and manure from pigs

With reference to Bøtner & Belsham (2012)[6] and Weesndorp et al. (2008)[7], the Group considered and agreed that the provisions in the amended draft ASF chapter was sufficient for CSFV inactivation in litter and manure from pigs.

Article 15.2.28.: Surveillance strategies

In response to a Member Country's comment, the Group added a reference to contingency planning while acknowledging that contingency planning should be part of an emergency response rather that part of a surveillance programme. The Group acknowledged the general need for guidance on contingency planning and understood that this was in the agenda of the OIE.

The Group partially agreed with the second comment of the Member Country and amended the text to further clarify that a surveillance strategy should estimate (not establish) the prevalence or demonstrate the absence of CSFV infection based on clinical investigation or on randomised and targeted sampling methods.

The Group emphasized that clinical investigation was a key element of CSF surveillance and should be retained.

In response to the comments of a Member Country, the Group proposed that the Spanish translation for 'targeted' should be 'dirigido' instead of 'especifico'.

The Group proposed to clarify the article by adding type of production systems as a risk factor of CSF transmission among the risk factors already mentioned i.e. temporal and spatial distribution of past outbreaks, pig movements and demographics.

The Group agreed with a Member Country's comment that, when designing a surveillance system, due to the recognised cross-reactivity with ruminant pestiviruses in the serological diagnosis of CSF, the factors mentioned in point 4 should be taken into account.

The Group agreed that the survey design should not be compromised when using sera collected for other purposes. The Group amended the paragraph for clarity and considered that survey populations and statistical design were implicit within the existing text.

The Group agreed that it was sensible to move the last paragraph and the four points (a, b, c and d) of the Article to the end of Article 15.2.27. for general conditions and methods for surveillance.

Article 15.2.31. Surveillance for classical swine fever virus in wild and feral pigs

The Group considered the definition of 'monitoring' and 'surveillance' provided in the glossary of the *Terrestrial Code* and did not agree with a Member Country's comment to use the term 'monitoring' instead of 'surveillance' in this article. The Group acknowledged that surveys to estimate the prevalence or to demonstrate absence of the disease in wild pig populations may be difficult to design, however, actions could still be taken based on the results of the surveillance. Therefore, the Group considered the term 'surveillance' as more appropriate term to be used throughout the article.

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6 Bøtner A. Belsham G.J. (2012). Virus survival in slurry: Analysis of the stability of foot-and-mouth disease, classical swine fever, bovine viral diarrhoea and swine influenza viruses. Volume 157, Issues 1–2, 25, 41–49.

7 Weesendorp E., Stegeman A., Loeffen W.L.A. (2008). Survival of classical swine fever virus at various temperatures in faeces and urine derived from experimentally infected pigs. Volume 132, Issues 3–4, 10 December 2008, 249–259.

The Group disagreed with a Member Country's proposal to include domestic pigs in the text, as this article was dedicated to wild and feral pigs. The Group clarified that the provisions on the interpretation of diagnostic results should correspond with the recommendations in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*).

Article 15.2.32.: The use and interpretation of diagnostic tests in surveillance

In response to a Member Country's comment, the Group concurred that any positive ELISA test result should be further investigated. The Group explained that differential neutralisation tests should indicate whether the virus involved was a ruminant pestivirus or CSFV and clinical signs may not always be present even if CSFV was involved, which would particularly be true in infected mature pigs or in pigs infected with moderate strains of CSFV.

The Group acknowledged that a direct fluorescent antibody test (FAT) may have some value as a preliminary screening test. However, as mentioned in the *Terrestrial Manual*, FAT does not completely rule out CSFV infection, and could generate large numbers of inconclusive results. Furthermore, FAT requires a high level of skill and training to perform and maintain and to the Group's knowledge there is not international ring trial for the FAT. The Group therefore concluded that PCR was the test of choice for virological screening of tissues, with sequencing and isolation used to confirm the identity of any positive results.

As requested by a Member Country, the Group proposed a text to explain the first flowchart.

However, the Group expressed concerns regarding translation of the definitions of a case into flowcharts. The Group discussed extensively how to capture the diagnostic algorithms in a single flowchart without causing confusion or misunderstanding, and concluded that schematic representations should be included in the *Terrestrial Manual* rather than in the *Terrestrial Code*. Furthermore, with new emerging diagnostics and science, only the *Terrestrial Manual* and not the *Terrestrial Code* would need to be updated. The Group suggested removing both flowcharts from the amended chapter.

4. The implication of the description of differentiate infected from vaccinated animals (DIVA) vaccines in the *Terrestrial Manual* Chapter 2.8.3. on CSF

The Group discussed the current situation of the DIVA vaccines, and agreed that there were no sufficiently validated vaccines or diagnostic methods to give confidence on DIVA vaccines. As a consequence, the Group proposed either to: i) delete the option of allowing for CSF freedom when vaccination is practised in point 4 of Article 15.2.3, or ii) keep the option as it is but indicate that this provision was under study. The Group decided not to modify the text while leaving the decision to the Scientific Commission.

The Group agreed that there was a need for review and updating the *Terrestrial Manual*, particularly to include the latest development in DIVA vaccines, and suggested that the Biological Standards Commission update the chapter accordingly.

5. Adoption of report

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

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…/Appendices

Appendix I

MEETING OF THE OIE AD HOC GROUP ON CLASSICAL SWINE FEVER

Paris, 5-6 July 2016

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Agenda

1. Opening
2. Adoption of agenda, and appointment of chairperson and rapporteur
3. Review of Chapter 15.2. on CSF of the *Terrestrial Animal Health Code*
4. Implication of the description of differentiate infected from vaccinated animals (DIVA) vaccines in the *Terrestrial Manual* Chapter 2.8.3. on CSF
5. Adoption of the report

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Appendix II

MEETING OF THE OIE AD HOC GROUP ON CLASSICAL SWINE FEVER

Paris, 5-6 July 2016

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Annex 14

Rationale for the amendments to:

Chapter 11.4. BOVINE SPONGIFORM ENCEPHALOPATHY provided by the Scientific Commission

Article 11.4.4. Controlled BSE risk

The Commission concurred with the proposal of the *ad hoc* Group that in case of occurrence of an indigenous case of classical bovine spongiform encephalopathy (BSE), detected in cattle born more than 11 years ago, the country's BSE risk status should be reclassified as 'controlled', provided that the country still complies with all the requirements of Article 11.4.4. The Commission clarified that evidence of compliance with all requirements of this Article should be accepted by the OIE. The Commission also stressed that this path should be defined in the procedure for OIE official recognition of disease status.

Article 11.4.12. Recommendations for the importation of meat and meat products from a country, zone or compartment posing an undetermined BSE risk – for fresh meat and meat products from cattle (other than those listed in point 1 of Article 11.4.1.)

While the *ad hoc* Group had removed point 2c. related to "*nervous and lymphatic tissues exposed during the deboning process*", the Commission advised that a risk could be associated with the mechanical deboning process and that point 2c should be maintained.

Article 11.4.14. Recommendations on commodities that should not be traded

The Commission extensively discussed the need to include a provision to mitigate the risk of atypical BSE transmission. The Commission noted that two different *ad hoc* Groups had advised that high risk tissues should be removed from the carcasses. Based on scientific data available and the extremely low number of cases of atypical BSE reported in animals younger than 96 months old, the Commission decided to limit the removal of high risk tissues from carcasses of animals older than 96 months regardless of the disease risk status of the country.

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Annex 15

Original: English
August 2016

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP

ON BOVINE SPONGIFORM ENCEPHALOPATHY

Paris, 23-25 August 2016

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A meeting of the *ad hoc* Group on bovine spongiform encephalopathy (BSE) (hereafter the Group) was held at the OIE Headquarters from 23 to 25 August 2016.

1. Opening

Dr Monique Eloit, Director General of the OIE, welcomed and thanked the experts for their commitment towards the OIE and for personal and professional time invested in this *ad hoc* Group.

Dr Eloit highlighted that in line with the objectives of the OIE 6th strategic plan, the procedure for the election process of the members of the Specialist Commissions and the appointment of experts to Working Groups and *ad hoc* Groups were being reviewed. The new procedure would be submitted to the approval of the OIE Council in September 2016 before it is presented to the World Assembly of OIE Delegates for adoption.

Dr Eloit emphasised that the revised procedure for the selection of OIE's experts aims at enhancing the transparency of the way in which experts are selected as well as at further reinforcing OIE's capacity to develop evidence-based international standards.

Dr Laure Weber-Vintzel, Head of Status Department, clarified that a previous BSE *ad hoc* Group had revised Chapter 11.4. of the *Terrestrial Animal Health Code* (*Terrestrial Code*), in 2014. However, the corresponding draft chapter was not adopted by the World Assembly during the 83rd General Session due to the limited time Member Countries were given for its revision. Nevertheless, Member Countries agreed at this time to insert a sentence specifying that atypical BSE was excluded for the purpose of official disease status recognition. She advised that both the current adopted chapter and the draft chapter elaborated by the *ad hoc* Group in 2014 be used as a basis for discussion.

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

Dr Armando Giovannini was appointed Chair and Dr Noel Murray appointed rapporteur. The Group endorsed the proposed agenda.

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

3. Review and update of the existing chapter on BSE in the *Terrestrial Code*

3.1. Revision of the draft chapter (Articles 11.4.1. to 11.4.19.)

The Group thoroughly reviewed the amended BSE chapter drafted in 2014 by the BSE *ad hoc* Group.

The Group agreed that only cattle, cattle-derived products and by-products trade represent a risk for the spread of BSE and therefore agreed to refer the trade recommendations to only cattle and not to "ruminants".

The origin of BSE is indeed still largely unknown. Hypothesises on BSE origin include cattle infected with atypical BSE or sheep and goats infected with scrapie. Thus, the feeding of meat-and-bone or greaves derived from small ruminants cannot be excluded as a potential route of introduction of BSE into a cattle population. Therefore, the Group was of the opinion that the provisions concerning the feed ban and meat-and-bone meal or greaves should apply to the ruminant population in general rather than to the cattle population. Changes were made accordingly all along the chapter.

- Article 11.4.1. General provisions

  During the 83rd General Session the World Assembly decided to only amend Article 11.4.1. by including the following sentence: "*For the purpose of official BSE risk status recognition, BSE excludes 'atypical BSE'*". The Group unanimously supported the opinion that official recognition of BSE risk status should only focus on the occurrence of classical BSE. However, as Articles 11.4.3. - Negligible BSE risk and 11.4.4. - Controlled BSE risk were to be revised, the Group considered that this preliminary statement in the General Provisions was no longer necessary.

  The Group decided to create two new articles. The first to include a case definition for classical and atypical BSE. The second dedicated to safe commodities.

- Article 11.4.1bis. Case definition

  The Group considered the case definitions for classical and atypical BSE proposed by Member Countries, the recently adopted chapter on BSE of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*) (Chapter 2.4.5.), and the case definition approach used in other adopted chapters of the *Terrestrial Code*.

  The Group discussed clinical and epidemiological criteria relevant for the BSE case definitions.

  BSE is an invariably fatal disease neurological prion infection of adult cattle. However, for clarity the Group decided not to include the age of the affected cattle in the case definition and to further specify this parameter in the section of the chapter dedicated to surveillance.

  At the time of writing, atypical BSE is generally considered to occur spontaneously. As shown by the data collected by the European Commission (Figure 1), the occurrence of atypical BSE in the European Union (EU) appears to be independent of feed controls. However, further scientific evidence would be needed to formally exclude contaminated feed as a potential source of infection for atypical BSE. On the other hand, classical BSE is mainly transmitted through contaminated feed. Overall, the Group considered that clinical and epidemiological criteria should be considered during the investigation of a BSE outbreak but without laboratory confirmation would not allow for the discrimination of classical and atypical BSE.

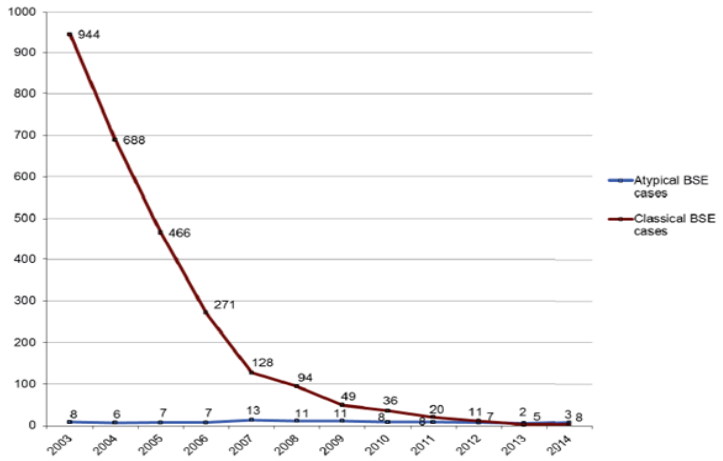

Figure 1. Evolution of the number of confirmed classical and atypical BSE cases in the EU 28 from 2003 to 2014
Source: European Commission (2014) (http://ec.europa.eu/food/safety/docs/biosafety_food-borne-disease_tse_ms-annual-report_2014.pdf)

The Group acknowledged that species other than cattle (e.g. goats) can be naturally infected with the BSE agent, however, in the presence of an effective ruminant-to-ruminant feed ban, these species are not considered to be epidemiologically significant. For the purpose of the *Terrestrial Code*, the Group recommended restricting the list of BSE susceptible species to cattle (*Bos taurus* and *B. indicus)*.

The Group pointed out that laboratory criteria were the sole basis for the differentiation of classical and atypical BSE. The Group advised that a stepwise approach should be followed for the laboratory confirmation of the infection, aiming, first, at confirming BSE, and, secondly, at distinguishing atypical and classical BSE. With regard to the laboratory tests to be performed, the Group decided to cross-reference the *Terrestrial Manual* and noted that currently only the Western immunoblot banding was recognised for the laboratory discrimination of classical and atypical BSE.

- Article 11.4.1ter. Safe commodities

The Group reviewed and endorsed the existing list of safe commodities and dedicated a sole article to safe commodities, for consistency with other chapters of the *Terrestrial Code*.

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

The current Article 11.4.2. specifies that an exposure assessment should be conducted if the entry assessment identifies a non-negligible risk of the entry of BSE into a country, zone or compartment. Considering the potential risk of recycling and amplification of atypical BSE (which is considered to occur spontaneously in all cattle populations), the Group was of opinion that an exposure assessment should be performed regardless of the outcome of the entry assessment. It was noted that in the context of official status recognition, such a change in the provisions for the exposure assessment would mean that Member Countries that may have been previously recognised as having a negligible BSE risk on the basis of an entry assessment only would now have to complement this assessment with an exposure assessment when reconfirming their official risk status (a transition period may be needed).

With regard to point 3 of Article 11.4.2., the Group specified that the notification of all cattle showing clinical signs consistent with BSE should be made to the Veterinary Authority and all cases should be subsequently investigated.

- Article 11.4.3 - Negligible BSE risk

Point 3a.: The Group clarified that the occurrence of atypical BSE would not affect the negligible risk status, provided it the animal has been completely destroyed. A reference to the case definition for atypical BSE provided in Article 14.4.1. was included.

The Group clarified why a period of seven years should apply to the provisions related to surveillance and risk assessment while a period of eight years was relevant for the provisions applicable to feed ban and prevention of cross contamination. The incubation period for classical BSE is seven years (95^{th} percentile of the incubation period). It is therefore advisable to consider an eight-year period for the feed ban since once it is implemented, an additional year is considered necessary to ensure the complete elimination of any remaining potentially contaminated feed.

Point 3b.: The Group agreed that Point 3b. of Article 11.4.3. addressing the occurrence of indigenous cases should only apply to classical BSE.

The Group questioned the provisions applicable to birth cohort animals in case of the identification of an indigenous case of classical BSE prescribed in Point 3b. iv. of Article 11.4.3. and whether any additional gain in risk reduction following the complete destruction of all cohort animals could be justified.

Some experts were of the opinion that provided measures including a feed ban and the removal and destruction of tissues listed in Article 11.4.14. had been and continue to be effectively implemented, any potential risks associated with cohort animals would be effectively eliminated so that the complete destruction of the whole cohort would not be warranted. However, the Group considered unpublished surveillance data from the European Union for the period 2008-2015. Overall, seven birth cohort animals from a total of 10,000 tested were positive. For that time period, this represented the second highest ratio of BSE cases confirmed in any of the surveillance sub-populations (fallen stock, emergency slaughtered, clinical signs at ante-mortem inspection, healthy slaughter, BSE eradication and BSE suspects).

The Group considered then the option of slaughter and testing cohort animals, and destroying the positive ones, rather than destroying the entire birth cohort, as prescribed in Point 3b. iii. The added-value of testing cohort animals as compared to destruction without testing would be to provide a broad indication of the effectiveness of control measures. While an isolated case may not necessarily reflect a breach in national level control measures, more than one infected animals in a given cohort might be indicative of shortfalls in the herd concerned. While recognising that this would indeed be of interest for the purpose of surveillance, some experts pointed out that it may have little impact on risk mitigation as it may be possible to miss animals at an earlier stage in their incubation period when they are unlikely to be positive to a test but still harbor infectivity in some tissues. While acknowledging that the levels of infectivity would be very low (below the detection threshold), the Group was of the opinion that, for the purpose of international trade, due to the presumably higher probability that some cohort animals associated with a confirmed BSE case could be infected, birth cohort animals should be destroyed and provisions of Point 3b.iv. of Article 11.4.3. should remain unchanged. On the other hand, for the purpose of monitoring the effectiveness of control measures, countries with an official BSE risk status may decide to test cohort animals. The Group therefore recommended including this aspect in the BSE surveillance streams and in the questionnaire on BSE for status recognition provided in Article 1.6.5.

- Article 11.4.4. - Controlled BSE risk

  Similarly to Article 11.4.3. and for the sake of clarity, a reference to the case definition for atypical BSE provided in the General Provisions was included in Point 3a. of Article 11.4.4.

  The Group discussed the consequences of the occurrence of an indigenous case of classical BSE detected in cattle born more than 11 years ago on the negligible BSE risk status. The Group recommended that the negligible risk status should be withdrawn but advised that a country's BSE risk status could be reclassified as controlled without delay, provided that the OIE assesses and endorses compliance with all requirements of Article 11.4.4, including the outcome of an updated risk assessment (entry and exposure).

- Article 11.4.6. - Recommendations for the importation of bovine commodities from a country, zone or compartment posing a negligible BSE risk

  The Group clarified that provisions of Article 11.4.6. for the importation of bovine commodities from countries posing a negligible BSE risk were not applicable to commodities listed as safe commodities (Article 11.4.1.) and to commodities for which recommendations were prescribed in other articles of this chapter (*i.e.* Articles 11.4.7., 11.4.10., and from 11.4.13. to 11.4.18.).

- Article 11.4.7. - Recommendations for the importation of cattle from a country, zone or compartment posing a negligible BSE risk but where there has been an indigenous case of 'classical' BSE

  The Group agreed that the recommendations provided in Article 11.4.7. should apply to the occurrence of classical BSE in cattle.

- Article 11.4.9.- Recommendations for the importation of cattle from a country, zone or compartment posing an undetermined BSE risk

  The Group concurred with the modification proposed by the previous *ad hoc* Group.

- Article 11.4.10. - Recommendations for the importation of meat and meat products from a country, zone or compartment posing a negligible BSE risk

  The Group clarified that the occurrence of indigenous BSE case(s) in countries with a negligible BSE risk relates to classical BSE (Point 3). The Group stressed the importance of the provisions in the current Code chapter recommending that cattle from which the fresh meat and meat products are destined for export should be born after the implementation of an effective feed ban. The Group advised that each country would have to determine the date at which the implementation of its feed ban can be considered effective based on adequate audit and monitoring.

  Considering that atypical BSE may have a zoonotic potential and in order to protect public health, the Group proposed a recommendation aiming at ensuring that the imported meat and meat products were not contaminated with tissues listed in the newly proposed point 4 of Article 11.4.14.

- Article 11.4.12. - Recommendations for the importation of meat and meat products from a country, zone or compartment posing an undetermined BSE risk

  The Group removed Point 2b. related to "*nervous and lymphatic tissues exposed during the deboning process*", as it was considered a safe commodity according to Article 11.4.1ter. which lists deboned skeletal muscle.

- Article 11.4.14. - Recommendations on commodities that should not be traded

  Point1: The Group reviewed EFSA's data[1] on the total infectivity of clinical case of BSE which estimates the infectivity of tonsil to be < 0.01% of the total amount of infectivity represented by the different tissues of a clinical case. The EFSA report cites the level of infectivity in tonsils to be $10^{-6.5}$ $CoID_{50}$/g, which is in the same order of magnitude as that for the peripheral nervous system (PNS). Such levels of infectivity are extremely low, so low in fact, that it would be biologically implausible to ingest a sufficient amount of tissue from an infected animal to pose a credible risk. This has been widely accepted for the PNS as it is not classified as a high risk tissue (SRM). As a result, it is reasonable to conclude that the risk posed by tonsillar tissue is negligible. The Group therefore recommended removing the restriction applicable to tonsils.

  Point 4: Considering the body of evidence related to zoonotic potential of atypical BSE, the Group concurred with the proposal made by the previous *ad hoc* Group that included brains, eyes, spinal cord and skull of older animals as the tissues that may pose a risk to public health and therefore should not be traded regardless of the BSE risk status of a country. Indeed, intracerebral inoculation studies suggested that low molecular weight type of atypical bovine spongiform encephalopathy (L-type BSE) may be more virulent than classical BSE for infecting primates (incubation periods were shorter than for classical BSE)[2] and histology and biochemistry studies showed that primates infected

[1] Source: EFSA, Scientific Opinion on the revision of the quantitative risk assessment (QRA) of the BSE risk posed by processed animal proteins, EFSA Journal 2011;9 (1):1947 (http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.1947/epdf)

[2] Baron T, Biacabe AG, Rouland S, Verdier JM and Mestre-Francés N, 2008. Transmission of atypical BSE to Microcebus murinus, a non-human primate: development of clinical symptoms and tissue distribution of PrPres. Proceedings Prion 2008 Conference. Madrid. 8-10 October 2008, 16.

with L-type BSE and MM2-cortical-type sporadic Creutzfeldt-Jakob disease (MM2 sCJD) patients exhibited similar lesion profiles[3]. Furthermore, experiments demonstrated the transmissibility of L-BSE to macaques by the oral route[4]. Finally, available collective data indicate that atypical BSE shares a similar tissue distribution to classical BSE cases with the exception of lymphoid or gastrointestinal tissues[5]. The Group agreed that this justified the definition of a limited list of most infectious tissues for countries with negligible BSE risk status in Article 11.4.14.

The Group discussed the age limit to be considered for the removal of those high risk tissues originating from a country, zone or compartment defined in Article 11.4.3. Most frequently atypical BSE occurs in cattle older than 8 years (≥ 96 months). However, based on retrospective BSE typing data from the European Commission [6], out of 112 atypical BSE cases, three cases were 6 years of age at the time of testing and another three cases were 7 years of age. Among these 112 atypical cases, the youngest animal was 75 months of age.

Although the Group agreed that overall the occurrence of cases of atypical BSE younger than 96 months was uncommon, it was of the opinion that these younger animals should be taken into consideration when setting the age limit for the purpose of trade of cattle products.

Some in the Group were of the opinion that the age limit could be based on these data (and should then be 6 years - 72 months) while others stressed that these data were based on a limited sample and that any inference should be drawn with caution (i.e. the youngest case identified in this sample might not represent the lowest possible age limit for an atypical BSE case). They therefore recommended that, in view of the precautionary principle, the age limit should be five years (60 months). In addition, they noted that, five years was also a practical threshold to determine the age of a cattle through dentition (the incisors in cattle are fully erupted by the age of five years). As, the Group did not reach a consensus on that matter, it was decided to seek the opinion of the Scientific Commission.

The Group also noted that in some countries, those high risk commodities may be used for human consumption and unanimously stressed the public health risk that may be associated with that practice.

- Article 11.4.15. - Recommendations for the importation of gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

  In order to address the risk that may be associated with atypical BSE in countries with a negligible BSE risk, the Group recommended that the skull from cattle over 60/72 months of age should be excluded. The provision to require *ante-* and *post-mortem* inspection was also added.

- Article 11.4.16. - Recommendations for the importation of tallow (other than as defined in Article 11.4.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

  The Group specified that tallow should not have been prepared using tissues listed in Article 11.4.14.

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3 Comoy E, Richt J, Durand V, Freire S, Correia E, Hamir A, Ruchoux MM, Brown P and Deslys JP, 2009. Transmission of bovine-passaged TME prion strain to macaque. Proceedings Prion 2009 Conference. Thessaloniki. 23-25 September 2009, 46.

4 Comoy E, 2010. Transmission studies in primates. Workshop on the epidemiology of human and animal TSEs. 30 April 2010, Torino, Italy. In: Food safety assurance and veterinary public health - volume 6 - Foodborne viruses and prions and their significance for public health. Eds Smulders, F.J.M., Noerrung, B. and Budka, H. Wageningen Academic Publishers The Netherlands, 2013. p. 296.

5 Source: EFSA, Scientific report on a Protocol for further laboratory investigations into the distribution of infectivity of Atypical BSE, *EFSA Journal*, 2014; **12**(7): 3798 (http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2014.3798/epdf)

6 Source: European Commission, Report on the monitoring and testing of ruminants for the presence of Transmissible Spongiform Encephalopathies (TSEs) in the EU in 2014 (http://ec.europa.eu/food/safety/docs/biosafety_food-borne-disease_tse_ms-annual-report_2014.pdf)

- Article 11.4.17. - Recommendations for the importation of dicalcium phosphate (other than as defined in Article 11.4.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices and Article 11.4.18. - Recommendations for the importation of tallow derivatives (other than those made from tallow as defined in Article 11.4.1.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

  The Group was of the opinion that tallow derivatives and dicalcium phosphate should originate from products compliant with the requirements of the relevant articles of this chapter.

3.2. Revision of the provisions of the draft chapter on surveillance (Articles 11.4.20. to 11.4.22.)

The Group discussed the need for a revision of the provisions for BSE surveillance because some of the modelling assumptions underpinning it and some of the default data used to feed the model may be outdated.

Surveillance to detect classical BSE: The Group took note of the goals of BSE surveillance listed in Article 11.4.20. and agreed that BSE surveillance provisions should not aim at detecting atypical BSE cases despite the inevitable detection of some cases during the course of surveillance for classical BSE. Given that the expected incidence of atypical BSE, based on extensive data from the EU (Figure 1), has been established (i.e. expected to be similar to the incidence of sporadic Creutzfeldt-Jakob Disease in humans (one case per million)), the Group pointed out that the detection of cases of atypical BSE is likely to be a reflection of the level of intensity of surveillance for classical BSE. The data from Europe together with observations elsewhere (Brazil, Canada, Japan and the United States of America) support the contention that atypical BSE is likely to arise spontaneously in all cattle populations at a very low rate.

New approach: The previous Group had proposed a new approach to estimate the level of the infection in the population. In that proposal, the probability of a positive test result (either classical or atypical BSE) was calculated for each age class and for the four surveillance streams (routine slaughter, fallen stock, casualty slaughter, and clinical suspect) based on a set of data from EU countries. The ratio of the probability of a positive test result to the overall probability of a positive test result was used to calculate the surveillance point value of an animal belonging to that specific age class and surveillance stream. Compared to the current surveillance point values, the proposed points place a greater weight on cattle older than seven years. As a consequence, those Member Countries that based their surveillance on younger animals may no longer comply with the surveillance requirements for the status maintenance.

Concerns were raised that the model proposed by the previous *ad hoc* Group placed too much emphasis on the increasing age of BSE cases. Increasingly older cases of classic BSE are more than likely a reflection of the effectiveness of control measures, as they reflect the tail of an extended incubation period. Ascribing considerably more weight (points) to older animals could lead to distortions in surveillance where the intensity of testing animals less than seven years of age could be curtailed. Given that an important goal of BSE surveillance continues to be monitoring its evolution (including detection of (re-)mergence) and the effectiveness of the feed ban, the existing approach might also remain valid.

Surveillance streams: The Group discussed simplifying the current four surveillance streams into two categories by considering: (i) “healthy slaughter” (i.e. routine slaughter), (ii) “at risk animals” (by merging the three current streams: fallen stock, casualty slaughter, and clinical suspect). While this approach would require the recalculation of surveillance point, this can be performed easily and transparently within the modelling framework provided by BSurvE. The Group acknowledged that it would reduce the weight of animals in the “clinical suspect” category, but considered that it would have merits as concerns were raised that some countries may be classifying more cattle as clinical suspects than could be reasonably expected. In addition, allocating animals into clinical suspects, casualty slaughter and fallen stock subpopulations can be an artificial construct, particularly in those circumstances where cattle are raised in more extensive conditions. In such cases cattle are unlikely to be

regularly scrutinised so that an animal that may have symptoms consistent with BSE may be missed only to be first see as recumbent or found dead. Such animals under the current approach would be ascribed much less value (points) than if observed as a clinical suspect. Combining clinical suspects, casualty slaughter and fallen stock into a single "risk" subpopulation provides a more reasonable and balanced approach that takes proper account of cattle rearing practices and opportunities for observation without compromising the integrity of the surveillance system.

The Group discussed a proposal that animals from the same birth cohort as an identified classical BSE case could provide a potentially new surveillance stream or, alternatively, could be included in the above-mentioned surveillance stream of "at risk animals".

Designed prevalence – Type A *vs* Type B surveillance: The Group also discussed whether the two current types of surveillance (Type A and Type B) should be maintained or if a simpler approach may be warranted with a single design prevalence.

Considering the collective goals of BSE surveillance as outlined in article 11.4.20., the Group was of the opinion that a design prevalence of one case per 50,000 would be sufficient to meet them. As a result, the Group recommended that the design prevalence for BSE surveillance should be that of Type B.

Next steps: The Group did not reach a consensus on the proposal from the previous Group and agreed that further work was required using updated data as well as revisiting previous assumptions. Results from the model described above as well as those from an updated BSurvE model would be compared and reviewed by the Group as soon as they are available and recommendations would be proposed for the revision of the provisions for BSE surveillance.

The Group drew the attention on the potential impact of the revisions of the surveillance provisions (i.e. surveillance points' values, surveillance streams, design prevalence) on Member Countries BSE risk status. If the requirements for surveillance were to be revised, the Group emphasised that it would be essential to allow for a transition period, so that countries having an official BSE risk status would be able to adapt their sampling strategy while maintaining their status.

3.3. Revision of the provisions of the draft chapter on risk assessment (Articles 11.4.23. to 11.4.29.)

The Group noted that the provisions on risk assessment (Articles 11.4.23. to 11.4.29.) were largely redundant with the questionnaire on BSE provided in Article 1.6.5. for Member Countries to apply for recognition of status and stressed that it was essential to ensure consistency and cross-referencing between these articles and Article 11.4.2.

The Group did not undertake a detailed review of the Articles related to risk assessment (11.4.23. to 11.4.29.). However, the Group proposed the following revisions:

- Article 11.4.23. - BSE risk assessment: introduction

  Regarding the entry assessment, the Group specified that point 1 b should refer to live cattle and not to live animals.

- Article 11.4.27.- The potential for the exposure of cattle to the BSE agent through consumption of meat-and-bone meal or greaves of bovine origin

  To take into consideration the risk that may be associated with small ruminants, the Group clarified that if potentially infected ruminants (*i.e*. not only infected cattle) or contaminated materials were rendered, there would be a risk that the resulting meat-and-bone meal could retain BSE infectivity.

- Article 11.4.28. - The origin of animal waste, the parameters of the rendering processes and the methods of animal feed production

  To be concise, the assumptions 1 to 4 were removed as the Group agreed this narrative was not essential for the purpose of assessing the rendering processes.

  Consistent with the recommendation of the previous Group, the Group was of the opinion that the BSE agent cannot be qualified as "*present at much higher titer*" in reticulo-endothelial tissue. In addition, the Group followed the advice of the Code Commission not to use the terminology "specified risk material" as it might be interpreted differently by different Member Countries and made references to Article 11.4.14. which defines a precise list of material.

4. Consideration on whether or not chronic wasting disease of cervids should be included in the OIE list

The Group was reminded that only the criteria for the inclusion of diseases, infections and infestations in the OIE list defined in Chapter 1.2 of the *Terrestrial Code* should be taken into consideration for listing/delisting any disease.

Dr Marija Popovic, representative of the OIE World Animal Health Information and Analysis Department, presented the most recent developments of the epidemiological situation of chronic wasting disease (CWD) in cervids. While endemic cases had previously only been reported in North America, three cases of CWD have been notified in Norway in 2016. The origin of these cases has not yet been elucidated.

The Group evaluated CWD against the criteria listed in Article 1.2.2.

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

   In 2001 and 2004, cases of CWD were reported in the Republic of Korea due to the import of elks infected with CWD from North America. This illustrates the potential for international spread of CWD via the trade of live animals.

2. Second criteria: *"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. "*

   According to the information made available to the Group, some countries implement an active surveillance program for CWD. However, in the absence of detailed information on these surveillance programmes, the Group felt it was difficult to assess if these countries should be regarded as free based on the provisions of Chapter 1.4.

   The Group took note of an EFSA scientific opinion on the results of an EU survey for CWD in cervids[7]. This survey was carried out in 2006-2010. Approximately 13,000 samples were collected in 21 EU Member States and Norway. No CWD positive results were found. However, EFSA concluded that the absence of positive cases in that survey could not exclude the presence of CWD infected animals.

   The Group was informed that an updated EFSA's scientific opinion on CWD should be published in two phases, the first phase by the end of 2016 and the second phase by the end of 2017. The Group recommended that a literature review should be carried out to further assess demonstration of freedom for CWD by some Member Countries and advised waiting for EFSA's opinion on this matter.

3. Third criteria: *"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 and infestations."*

   The Group noted that there is no accredited commercially available test available to diagnose the presence of the disease in live animals. The identification of the agent relies on post mortem testing. However, the Group felt that a more in depth review of scientific evidence would be necessary to properly assess this issue.

[7] EFSA, Scientific Opinion on the results of the EU survey for Chronic Wasting Disease (CWD) in cervids. EFSA Journal 2010;8(10):1861 (http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2010.1861/epdf)

4. Fourth criteria

4a) "Natural transmission to humans has been proven, and human infection is associated with severe consequences"

To the best knowledge of the Group, there is no demonstrated evidence of transmission of the CWD agent to 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."

It was clarified that according to OIE terminology, cervids should be considered as wildlife, and the impact of CWD should be assessed against criteria 4.c.

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."

The Group questioned at what level the impact on the health of wildlife should be considered "significant". The Group agreed that the disease can cause significant mortality at the farm or local level but does not have a significant impact at either the national or regional level at this stage. A significant concern in North America is associated with potential spill-over into the densely populated wild caribou (reindeer) herds as CWD continues its relentless spread. If this were to occur it is likely there would be significant impacts at a regional level. The Group recommended that a literature review be performed to further analyse this criteria.

In conclusion:

The Group acknowledged the potential for CWD's international spread but felt that there were gaps in the Group's knowledge on CWD, especially regarding the demonstration of freedom (criteria 2), the means of detection and diagnosis and the case definition (criteria 3), and the impact on the health of wildlife (criteria 4c). The Group recommended that a literature review should be conducted and subject matter and wildlife experts contacted to further assess these criteria before elaborating any recommendation regarding the relevance of CWD's inclusion in the OIE list.

5. Finalisation and adoption of the draft report

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

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…/Appendices

Appendix I

MEETING OF THE OIE AD HOC GROUP ON
BOVINE SPONGIFORM ENCEPHALOPATHY (BSE)
Paris, 23-25 August 2016

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Agenda

1. Opening
2. Adoption of the agenda and appointment of chairperson and rapporteur
3. Review and update of the existing chapter on BSE in the Terrestrial Code
   - 3.1. Revision of the draft chapter (Articles 11.4.1. to 11.4.19.)
   - 3.2. Revision of the provisions of the draft chapter on surveillance (Articles 11.4.20. to 11.4.22.)
   - 3.3. Revision of the provisions of the draft chapter on risk assessment (Articles 11.4.23. to 11.4.29.)
4. Consideration on whether or not chronic wasting disease of cervids should be included in the OIE list
5. Finalisation and adoption of the draft report

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Appendix II

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY

Paris, 23-25 August 2016

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List of participants

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Annex 16

REPORT OF THE

JOINT MEETING BETWEEN THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

AND THE OIE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSION

Paris, 8 September 2016

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A joint meeting of the Scientific Commission for Animal Diseases (Scientific Commission) and the Terrestrial Animal Health Standards Commission (Terrestrial Commission) was convened at the OIE Headquarters in Paris on 8 September 2016. The participants are listed in Appendix I. The meeting was chaired by Dr Monique Eloit, Director General of the OIE.

The Director General welcomed the members of both Commissions, and introduced Dr Matthew Stone as new Deputy Director General and Ms Ann Backhouse as new Head of the Standards Department (formerly known as the International Trade Department).

The Director General informed the Commissions that the Headquarters has taken action to address requests previously made by the Member Countries: 1) the direct access to *ad hoc* group reports on the OIE website and 2) the alignment of *Codes* and *Manuals* with the adoption and revision dates.

The Presidents of both Commissions welcomed and commended the work being undertaken.

Summary of the discussions

1. Issues of mutual interests (*Terrestrial Code*)

a) Glossary

The President of the Code Commission advised that an overall review of the glossary was being undertaken to address the lack of consistency in the definition and application of defined terms within the *Terrestrial Code*. For example, some defined terms are not used or not italicised within the chapters or their use in the *Terrestrial Code* does not differ from the common dictionary definition. He indicated a step-by-step approach would be used, noting that the first step would be proposing some deletions and editorial amendments, and then amending definitions together with the related revised chapters.

Acknowledging that the term "pathogenic agent" was not uniformly used throughout the *Terrestrial Code* and that some other terms were used for the same concept, he indicated the intention of the Code Commission to harmonise this wording by proposing a new definition.

The President of the Scientific Commission suggested that the two Commissions work in parallel on the definition of 'zoning' and 'compartmentalisation', as it would impact the disease status recognition.

b) Horizontal chapters

i) Chapter 1.4. Animal health surveillance

Given the cross-cutting nature and importance of Chapter 1.4., and the request of some Member Countries to revise the content and structure of the chapter, it was agreed to suggest that OIE Headquarters convene an *ad hoc* group to review this chapter, based on the revised version drafted by the Code Commission that includes comments already sent by Member Countries.

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

The President of the Scientific Commission advised that the questionnaires related to official recognition of disease status were still in revision. Given on the one hand the importance and impact of these questionnaires, and on the other hand the need to update them very frequently, the Code Commission committed to consider the updated questionnaires provided by the Scientific Commission at its February 2017 meeting with the aim of proposing a solution for Chapter 1.6. for adoption in May 2017.

iii) Chapter 2.X. Draft new chapter on criteria for assessing the safety of commodities

The President of the Code Commission advised that the draft chapter would be proposed for adoption at the General Session in May 2017. The Code Commission pointed out that the purpose of this chapter was to guide *ad hoc* Groups and Specialist Commissions in the process of evaluating the safety of certain commodities rather than to provide guidance to Member Countries to assess the safety of commodities.

iv) Chapter 4.3. Zoning and compartmentalisation

Since the *ad hoc* Group on FMD and the Scientific Commission proposed new concepts for zoning when working on the FMD chapter (see below point c)i), their proposals will be incorporated into the current revision of Chapter 4.3. and the related definitions of the Glossary. Given the importance of the change, the Code Commission will not propose them for adoption in 2017.

v) Proposal to draft a chapter on outbreak management

The President of the Code Commission advised that preliminary work was being conducted to develop a new chapter on outbreak management. The President of the Scientific Commission welcomed the initiative and suggested considering the OIE Guidelines for Animal Disease Control as the basis for the future chapter. The President of the Code Commission assured that this was already the case, and that the FAO/OIE Guidelines on Good Emergency Management Practices had also been considered.

vi) Chapter 6.7. Harmonisation of national antimicrobial resistance surveillance and monitoring programmes

The President of the Code Commission advised that Chapter 6.7. was under revision, to take into consideration the comments provided by the Scientific Commission and the *ad hoc* Group on Antimicrobial Resistance. He added that considering the nature of the modifications it would be necessary to circulate the proposed amendments to Member Countries before proposing them for adoption.

vii) HHP Veterinary Certificates drafted by an ad hoc expert group

The President of the Code Commission advised that the newly drafted HHP Veterinary Certificates would be reviewed to ascertain their consistency with Chapter 4.16. on high health status horse subpopulation, and that Chapter 4.16. will be updated to include the correct reference to the HHP Handbook.

c) Disease-specific chapters

i) Chapter 8.8. Infection with foot and mouth disease virus

The Vice-President of the Scientific Commission provided an update of the most significant modifications proposed on Chapter 8.8. and referred to the report of the *ad hoc* Group on FMD for more details on the newly developed concepts (e.g. compartment with vaccination, larger containment zone, movement of vaccinated animals). The modifications may impact some of the *Terrestrial Code* horizontal chapters (e.g. Chapter 4.3. and glossary) and, therefore, it would be necessary to ensure consistency should the new and amended concepts be adopted.

ii) Chapter 8.X. Infection with *Mycobacterium tuberculosis* complex

The President of the Scientific Commission advised that OIE experts were contacted to explore the existence of a validated tuberculosis test on goats to substantiate that an individual goat is free from tuberculosis. He also indicated that no further evidence was available on the role of New World camelids in the epidemiology of the disease. The Code Commission noted that it had also sought advice on the same questions from the Biological Standards Commission (Laboratories Commission) and received feedback, showing that under some circumstances New World Camelids may play a role.

iii) Chapter 8.13. Infection with rabies virus

The Commissions discussed the need to update Chapter 8.13. Infection with rabies virus and agreed on the need for updating and recommended the Director General convene an *ad hoc* group to undertake the revision, considering the recommendations made during recent international and global conferences on rabies.

iv) Chapter 11.4. Bovine spongiform encephalopathy (BSE)

The President of the Scientific Commission advised that the *ad hoc* Group on BSE had extensively revised this chapter to include case definitions, differentiation of classical and atypical BSE and review the articles on surveillance.

iv) Chapter 11.11. Lumpy skin disease

The Commissions discussed the revision of Chapter 11.11. including a new article on recovery of freedom and agreed that the revised chapter would be circulated for Member Countries' comments with a view to adopting it at the General Session in May 2017.

v) Chapter 12.10. Infection with *Burkholderia mallei* (Glanders)

The President of the Scientific Commission advised that a new article on surveillance had been drafted as requested by Member Countries.

The Commissions discussed the difficulty of demonstrating country or zone freedom in light of very low prevalence of the disease and the low specificity of the test.

vi) Chapter 15.1. Infection with African swine fever virus

The Commissions discussed the revision of Chapter 15.1. on ASF in light of the recent adoption of a revised Chapter 15.2 on CSF. It was agreed that based on the nature of the comments this chapter may be proposed for adoption at the General Session in May 2017.

vii) Chapter 15.2. Infection with classical swine fever virus

The Commissions agreed that the diagrams on diagnostic tests currently included in the *Terrestrial Code* should more appropriately be included in the *Terrestrial Manual* and referred this topic to the Laboratories Commission for its consideration.

viii) Chapter 15.X. Draft chapter on Infection with porcine reproductive and respiratory syndrome virus

The Commissions discussed and agreed that fresh meat should be considered as a safe commodity as proposed by some Member Countries that provided strong arguments.

ix) Chapter 10.4. Infection with avian influenza viruses

The President of the Code Commission advised that scientific information on inactivation of AI virus in egg products had been received and would be considered when reviewing the relevant article. The Commissions discussed the need for an overall review of the chapter in view of the difficulties encountered by Member Countries in applying the recommendations of the chapter and the impact on trade of the notification of low pathogenic avian influenza. The Commissions agreed that the revision of this chapter should be included in their work programmes.

2. Other issues

a) Coordination of Commissions' work

The Director General explained the new concept of a common Secretariat encompassing the secretariats of the four Specialist Commissions that would be implemented progressively in the OIE.

Dr Stone added that the Headquarters was internally examining the role and functions of the Secretariats across all expert groups and Specialist Commissions, including the role each of them could play to better assist the Commissions. He added that as a starting point, Headquarters would establish a set of principles for the Secretariat functions and promote effective communications between the Commissions and with Headquarters' staff to ensure a succinct capture of discussion and rationale.

Both Commissions suggested that Headquarters consider the publication of both Commissions' reports on the OIE website in a coordinated manner to facilitate the communication with Member Countries. The President of the Code Commission suggested that Headquarters conduct a preliminary screen of Member Countries' comments to identify the issues which should be addressed by the Scientific Commission. This would also enhance the effectiveness of exchange of information between the Commissions.

3. General information

a) Recent & upcoming *ad hoc* group meetings

The Commissions summarised the upcoming *ad hoc* groups and agreed to advise the Director General to convene two additional groups on animal health surveillance and on rabies.

b) *Terrestrial Code* chapters that may be proposed for adoption during the 85th General Session

The President of the Code Commission confirmed that draft chapters to be proposed for adoption in May 2017 would be indicated in the September 2016 meeting report to give Member Countries more time to consider their content and implementation details ahead of adoption.

4. Updating Commissions' work programme

The Commissions shared with each other their updated work programmes.

5. Dates of next meetings

The Commissions agreed to keep the dates of their February meetings as previously planned.

Appendix I

List of participants

The Scientific Commission:

Dr Gideon Brückner, President of the Scientific Commission

Dr Kris de Clercq, the 1st Vice-President

Dr Baptiste Dungu, Member

Dr Silvia Bellini, Member

Dr Juan Antonio Montaño Hirose, Member

The Code Commission:

Dr Etienne Bonbon, President of the Code Commission

Pr Stuart MacDiarmid, Vice-President

Dr Gaston Maria Funes, Vice-President

Pr Salah Hammami, Member

Dr Emmanuel Couacy-Hyman, Member

Dr Masatsugu Okita, Member

OIE Headquarters:

Dr Monique Eloit, Director General of the OIE

Dr Matthew Stone, Deputy Director General of the OIE

Dr Ann Backhouse, Head of the Standards Department

Dr Elisabeth Erlacher-Vindel, Head of the Science and New Technologies Department

Dr Laure Weber-Vintzel, Head of the Status Department

Dr Gillian Mylrea, Deputy Head of the Standards Department

Dr Tomoko Ishibashi, Senior Manager, Standards Development and Horizontal Management Framework

Dr Leopoldo Humberto Stuardo Escobar, Chargé de mission, Standards Department

Dr Gregorio José Torres, Chargé de mission, Science and New Technologies Department

Dr Jae Myong Lee, Chargé de mission, Standards Department

Work programme of the scientific commission for animal diseases (sept. 2016)

Topics	Progress before Sept 2016 SCAD meeting	Summary of agenda items	SCAD decision Sept 2016	Future action plan	Priority 1 = top priority
Terrestrial Animal Health Code Chapters					
Glossary: Zone, free zone, containment zone, protection zone	Circulated for comments after Feb. 2016 TAHSC meeting	Review Member Country comments on the amended definitions related to zoning and compartmentalisation	Revision of the concepts should be in line with the revision of Chapter 4.3 on zoning and compartment and proposed amendments to the FMD chapter. Proposed amendments sent to TAHSC	Follow up	1
Ch. 1.4 Animal Health Surveillance	Circulated for comments after Feb. 2016 TAHSC meeting	Review Member Country comments to the amended chapter	To further discuss the need for convening an AHG for full revision	Proposal for an AHG to review the chapter	1
Ch. 1.6 Procedures for self-declaration and official recognition	The disease-specific questionnaires for official recognition were amended by the responsible AHGs and harmonised by OIE HQ		Endorsed with minor modifications. SCAD members to submit their comments electronically following the meeting	The integration in *Terrestrial Code* to be discussed with TAHSC in Feb. 2017.	1
	Review the procedures for self-declaration			The procedures for self-declaration to be further reviewed, as well as the structure and content of Chapter 1.6.	2
Ch.2.X on Criteria for assessing safe commodities	The TAHSC drafted a new chapter on safe commodities that was discussed and endorsed by SCAD	For SCAD information	Draft chapter reviewed and supported by SCAD	Follow up	2
Chapter 4.3 zoning and compartmentalisation	The TAHSC amended the chapter and circulated for Member Country comments. The AHG on FMD also provided its opinion on definitions	Review amended chapter and AHG opinion	The new definitions discussed by the AHG on FMD should be considered when revising Chapter 4.3.	Coordinate the revision with the FMD chapter	1
Ch. 8.8 Infection with foot and mouth virus	AHG convened in June 2016 and proposed changes to relative Articles	Revise pending issues (compartment, containment, movement of vaccinated animals, etc.) discussed by the AHG	Proposed modifications and sent to TAHSC	Further elaborate the new concepts Further work by AHG on review of alternatives for recovery period	1 1

Topics	Progress before Sept 2016 SCAD meeting	Summary of agenda items	SCAD decision Sept 2016	Future action plan	Priority 1 = top priority
Ch. 8.X *Mycobacterium tuberculosis* complex	Circulated for comments after Feb. 2016 TAHSC meeting	Review Member Country' comments	Proposed amendments and sent to TAHSC	Follow up	1
Ch 8.X *Trypanosoma evansi* **Ch 12.3 Dourine**	AHG convened June 2016	Review the draft chapter on Surra and amend the Chapter 12.3 on dourine proposed by the AHG	Revised two chapters, agreement on the scientific content but not on its structure	OIE HQ to restructure the chapter	2
CH. 8.13 Infection with rabies virus		Evaluate the need of updating the chapter	Chapter should be revised based on recommendations of Global conferences	Request DG that an AHG be convened	1
Ch. 11.11 Lumpy skin disease	The chapter was extensively amended in January 2016. Circulated for comments after Feb. TAHSC meeting 2016	Review Member Country Comments on the amended chapter	Proposed amendments and sent to TAHSC	Follow up	1
Ch. 11.4 BSE	The AHG (August 2016) amended the chapter to exclude atypical BSE and review the surveillance articles	Review the amended chapter considering the Member Country comments made during the 84 GS to consider the impact of atypical BSE	Endorsed case definition. Proposed amendments and sent to TAHSC and requested that interim changes be considered and not wait for revision of surveillance Articles Surveillance revision to be continued	Follow up Ongoing	1 1
Ch. 11.12 Theileriosis				AHG to revise the chapter be convened	2
Ch. 12.10 Glanders	OIE experts consulted to draft Articles on surveillance	Revise the draft Article on surveillance proposed by OIE experts	Proposed amendments and sent to TAHSC	Follow up	1
Ch. 15.1 African swine fever	Circulated for comments after Feb. TAHSC meeting 2016	Review Member Countries Comments	Proposed amendments and sent to TAHSC. SCAD agreed on need to continue process to harmonise ASF and CSF chapters	Follow up	1
Ch 15.2 Classical swine fever	Draft chapter amended by the AHG (July 2016)	Review the proposal made by the AHG.	Proposed amendments and sent to TAHSC. See comments ASF	Follow up	1

Topics	Progress before Sept 2016 SCAD meeting	Summary of agenda items	SCAD decision Sept 2016	Future action plan	Priority 1 = top priority
Ch. X.X Vaccination	Two AHGs meetings were organised to draft this chapter. During the Feb. meeting BSC, SCAD and TAHSC endorsed the outline proposed by the AHG. The AHG finalised the draft chapter during it last meeting	Review the draft chapter proposed by the AHG	Draft chapter sent to TAHSC	Follow up	1
Ch. X.X PRRS	Circulated for comments after Feb TAHSC meeting 2016	Review Member Country Comments	Proposed amendments and sent to TAHSC	Follow up	2
Equine disease chapters revision		Consider the revision of equine disease chapters	Request harmonisation by HQ	Follow up	3
Ad hoc Group (AHG) and Working Group on Wildlife					
AHG on Antimicrobial Resistance	The AHG convened to provide advice to the OIE on how to combat antimicrobial resistance through a One Health approach. The Group proposed a data collection system on the use of antimicrobial agents in animals	Review the AHG report	AHG report revised	Ongoing. Next meeting Jan. 2017 (data collection, chapter on surveillance)	1
Working Group on Wildlife	Review the information and advice on health problems that involve wild animals	Review the next meeting agenda	Agenda revised with minor modifications	Ongoing	1
Official Disease Status Recognition					
Evaluation of Member Country dossiers	NA	NA	NA	For SCAD Feb. meetings	1
Experts missions to Member Countries	Field mission conducted	Review the outcome of the mission conducted in Bolivia, Paraguay and Mexico	The need of other in-country missions discussed	Consider the deployment of other missions	1
Follow up of Member Countries with official disease status or with suspended status	Ongoing	Review the situation and progress made in countries under specific scrutiny	Situation in the listed countries revised	Follow up	1
Review of– annual reconfirmations	Ongoing	Identify countries for a comprehensive review of their annual reconfirmation	Countries for comprehensive SCAD review in Feb. 2017 selected	Comprehensive review of the selected annual reconfirmations in Feb. 2017	1

Topics	Progress before Sept 2016 SCAD meeting	Summary of agenda items	SCAD decision Sept 2016	Future action plan	Priority 1 = top priority
Publication in the website of maps showing the official zonal freedom recognition	Done in June 2016			To be updated regularly by OIE HQ	1
Harmonisation the requirements in the *Terrestrial Code* Chapters for official disease freedom (OIE HQ)	to be planned	to be planned		Follow up the progress made by OIE HQ	3
Identification of PVS Critical Competences relevant for endorsement of official control programme and official status recognition		Consider the PVS tool during the assessment for the official status recognition	OIE HQ to identify the cc that may be relevant for disease status recognition	Follow up the progress made by OIE HQ	3
Liaison with other Commissions					
TAHSC	Ongoing	Discuss issues of common interest	Joint meeting celebrated		1
BSC	Ongoing	Update on the proposal for replacement International Standard Bovine Tuberculin Update of the *Terrestrial Manual* chapter on lumpy skin disease	Request financial support from public and private partnerships to support		1 1
Global Control/Eradication Strategies					
Global eradication of PPR	Ongoing	Update of the progress made		Follow up	2
Global control of FMD	Ongoing	Update of the progress made		Follow up	2
Evaluation of applications for OIE Collaborating Centre status					
Senegal application	Modification in the application made by the Senegal	Evaluation application made by Senegal	Recommended its approval by the OIE Council	Follow up	1
MC's application		Evaluation application made by MC	Propose the applicant address their application to Codex	NA	NA

Topics	Progress before Sept 2016 SCAD meeting	Summary of agenda items	SCAD decision Sept 2016	Future action plan	Priority 1 = top priority
Follow up of conferences, meeting, mission with impact in the OIE mandate					
Updated on events relevant to the SCAD mandate	Ongoing	Follow up the events relevant to the SCAD mandate			1
Disease/infection specific issues					
FMD	Request sent by a Member Country on the use of combination of FMD vaccines	Provide advice on the combination of FMD vaccine with other agents	Expert opinion provided		
MERS-CoV	Case definition was drafted by an expert	Revise the case definitions of MERS-CoV infection in camels	Request opinion of member of the AHG on camelids	Follow up	3
Chronic wasting disease of cervids	After the adoption of Chapter 1.2 and latest spread of the disease, one Member Country request evaluate the disease against the criteria to be included in the OIE list	Consider the AHG BSE opinion that evaluated if the disease match the listing criteria	Request Wildlife WG opinion	Follow up	2
Rinderpest eradication	Ongoing	Update on the elimination of rinderpest virus material activities		Follow up Revised the proposal to modify Resolution No. 18 (79 GS, May 2011).	3 2
Avian Influenza	Ongoing	Member Countries request to evaluate if the chapter is updated according the latest scientific knowledge about the disease. Assess the impact of LPAI on international trade	Discussed with TAHSC	Follow up	2
Biological threat reduction	Ongoing	Update on the activities related to biological threat reduction		Follow up	2