WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future

Original: English
September 2019

REPORT OF THE MEETING

OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 9–13 September 2019

———

A meeting of the OIE Scientific Commission for Animal Diseases (the Commission) was held at OIE Headquarters in Paris, France, from 9 to 13 September 2019.

1. Welcome

Dr Matthew Stone, OIE Deputy Director General International Standards and Science, welcomed the members of the Commission and thanked them, their institutions and their governments for making their expertise and time available to support the OIE's work.

Dr Stone provided the Commission with a brief overview of the development of the draft 7th Strategic Plan, noting its focus on scientific expertise and the use of multidisciplinary evidence in standard setting and capacity building; ensuring the OIE is a good partner, and targets collaborations for impact; improving monitoring and evaluation to demonstrate performance across our strategies, programmes and projects; and the development of internal data management, stewardship and governance practices that support the ongoing digital transformation of the OIE. He also provided a brief update on the culmination of the design phase of the OIE Observatory project; the OIE-WAHIS development project; and the ongoing work on the OIE Reference Centre system.

Dr Stone noted that the OIE's continuous improvement approach to ensuring good coordination across all the Specialist Commissions through the internal mechanism of the Common Secretariat is maturing and demonstrating its benefits. The recent focus had been on identifying and supporting discussions between Commissions on common issues. He finished his opening remarks by reassuring members that the OIE's performance management system for Specialist Commissions was providing very useful feedback, and all parties could now appreciate the process was important to optimise the performance of the elected Commissions and the OIE Secretariat working in partnership.

2. Adoption of the agenda

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

3. Feedback from the 87th General Session

Dr Zepeda briefed the Commission on the 87th General Session of the World Assembly of OIE delegates, including the positive feedback received on the presentation made on the work of the Commission. The benefit of having meetings with Members during the General Session to discuss issues related to official diseases status recognition was noted. Such meetings should be encouraged but would require high prioritisation to utilise the limited time available during the General Session.

4. *Terrestrial Animal Health Code*

4.1. Member comments received for SCAD consideration

a) Chapter 1.3. Diseases, infections and infestations listed by the OIE (Article 1.3.1.)

The Commission agreed with a Member proposal suggesting that diseases listed in Chapter 1.3. and volume two of the *Terrestrial Animal Health Code* (*Terrestrial Code*) should be aligned.

The Commission highlighted the need for a better definition of multiple species for the purpose of the *Terrestrial Code* and recommended that all species that play a significant role in the epidemiology of a disease be listed under the case definition in the disease-specific chapters. Chapter 1.3. of the *Terrestrial Code* should be amended accordingly.

In response to a Member, the Commission noted that no case definition is provided for equine encephalomyelitis (Eastern and Western) and Venezuelan equine encephalomyelitis in the *Terrestrial Code*. The Commission was of the opinion that, if a disease matches the listing criteria of Chapter 1.2. of the *Terrestrial Code*, it should have a dedicated chapter, which should provide a clear case definition to support the notification obligation of Members. The Commission recommended that, for listed diseases without a dedicated chapter in the *Terrestrial Code*, the relevant OIE Reference Centres or subject-matter experts should be contacted, to develop a case definition. The Biological Standards Commission should also be involved in the process.

The Commission invited OIE Headquarters, in consultation with the relevant Specialist Commissions, to develop a strategy to address this issue.

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

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

The Commission addressed the Member comments received on the amended chapter that was circulated for the third time after the Specialist Commission meetings in February 2019.

The Commission noted a Member comment requesting clarity on the established procedure for the publication of a self-declaration (Standard Operating Procedure, SOP), particularly related to addressing the provisions on surveillance. The Commission clarified that in the absence of specific requirements or unless otherwise specified in the disease-specific chapter for freedom from a particular disease, provisions in the relevant horizontal chapters of the *Terrestrial Code* should be applied. The requirements of a disease-specific chapter provide the clearest framework for interpretation of compliance by adding specificity to requirements in a horizontal chapter. If the scope of a self-declaration is based on historical freedom, unless specified differently in the specific chapter, the self-declaration of a Member should provide a description of its surveillance in accordance with Article 1.4.6. point 2. b) without formally applying a pathogen-specific surveillance programme. The Commission recommended that OIE Headquarters clarify the guidance for self-declarations made on the basis of historical freedom in the SOP.

Similarly, the Commission added that unless the disease-specific chapter specifies the criteria on the establishment of compartments, the horizontal chapters (i.e. Chapters 4.4. and 4.5. of the *Terrestrial Code*) would apply for the self-declaration of disease freedom of a compartment.

In response to Member comments on the overall objective of having an official control programme for dog-mediated rabies endorsed by the OIE when there is currently no procedure for official recognition of animal health status, the Commission highlighted that the purpose of this endorsement process is for Members to progressively improve on their public health situation related to dog-mediated rabies, and to eventually make a self-declaration as a country or zone free from dog-mediated rabies. This mechanism is considered a good tool to support and contribute to the Global Strategic Plan to end human deaths from dog-mediated rabies by 2030, and in response to Members' requests to have an international recognition procedure for their progress towards the 2030 goal.

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

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

c) Chapter 8.11. Infection with *Mycobacterium bovis* and *M. caprae*

In light of comments from several Members asking to reinstate *M. tuberculosis* as part of the *Mycobacterium tuberculosis* complex, and acknowledging that available scientific evidence led experts to contradictory opinions on the possibility of transmission of *M. tuberculosis* from animals to humans or other animals, the Commission recommended placing the delisting of *M. tuberculosis* on hold while waiting for new information to become available.

The Commission agreed to reconsider the listing or delisting of *M. tuberculosis* at its September 2020 meeting, and invited Members to provide new scientific evidence as it becomes available.

The Commission referred to its opinion of 2013 that, if the chapter includes goats as an epidemiologically important susceptible species, it should include provisions for country or zone free from infection in goats. In addition, the Commission noted that scientific evidence showing infection and transmission of *M. caprae* in sheep has been reported,[1] and recommended consultations with the OIE Reference Laboratory experts on whether or not sheep should be added to the list of susceptible species for the purpose of the *Terrestrial Code*.

The Commission noted that the term 'New World camelids' would be better replaced with 'South American camelids', as it is used in other chapters (e.g. Chapter 8.8.). Given that South American camelids were added to the list of susceptible species, the chapter should be reviewed to include them wherever relevant, including in provisions for country freedom.

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

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

d) Chapter 8.15. Infection with Rift Valley fever virus

The Commission discussed the Member comments on the amended chapter that was circulated for the first time after the February 2019 Specialist Commission meetings.

The Commission emphasised that the OIE, in addition to amending the *Terrestrial Code* to improve notification, should also continue to be active in supporting its Members to control the disease through training and technical support.

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

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

e) Chapter 14.7. Infection with peste des petits ruminants virus (Articles 14.7.3. & 34.)

The Commission noted that Chapter 14.7. was first circulated to Members as a model chapter for presenting the work undertaken on the harmonisation of provisions for the official recognition of disease status, for the endorsement of official control programmes, and for their maintenance of freedom as it was the most recently adopted chapter and there had been no ongoing or pending issues since its adoption.

The Commission addressed the Member comments received on the amended chapter that was circulated for the first time after the Specialist Commission meetings in February 2019.

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

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

---

[1] Villarreal-Ramos B., Berg S., Whelan A., Holbert S., Carreras F., Salguero F. J. [...] & Gordon S.V. (2018). – Experimental infection of cattle with *Mycobacterium tuberculosis* isolates shows the attenuation of the human tubercle bacillus for cattle. *Sci. Rep.*, **8** (1), 894. doi:10.1038/s41598-017-18575-5.

4.2. Other considerations

a) Draft Chapter 8.Y. Infection with animal trypanosomes of African origin (Articles 8.Y.3. & 8.Y.6.)

In response to expert opinion received after the February 2019 meeting, the Commission reiterated its position not to recommend the importation of live animals from infected countries. The Commission clarified that if susceptible animals from countries or zones infected with animal trypanosomes of African origin were introduced, the importing country or zone would lose its disease freedom status. In addition, the Commission noted that, if susceptible animals from a free country or zone transit an infected zone, measures need to be taken to ensure that they are not exposed to any source of infection during transportation.

The opinion of the Commission was forwarded to the Code Commission for its consideration.

b) Draft revised Chapter 10.4. Infection with avian influenza viruses (outcome of the 3rd *ad hoc* Group meeting on avian influenza: 11–13 June 2019)

The Commission commended the work performed by the *ad hoc* Group that was convened to undertake a revision of Chapter 10.4. of the *Terrestrial Code*, and considered the report and the amended chapter that had been drafted.

The Commission agreed with the *ad hoc* Group that continued monitoring of any haemagglutinin subtype of low pathogenicity avian influenza (LPAI) should be recommended and that monitoring of H5 and H7 LPAI in poultry is justified to support freedom from high pathogenicity avian influenza (HPAI).

The Commission noted the *ad hoc* Group's restating of the fact that the absence of the disease and infection could be effectively demonstrated, even after vaccination, if adequate surveillance is in place and recommended a review of the surveillance articles of the chapter, taking into consideration the use of a differentiating infected from vaccinated animals (DIVA) approach.

The Commission agreed with the *ad hoc* Group proposal to reduce the minimum recovery period to 28 days (i.e. two flock-level incubation periods), provided that it is supported by surveillance to demonstrate the absence of infection, in accordance with provisions in Chapter 1.4. and the relevant articles of Chapter 10.4. of the *Terrestrial Code*.

The Commission mentioned that in light of the changes to the proposed chapter, the definition of LPAI should also refer to the *Terrestrial Manual* as is the case for HPAI.

c) Harmonisation of requirements for disease free status recognition and maintenance in disease-specific chapters

i. <u>Chapter 15.2. Infection with classical swine fever virus (Articles 15.2.2. & 3.)</u>

The Commission disagreed with Member comments proposing to remove the draft articles on direct transfer of pigs within a country from an infected zone (15.2.6bis.) and from a containment zone (15.2.6ter.) to a free zone for slaughter. These provisions not only reference the procedure for the inactivation of the virus, but also provide measures to be implemented to prevent the spread of classical swine fever (CSF) virus within the country without jeopardising the status of the free zone.

The Commission mentioned that for the purpose of the *Terrestrial Code*, description of the incubation period of 14 days was sufficient and proposed to delete the mention on infective periods. The description of infective periods was suggested for inclusion in the *Terrestrial Manual*.

With regard to the harmonisation of requirements for disease free status recognition and maintenance, the Commission agreed to merge Articles 15.2.2. and 15.2.3. deleting the redundant provisions already described under Chapter 1.4. and keeping the remaining provisions in a single article.

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

ii. Other provisions for harmonisation: containment zone, recovery of status

A general overview on the comparison of containment zone and recovery of status articles was presented to the Commission by the OIE secretariat for the diseases that are part of the official recognition procedure.

The Commission suggested that the containment zone articles in the specific chapters for the diseases that are part of the official recognition procedure should be aligned with Article 4.4.7., which was more recently adopted by the World Assembly of OIE Delegates in May 2018.

The Commission discussed the current provisions for the establishment of a containment zone within a foot and mouth disease (FMD) free country or zone, and made note that a stamping-out policy should not be the only option. Effective emergency control strategies aimed at eradicating the disease, as stated in Article 4.4.7., would be acceptable as long as the alternative measure would be as effective as the stamping-out policy. The amended article, making reference to and deleting the provisions already covered in Article 4.4.7. and adding the description of the consequences when an outbreak occurs in the protection zone following the option under Article 4.4.7. point 4. b) of the containment zone, was referred to the Code Commission.

Furthermore, while reviewing Chapter 14.7. on PPR, the Commission suggested that the applicability of an alternative policy to stamping-out should be further assessed for PPR by the *ad hoc* Group. For Chapter 15.2. on CSF, the Commission considered the current provisions in Article 15.2.5. appropriate for the disease.

d) Information paper on a new approach to the consistent use of the terms 'diseases', 'infection' and 'infestation' in the OIE *Terrestrial Code*

The Commission was updated on the Code Commission's approach to the commonly used terms 'disease', 'infection' and 'infestation' in the OIE *Terrestrial Code*.

The Commission was informed that, as a general principle, the term 'disease', is to be used throughout the *Terrestrial Code* to refer to general aspects pertaining to the expression, epidemiology and transmission of pathogenic agents, whereas the terms 'infection' and 'infestation', which are defined terms, are to be used in more specific contexts relating to cases, incursion, outbreaks, control and eradication.

The Commission highlighted that, for the purpose of the *Terrestrial Code*, freedom from disease means freedom from infection or infestation.

e) Revision of the definitions for Competent Authority, Veterinary Authority and Veterinary Services

The Commission was updated on the proposed revisions by the Code Commission on the current definitions for Competent Authority, Veterinary Authority and Veterinary Services in the glossary of the *Terrestrial Code*. The Commission was informed that the OIE Secretariat is seeking input from all Specialist Commissions reviewed the proposed definitions in relation to the Commission's work and the relevant standards, and also considered any consequences these amendments may have in the implementation of OIE standards.

f) Definition of epidemiological unit for the purpose of the *Terrestrial Code*

In response to a Code Commission request on the definition of an epidemiological unit for the purpose of the *Terrestrial Code*, the Commission noted the relevance of retaining the definition of "epidemiological unit" in the Glossary, as the term is used in several chapters. However, it proposed an abbreviated definition, limited to the first sentence of the current definition (i.e. "means a group of animals with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogenic agent"), while providing more details in Article 1.4.3., as proposed.

5. *Ad hoc* and Working Groups

5.1. Meeting reports for endorsement

a) *Ad hoc* Group on revision of BSE standards – risk assessment and surveillance: 18–22 March 2019

The Commission reviewed the report of the *ad hoc* Group on bovine spongiform encephalopathy (BSE) risk assessment and surveillance which finalised the revision of the provisions for the categorisation of BSE risk status and of the BSE questionnaire (Chapters 11.4. and 1.8. of the *Terrestrial Code*) initiated in July 2018. The Commission commended the four *ad hoc* Groups for the extensive work undertaken.

The Commission noted that the BSE risk status of a cattle population would be determined based on: (i) a comprehensive risk assessment, (ii) the continuous implementation of a passive surveillance programme to detect the emergence or re-emergence of classical BSE, and (iii) the history of occurrence and management of cases of classical or atypical BSE.

Following the Commission's recommendations at its February 2019 meeting, the *ad hoc* Group prepared a literature review on 'Atypical BSE: the risk of being recycled in a cattle population and its zoonotic potential' to clarify, and further justify, the impact of atypical BSE on the recognition and maintenance of an official BSE risk status. The Commission discussed and endorsed the literature review, and referred it to the Biological Standards Commission for its consideration in the update of Chapter 3.4.5. of the *Terrestrial Manual*. The Commission concurred with the *ad hoc* Group that as atypical BSE (L-type) can be orally transmitted, it could be potentially recyclable if cattle were exposed to contaminated feed. Therefore, the Commission agreed that recycling of both atypical and classical BSE strains should be avoided, and consequently, that an assessment of the likelihood of the cattle population being exposed to the BSE agents (classical or atypical) should be performed regardless of the outcome of the entry assessment. On a related note, the Commission concurred with the recommendation of the *ad hoc* Group that atypical BSE cases, and imported BSE cases (regardless of the strain), should not impact a country's BSE risk status as long as they do not enter the animal feed chain.

The Commission took note of the criteria applied for assessing the safety of commodities according to Chapter 2.2. of the *Terrestrial Code.* The Commission agreed that, as deboned skeletal muscle and blood and blood by-products require specific measures for BSE to mitigate the risk of cross-contamination, they should not be listed as safe commodities. The Commission agreed that these commodities would need to be addressed in separate articles of Chapter 11.4.

The Commission amended the proposal of the *ad hoc* Group on the provisions for the importation of blood and blood products (draft Article 11.4.13.) as the critical point was to ensure no cross-contamination of blood and blood products with nervous tissue – avoiding methods such as stunning with a device injecting compressed air or gas into the cranial cavity or pithing – irrespective of the risk status of a country, zone or compartment.

The Commission reviewed the requirements for retention on the list of countries or zones having an official BSE risk status and concurred on the need to request annually documented evidence on passive surveillance and on the regular monitoring of the risk assessment. Furthermore, to clearly state the requirements for maintenance of a BSE risk status, the Commission updated a section in draft Articles 11.4.3. and 11.4.4.

The Commission strongly agreed with the requirement that protein meal derived from ruminants should not have been fed to ruminants regardless of the pathway for achieving a negligible BSE risk status (i.e. husbandry practices or effective and continuous mitigation of each identified risk).

The Commission endorsed the report and the amended Chapters 11.4. and 1.8. of the *Terrestrial Code*, and forwarded them to the Code Commission for further consideration. A report summarising the work of the four *ad hoc* Groups and providing the detailed rationale for the proposed amendments is attached to the September 2019 report of the Code Commission.

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

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

a) *Ad hoc* Group on the evaluation of BSE risk status: 25 September 2019 (electronic consultation)
b) *Ad hoc* Group on rabies: 8–10 October 2019
c) *Ad hoc* Group on the evaluation of CSF status: 22–24 October 2019
d) *Ad hoc* Group on the evaluation of FMD status: 5–7 November 2019
e) *Ad hoc* Group on the evaluation of CBPP status: 19–20 November 2019
f) *Ad hoc* Group on the evaluation of PPR status: 9–11 December 2019

g) Working Group on antimicrobial resistance: 1–3 October

The Commission was updated on the ongoing activities on antimicrobial resistance (AMR), including follow-up of the recommendations of the 2nd OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents in Animals Putting Standards into Practice held in Marrakesh, Morocco, 29–31 October 2018.

The Commission was informed that the Working Group on AMR, which was set up following Resolution No. 14 on the OIE's Engagement in the One Health Global Effort to Control Antimicrobial Resistance adopted at the General Session in May 2019, will have its first meeting from 1 to 3 October 2019.

The Working Group on AMR will support the implementation of the OIE Global Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobial Agents in Animals and will guide the work on the collection of data on antimicrobial agents intended for use in animals and the further development of the OIE list of antimicrobial agents of veterinary importance in animals.

h) Wildlife Working Group: 3–6 December 2019

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

i) *Ad hoc* Group on ASF compartmentalisation (dates to be confirmed)

The Commission was informed on the ongoing work to develop guidelines on compartmentalisation for Member Countries and private industry to establish, validate and maintain compartments for ASF, and the basis for certification to be provided to national and international trading partners. This *ad hoc* Group would be convened in the first semester of 2020 to contribute to and review the guidelines.

j) *Ad hoc* Group on rinderpest (dates to be confirmed)

The Commission took note of the draft terms of reference of the *ad hoc* Group and reiterated its previous position on the fact that, contrary to other disease-specific chapters where the objective is disease prevention and safe international trade, Chapter 8.16. of the *Terrestrial Code* is a unique chapter that concerns an eradicated disease. The purpose of the chapter should be to maintain global freedom and its prompt recovery should there be rinderpest re-emergence.

The Commission recommended adding an introductory section making clear to all Members that the main objective in the event of a re-mergence is to quickly regain global freedom and not to facilitate safe international trade. Thus, the Commission agreed on the proposal to limit trade provisions to safe commodities.

The Commission noted the proposal to divide the chapter into two sections, one containing general provisions relevant in the post-eradication era and another including provisions relevant in the event of re-emergence, so as to improve clarity and better articulate provisions.

The Commission suggested that the Director General invite a member of the Commission to attend the meeting of the *ad hoc* Group.

6. Official disease status

6.1. Expert missions to Member Countries requested by the Commission

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

- ***Thailand (PPR free country status and endorsed official control programme for FMD)***

Following the mission conducted in March 2019 to assess the progress made along Thailand's endorsed official control programme for FMD as well the continual compliance of the country with the provisions of the *Terrestrial Code* for the maintenance of its PPR free status, Thailand provided the OIE with an action plan to ensure the implementation of the recommendations. At its meeting, the Commission reviewed Thailand's action plan and requested further clarification to be submitted by the country for its consideration.

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

Madagascar was officially recognised as historically free from FMD in 1996. An OIE mission took place in April 2017 to assess the continual compliance of Madagascar with the requirements of the *Terrestrial Code*. The Commission reviewed the report provided by Madagascar detailing the progress made regarding the implementation of the recommendations of this OIE mission.

The Commission noted proof of secured funds by Madagascar to conduct FMD activities, including those to support serological surveillance, awareness activities and training of animal health officers.

At its February 2019 meeting, the Commission strongly recommended that passive clinical surveillance should be strengthened and requested documented evidence, including the number of suspicions reported, follow-up procedures and tests performed to exclude FMD and reach a differential diagnosis, and on the procedures in place for the early detection of FMD, be provided to the OIE when submitting its next update of progress.

The Commission also noted that milk products were imported into Madagascar from countries not officially recognised as free from FMD. The Commission stressed that importation of these commodities should be compliant with the requirements of Articles 8.8.24. and 8.8.25. of the *Terrestrial Code* and requested documented evidence of compliance be provided in the annual reconfirmation to be submitted in November 2019.

b) State of play and prioritisation

The Commission reviewed and prioritised the missions for the maintenance of disease status to be performed. The prioritised list of missions is expected to be confirmed following consultation with the Director General of the OIE.

6.2. Specific update on official disease status

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

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

The Commission considered a report from Morocco providing an update on its FMD control activities and on progress made in accordance with the OIE endorsed official control programme after the outbreaks reported at the beginning of 2019. Whilst the Commission commended Morocco's prompt actions in response to the outbreaks and its continuous efforts in FMD control, it requested further clarification and information to be submitted by the country when submitting the annual reconfirmation in November.

6.3. Disease status recognition procedure

a) Selection of status for comprehensive review of 2019 annual reconfirmations

The Commission selected the list of Members' 2019 annual reconfirmations for comprehensive review during its forthcoming meeting in February 2020. The selection was based on a set of criteria described in the SOPs. The Commission will review a total of 44 annual reconfirmations during its February 2020 meeting. The Members selected for comprehensive review of their annual reconfirmations will be notified officially by letter by the OIE in October.

6.4. Standards related to official status recognition

a) Link between PPR virus holding facilities and the procedure for PPR official status recognition

The Commission considered a discussion paper proposing to link the documentation of holdings of PPR virus containing materials (PVCM) with the OIE procedure for official recognition with regard to PPR by including a relevant requirement in Chapter 14.7, and the questionnaires under Chapter 1.12. of the *Terrestrial Code*.

The Commission welcomed the proposal to request information from Members on PVCM holding facilities as part of their application for official recognition of PPR free status. The Commission pointed out that maintenance of PVCM by facilities of countries that have eradicated PPR should not impact the granting of official status, provided that appropriate and secure handling of PPR virus is demonstrated. The biosecurity requirements for such facilities depends on the nature of the activities undertaken (e.g. research, keeping stocks of PVCM).

The Commission agreed that the *ad hoc* Group on the evaluation of PPR status should address this issue at their next meeting by identifying criteria to clearly define adequate PVCM facilities. The impact of the requirements to be proposed on the already recognised PPR status of Members should also be considered.

b) Assessment of impact related to the revised BSE standards and list of countries already having an official risk status by the OIE: follow-up on countries with non-negligible BSE exposure assessment

The Commission noted that, according to the current provisions of Article 11.4.2. point 1. b), an exposure assessment should be conducted if a risk factor is identified by the entry assessment. Consistent with this provision, some Members were granted an official BSE risk status based on a negligible risk of entry despite a non-negligible exposure assessment. The OIE and the Commission noted that the revised draft BSE provisions would require conducting an exposure assessment regardless of the outcome of the entry assessment, and that this significant change may have an impact on the BSE risk status of some Members.

The Commission reviewed and endorsed the proposed approach to assess the potential impact of the revised BSE provisions, which was endorsed by the *ad hoc* Group on BSE risk assessment and surveillance that met in March 2019. The approach focuses, firstly, on identifying Members with a non-negligible exposure assessment at the time of official status recognition, the issues that led to the conclusion of a non-negligible exposure assessment, and if the issues have been addressed since the time of recognition. Secondly, it focuses on identifying the remaining issues to be clarified as needed during the 2019 annual reconfirmation campaign for each Member. Lastly, depending on the progress made on the adoption of the revised chapter on BSE, the results of the assessment and the additional information would be sent to the *ad hoc* Group on BSE risk status evaluation of Members for assessment and subsequent endorsement by the Commission.

The Commission highlighted the importance of conducting a complete risk assessment. The results of an exposure assessment should not be considered in isolation but as part of the risk assessment process to avoid a disproportionate impact on individual Members.

7. Global control and eradication strategies

7.1. Foot and mouth disease: Global Control Strategy

The Commission was updated on the activities that had been conducted since its previous meeting in February 2019 on the framework of the Global FMD Control Strategy.

The 8th FMD roadmap meeting for West Eurasia took place in Iran on 4–7 March 2019 and 14 countries were represented. The second FMD roadmap meeting for West Africa took place in Senegal on 4–6 September 2019 and was attended by representatives of 16 countries. The national FMD situation, progress on implementation of the national FMD control plans since the last meetings and the challenges and needs of the strategy were presented by the country's representatives. The activities of the FMD Working Group, expertise and assistance offered by the OIE FMD Reference Laboratories and other partners to countries to assist them in the implementation of the Global FMD Control Strategy were highlighted. The Commission noted the challenges faced by the countries and the tools and activities developed to meet such challenges, including support given to countries in the selection of appropriate vaccines by the network of OIE Reference Laboratories for FMD.

Progress in the updates on the Progressive Control Pathway (PCP) tool, including the self-assessment tool was noted. All the attending Members in West Africa used the online PCP self-assessment tool satisfactorily for the first time to undertake an assessment of their countries regarding the PCP-FMD.

The Commission was informed of the next planned epidemiology and laboratory network meeting for the Middle East and the South Asian Association for Regional Cooperation (SAARC) region in November 2019 and March 2020, respectively, and the roadmaps for East Africa, southern Africa and Central Africa in 2020.

The Commission was also informed of the outcomes of the Global Framework for the progressive control of Transboundary Animal Diseases (GF–TADs) FMD Working Group biannual meeting held in July 2019 in Paris, including the identification of the potential areas of synergies in the global strategies to strengthen collaboration between the Working Group, the PPR Secretariat and the Rinderpest Secretariat, the improvement to PCP support tools and assistance to countries.

Finally, the Commission was informed of the efforts by the OIE to strengthen the Regional Secretariats and on the upcoming meeting of the GF–TADs Management Committee in Rome, Italy, in September 2019.

7.2. Peste des petits ruminants: Global Control and Eradication Strategy

The Commission was updated on the activities that had been conducted since its previous meeting in February 2019 on the framework of the PPR Global Control and Eradication Strategy.

The Commission was informed that in March and April 2019, the second PPR roadmap meetings were organised for three regions, namely northern, western and southern Africa and, in parallel, the third round was launched in August 2019 with the organisation of the meeting for Economic Cooperation Organization in Tashkent, Uzbekistan. During these meetings, progress was reported by several countries moving from stages 1 (assessment stage) to 2 (control stage), 3 (eradication stage) or even stage 4 (post-eradication stage) of the Strategy's stepwise approach. However, some concerns were raised that certain countries are vaccinating ineffectively without first conducting an epidemiologic assessment to map the disease, identifying the target populations most in need of vaccination and vaccinating them to the levels necessary to establish a protective herd immunity.

In addition, two workshops on the OIE procedures for the official recognition of PPR free status and endorsement of official national control programmes for PPR were held for countries in Eastern Europe and Central Asia in April 2019, and those in Africa in June 2019, targeting countries that had implemented control and eradication programmes and thus that could indicate some progress along the stepwise approach of the PPR Global Strategy, as well as countries that had never reported the disease. An infographic was developed to present the link between the PPR Strategy and OIE procedures for official recognition.

The Commission noted that Performance of Veterinary Services (PVS) follow-up missions with a PPR-specific content were conducted in 2019 in Nigeria, Chad, Burundi and Liberia. Two more missions, namely in Iran and Mongolia, will be undertaken before the end of 2019.

In March 2019, a meeting on 'Controlling PPR at the livestock/wildlife interface' was held in Rome, where the ongoing project undertaken by the OIE Working Group on Wildlife and the Global Research and Expertise Network (GREN) on developing 'Guidelines for the prevention of PPR in wildlife populations' was discussed among others. Finally, in April 2019, the third PPR vaccine producers meeting took place in Amman, Jordan.

The main actions planned for 2019–2020 are the organisation of a second meeting of the PPR GREN in Nairobi, Kenya, in November 2019 and the initiation of an in-depth review process of the PPR Monitoring and Assessment Tool (PMAT). This tool is mainly used to categorise countries according to the four different stages identified in the Global Strategy and its revision was decided upon in response to the challenges faced by countries using it.

The Commission underlined that strategic vaccination is critical for the success of PPR eradication and urged the OIE to undertake concerted efforts to explore mechanisms for supporting countries in their conduct of vaccination campaigns based on the epidemiology of PPR in the country or region.

7.3. Rabies: The Global Strategic Plan to Prevent Human Deaths from Dog-Transmitted Rabies by 2030. Zero by 30

The Commission was informed on the progress made on the implementation of the Global Strategic Plan to end human deaths from dog-mediated rabies by 2030. The annual report will be made available on World Rabies Day, 28 September 2019. The report will highlight last year's United Against Rabies (UAR) (OIE, Food and Agriculture Organization of the United Nations [FAO], World Health Organization [WHO] and Global Alliance for Rabies Control [GARC]) achievements on rabies communication and awareness, dog rabies vaccination, human post-exposure prophylaxis, training and capacity-building activities, among others.

The Commission noted that the specific methodology to conduct a PVS evaluation with rabies-specific content is ready to be piloted in December 2019.

The Commission was informed on the progress toward the establishment of the OIE Rabies Laboratory network. The network will include not only OIE Reference Laboratories, but also regional and national laboratories, with the aim of encouraging the sharing of knowledge and information.

The Commission was updated on OIE regional activities since its last meeting. In Asia, in Kathmandu, Nepal, a meeting of the SAARC was held in June 2019, where the implementation of the region's activities in the control of rabies was discussed. In Africa, the OIE organised a regional meeting in Tunisia where the Moroccan, Algerian and Tunisian rabies elimination strategies were discussed. In Namibia, Angola and Kenya, the OIE is supporting the implementation of massive vaccination campaigns and other dog-mediated rabies elimination activities.

7.4. African swine fever: Global Control Initiative

The Commission was updated on the progress of the GF–TADs Global Initiative for the control of African swine fever (ASF), that was mandated by OIE Member Countries during the last General Session through Resolution No. 33. The OIE and FAO are developing a strategic plan that would provide a structure to reach the specific objectives needed to support global control of ASF using the GF–TADs framework to harmonise and coordinate national and regional efforts. The importance of the monitoring and evaluation component was emphasised.

The Commission indicated its willingness to be involved in the drafting stage of the strategy, similar to what occurred for the other Global Control and Eradication strategies (i.e. FMD, PPR). A member of the Commission was nominated to become part of the Global Initiative drafting team.

The Commission emphasised that the focus should not only be on ASF Genotype II, responsible for the recent outbreaks in Europe and Asia, but also on addressing the situation of other genotypes endemics in Africa. The OIE is working to establish a Reference Laboratory network for ASF. The OIE expert from South Africa was invited to lead the network.

8. Liaison with other Specialist Commissions

8.1. Terrestrial Animal Heath Standard Commission

a) Meeting of the Bureaus of the Code Commission and the Commission

The Bureaus (i.e. the President and two Vice-Presidents) of the Code Commission and the Commission held a meeting chaired by Dr Stone. The purpose of the meeting was to provide an occasion where the two Bureaus could be informed about relevant topics of common interest and, where necessary, agree on the process to manage these topics.

b) Technical working group meeting related to the concept of 'protection zone'

The Presidents and First Vice-Presidents of the Code Commission and Commission held a third technical working group meeting chaired by Dr Stone. Previous meetings had been held in September 2018 and February 2019.

The aim of these discussions was to agree on a mechanism that would allow Member Countries to implement enhanced preventive measures, in advance, to protect their animal health status in response to an increased risk of disease incursion, while minimising the impact on their statuses and consequently on trade.

The principles to be applied for the incorporation of the concept were agreed and possible amendments to existing provisions in Chapter 4.4. of the *Terrestrial Code* were discussed, in particular those related to a protection zone. The potential impact on the OIE procedure for official recognition of disease status was also noted.

The OIE secretariat was requested to prepare draft amendments to Chapter 4.4., based on the outcome of the discussions, to be considered by both Commissions in February 2020.

c) Procedure for the evaluation of disease against the listing criteria of *Terrestrial Code* Chapter 1.2.

In preparation of the meeting of the Bureaus of the Commissions, the draft SOP prepared by OIE Headquarters for guiding decisions to list pathogenic agent was reviewed. OIE Delegate(s), international organisations, OIE Reference Centres, Specialist Commissions, OIE Working Groups and OIE Headquarters could request a listing decision. When the assessment of a pathogenic agent is to be performed by subject-matter experts through online consultation, the Commission recommended these to be selected following the normal procedures followed by the OIE (e.g. to identify members for *ad hoc* Groups).

d) Strategy for placement of the questionnaire for endorsement of official control programme for dog-mediated rabies outside of the *Terrestrial Code*

In preparation of the meeting of the Bureaus of the Commissions, the Commission was informed about the proposal to publish the questionnaire for the endorsement of official control programmes for dog-mediated rabies on the OIE website and not in the *Terrestrial Code*. Members would still have the opportunity to review and make comments to the published questionnaire which will be annexed to the Commission's February 2020 meeting report.

8.2. Biological Standards Commission

a) Role of carriers in the epidemiology of ASF

In response to a request by the Biological Standards Commission, the Commission provided its opinion on the concept of "carrier pig" and their possible role in the epidemiology of ASF. The Commission noted the lack of a clear definition of carrier for ASF in the available scientific literature. It was noted that, in general, the carrier status is the consequence of an infection resulting in a prolonged period of infectiveness.

The Commission reviewed the opinions of the three OIE Reference Laboratory experts who were consulted prior to its meeting and recent scientific literature[2] and concluded that, while the existence of carriers capable of transmitting ASF was described by some authors, their role in the epidemiology of the disease was not clear; neither was the duration of the carrier status. However, the relevance of serosurveillance for control of ASF was noted. The Commission stressed the difference between the epidemiology of the disease in endemic and epidemic situations, and in different epidemiological contexts, and recommended that the OIE continuously ensure experts with recognised experience in ASF in endemic and epidemic settings are duly considered when discussing disease control strategies and future revisions of the international standards on ASF.

The opinion of the Commission was forwarded to the Biological Standards Commission, including the relevant references for its consideration.

b) Use of pen-side tests for ASF

The Commission took note of the use of pen-side tests by the private sector as part of national control programmes. The Commission acknowledged the difficulty of Veterinary Authorities when conducting the pre-movement test of all pigs at the farm level, which led to testing by the private sector being encouraged.

The Commission recognised the potential benefit for ASF control of using pen-side tests by the private sector, in particular prior to movement. However, potential risks resulting from non-coordinated testing using non-approved tests and possible non-reporting of positive cases were identified.

The Commission recommended that the use of pen-side tests by the private sector be integrated into a control programme that includes the validation of diagnostic tests, training and clear guidelines for testing, that should ideally happen under veterinary supervision. This could also be integrated into a certification procedure before movement that should be conducted under the supervision of the Veterinary Authority. The Veterinary Authority should provide appropriate incentives for the private sector to report the positive and negative results.

9. Conferences, workshops, meetings, missions

The Commission was updated on the main conclusions of the following meetings in which the OIE had been involved since the Commission's February 2019 meeting:

- Kick-off meeting of the Standing Group of Experts on Rabies, Brussels, Belgium, 13 February
- 8th meeting of the GF–TADs Standing Group of Experts for LSD, Paris, France, 28 May

---

2 Eblé P.L., Hagenaars T.J., Weesendorp E., Quak S., Moonen-Leusen H.W. & Loeffen W.L.A. (2019). – Transmission of African Swine fever virus via carrier (survivor) pigs does occur. *Vet. Microbiol.*, **237**, (in press). doi:10.1016/j.vetmic.2019.06.018.
Ståhl K., Sternberg-Lewerin S., Blome S., Viltrop A., Penrith M.L. & Chenais E. (2019). – Lack of evidence for long term carriers of African swine fever virus – a systematic review. *Virus Res.*, **272**, (in press). doi:10.1016/j.virusres.2019.197725.
Gallardo C., Soler A., Nieto R., Sánchez M.A., Martins C., Pelayo V. [...] & Sánchez-Vizcaíno J.M. (2015). – Experimental transmission of African swine fever (ASF) low virulent isolate NH/P68 by surviving pigs. *Transbound. Emerg. Dis.*, **62** (6), 612–622. doi:10.1111/tbed.12431.

- 12th meeting of the GF–TADs Standing Group of Experts on African swine fever in Europe, Prague, Czech Republic, 11–12 March
- African Swine Fever Forum, Ottawa, Canada, 30 April–1 May
- 13th meeting of the GF–TADs Standing Group of Experts on African swine fever in Europe, Paris, France, 29 May
- Launch meeting of the Standing Group of Experts on ASF for Asia, Beijing, China, 10 April
- 2nd Standing Group of Experts on African swine fever in Asia, Tokyo, Japan, 30–31 July

10. Disease control specific issues

10.1. Evaluation of diseases against listing criteria

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

i. Low pathogenic avian influenza

The Commission considered the *ad hoc* Group assessment of 'H5 and H7 low pathogenicity avian influenza (LPAI)' against the criteria in Article 1.2.2. of Chapter 1.2. of the *Terrestrial Code*.

The Commission noted the difficulties experienced by the *ad hoc* Group in evaluating LPAI against the listing criteria of *Terrestrial Code* Chapter 1.2., especially for criteria 4.a) and 4.b), because of the complexities of assessing a group of viruses where the characteristics of different strains or lineages/genotypes varies, and the diversities of poultry sector and avian species involved.

The Commission highlighted the need to ensure the approach to assessing diseases against Chapter 1.2. of the *Terrestrial Code* be consistent, transparent and objective to avoid ambiguity of the listing and delisting process.

The Commission agreed with the *ad hoc* Group's recommendation that, taking into account the caveats observed by the experts, LPAI does not meet the criteria for inclusion in the OIE List. Despite the delisting of LPAI, the Commission stressed the obligation of Members to notify any sudden and unexpected increase in the virulence of LPAI viruses in poultry, and the infection of domestic and captive wild birds with LPAI viruses having proven natural transmission to humans associated with severe consequences, as emerging disease, in accordance with Article 1.1.4. of the *Terrestrial Code*.

10.2. Prion disease in dromedary camels

The Commission was informed that, in May 2019, the OIE received an immediate notification from Tunisia of a case of camel prion disease (CPD) as an emerging disease. The OIE did not publish the immediate notification in accordance with the Commission recommendation of February 2019 that more evidence should be collected to assess whether this disease should be considered as an emerging disease as defined in the Glossary of the *Terrestrial Code*.

The Commission noted that Tunisia has become the second country after Algeria to detect a case of CPD within a year. After analysing the information available, the Commission was concerned about the limited surveillance information on the disease to make an assessment on the need to consider it as an emerging disease. However, the Commission reiterated its position that CPD should be considered as a new disease and should not be overlooked.

The Commission encouraged Member Countries to gather surveillance and research information on this disease in countries with important dromedary camel populations to measure the impact of the disease, and to provide new scientific evidence to the Commission, when it becomes available, to reassess CPD as an emerging disease.

The Commission was informed that CAMENET is drafting a preparedness and response plan, including epidemiological surveillance for CPD, that would be discussed with CAMENET members during the Conference of the OIE Regional Commission in the Middle East to be held in Abu Dhabi, United Arab Emirates, in November 2019. The purpose of the preparedness and response plan will be to assist countries in prevention, early detection and timely response to the disease and facilitate countries being well prepared for this threat.

10.3. Vaccination of animals of high conservation value

The Commission took note of the proposal by the OIE Wildlife Working Group (WWG) to have vaccination as one component of protection of animals of high conservation value against transboundary animal diseases.

The Commission was informed that Australia, in the framework of the Australian Veterinary Emergency Plan, developed a guidance document for the 'Risk-based assessment of disease control options for rare and valuable animals'.

The Commission agreed that this document could be used as a model to revise the paper entitled 'Vaccination of animals of high conservation value' being drafted by the WWG.

The Commission invited the WWG to consider that the emergency vaccination of zoological animals of high conservation value may require off-label use of vaccines and that approval by Competent Authorities may be necessary.

10.4. Seasonal freedom

The Commission commended OIE Headquarters for the work done in collecting and presenting information on the use of the *Terrestrial Code* concept of seasonal freedom from bluetongue and on the type and validity of the criteria used for defining such a period by Members.

The Commission noted that additional information should be collected to assess the relevance of the identified outbreaks that occurred during the seasonal free period to rule out transplacental infection of bluetongue virus serotype 8. It would also be necessary to consider the number of countries applying this concept among those having trade restrictions due to bluetongue.

The Commission requested OIE Headquarters to collect the above information for further assessment. Depending on the outcome of this assessment, a review of Chapter 1.5. and the subsequent adaptation of surveillance articles for vector-borne pathogens might be considered.

The Commission considered seasonal freedom to be a valid risk mitigation concept to facilitate the safe international trade of animals and their products and noted that it is being currently used by some Members. However, it also noted that the current concept of seasonal freedom could be better reflected as 'seasonal absence of transmission'.

11. For the Commission's information

11.1. Update on rinderpest activities

During the 87th General Session, two new rinderpest holding facilities (RHFs) were designated in categories A and B, and all five RHFs that had been designated in 2015 had their mandates extended for another three-year period. At the moment, there are RHFs in the People's Republic of China (China), Ethiopia, France, Japan, the United Kingdom and the United States of America. Two RHF applications are still pending.

The network of RHFs will have its second meeting on 14–15 November 2019, in Tokyo, Japan. Representatives of countries holding rinderpest virus-containing material outside of RHFs would also be invited.

The Commission was informed that the Sequence and Destroy project reached its conclusion at the Pirbright Institute, where more than 3,000 samples of rinderpest virus (RPV) were destroyed in June. The Agricultural Research Centre for International Development (CIRAD) will follow suit from September onwards. Publications on the project's findings are expected in the future.

The Commission noted that as presented at the last General Session, rinderpest virus-containing materials are held outside of RHFs in eight countries.

The FAO–OIE Rinderpest Joint Advisory Committee (JAC) had been consulted between meetings to advise on the approval of a number of research applications using RPV submitted by RHFs.

The Commission was informed of the proposed plan to produce vaccines to replenish the emergency reserve in the Africa region and emphasised the importance of strictly assessing compliance with the criteria for rinderpest vaccine manufacturers and the responsibility of the OIE and FAO in maintaining the global eradication of rinderpest. The Commission requested to be kept up to date regarding this matter.

11.2. Project update: replacement International Standard Bovine Tuberculin

The Commission was updated on an ongoing project to prepare and calibrate a new reference tuberculin to replace the current International Standard Bovine Tuberculin (ISBT), which was produced in 1986 and has become depleted. The project is being coordinated by an *ad hoc* Group under the Biological Standards Commission. The project involved a preliminary evaluation where the potency and specificity of two candidate tuberculins were evaluated in comparison with the current ISBT, and the results were satisfactory. A larger scale international collaborative study was subsequently conducted to further evaluate and calibrate the candidates in guinea pigs, and to evaluate the candidate's fitness for purpose in cattle. This second phase of testing has now been completed, except for some cattle studies that were temporarily delayed. A second *ad hoc* Group is scheduled to meet in November 2019 to finalise the ISBT project and prepare a summary report for presentation to the Biological Standards Commission in February 2020, for endorsement.

The *ad hoc* Group will also review the current Bovine Tuberculosis chapter, Chapter 3.4.6., of the *Terrestrial Manual* and prepare a draft updated text.

11.3. Update on the SIRCAH STAR–IDAZ International Research Consortium

The Commission was updated on the recent activities performed by the STAR–IDAZ International Research Consortium on Animal Health (IRC) and by its Secretariat (SIRCAH), which is co-hosted by the OIE. The consortium now comprises 28 partners, including both public and private research funders and international donors.

Working groups of experts delivered draft research roadmaps for a number of priority diseases/infections/issues, including bovine tuberculosis, ASF, FMD and helminths. These are published on the consortium's website and were presented at the last STAR–IDAZ IRC Executive Committee meeting, which was held in Beijing, China, in March 2019. The meeting was organised back-to-back with a workshop aimed at increasing collaboration on international research on pig diseases, with a focus on ASF, and with a meeting of the STAR–IDAZ regional network for Asia and Australasia, so as to collect information on research activities and priorities and increase research coordination in the region.

Workshops dedicated to the update and validation of the research roadmaps by dedicated groups of subject-matter experts are being organised. Roadmaps for vaccine, diagnostic, therapeutics and disease control for helminths were discussed at a meeting in Ghent, Belgium, in August 2019, while a validation workshop for roadmap for vaccine, diagnostic and disease control strategies is being organised as a satellite meeting to the upcoming meeting of the Global FMD Research Alliance (GFRA), that will be held in Bangkok, Thailand, in October 2019.

The Commission commended the efforts made, recognising the importance of improving research coordination on animal health, and noted possible issues that could derive from intellectual property rights in this regard.

12. Any other issues

None at this meeting.

13. Programme and priorities

13.1. Update and prioritisation of the work plan

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

The updated work programme is attached as Annex 8.

14. Adoption of the report

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

15. Date of next meeting

The next meeting of the Scientific Commission is scheduled for 3–7 February 2020.

16. Meeting review

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

_____

…/Annexes

Annex 1

MEETING OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 9–13 September 2019

_____

Agenda

Opening

1. Welcome

2. Adoption of the agenda

3. Feedback from the 87th General Session

4. *Terrestrial Animal Health Code*

4.1. Member Country comments received for SCAD consideration

a) Chapter 1.3. Diseases, infections and infestations listed by the OIE (Article 1.3.1.)
b) Chapter 1.6. Procedures for self declaration and for official recognition by the OIE
c) Chapter 8.11. Infection with *Mycobacterium bovis* and *M. caprae*
d) Chapter 8.15. Infection with Rift Valley fever virus
e) Chapter 14.7. Infection with peste des petits ruminants virus (Articles 14.7.3. & 34.)

4.2. Other considerations

a) Draft Chapter 8.Y. Infection with animal trypanosomes of African origin (Articles 8.Y.3. & 8.Y.6.)
b) Draft revised Chapter 10.4. Infection with avian influenza viruses (outcome of the 3rd *ad hoc* Group meeting on avian influenza: 11–13 June 2019)
c) Harmonisation of requirements for disease free status recognition and maintenance in disease-specific chapters
    a. Chapter 15.2. Infection with classical swine fever virus (Articles 15.2.2. & 3.)
    b. Other provisions for harmonisation: containment zone, recovery of status
d) Information paper on new approach to the consistent use of terms 'disease', 'infection' and 'infestation' in the OIE *Terrestrial Code*
e) Revision of the definitions for Competent Authority, Veterinary Authority and Veterinary Services
f) Definition of epidemiological unit for the purpose of the *Terrestrial Code*

5. *Ad hoc* and Working Groups

5.1. Meeting reports for endorsement

a) *Ad hoc* Group on revision of BSE standards – risk assessment and surveillance: 18–22 March 2019

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

a) *Ad hoc* Group on the evaluation of BSE risk status: 25 September 2019 (electronic consultation)
b) *Ad hoc* Group on rabies: 8–10 October 2019
c) *Ad hoc* Group on the evaluation of CSF status: 22–24 October 2019
d) *Ad hoc* Group on the evaluation of FMD status: 5–7 November 2019
e) *Ad hoc* Group on the evaluation of CBPP status: 19–20 November 2019
f) *Ad hoc* Group on the evaluation of PPR status: 9–11 December 2019
g) Working Group on antimicrobial resistance: 1–3 October
h) Wildlife Working Group: 3–6 December 2019
i) *Ad hoc* Group on ASF zoning and compartmentalisation (dates to be confirmed)
j) *Ad hoc* Group on rinderpest (dates to be confirmed)

6. Official disease status

6.1. Expert missions to Member Countries requested by the Commission

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

6.2. Specific update on official disease status

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

6.3. Disease status recognition procedure

a) Selection of status for comprehensive review of 2019 annual reconfirmations

6.4. Standards related to official status recognition

a) Link between PPR virus holding facilities and the procedure for PPR official status recognition

b) Assessment of impact related to the revised BSE standards and list of countries already having an official risk status by the OIE: follow-up on countries with non-negligible BSE exposure assessment

7. Global control and eradication strategies

7.1. Foot and mouth disease: Global Control Strategy

7.2. Peste des petits ruminants: Global Control and Eradication Strategy

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

7.4. African swine fever. Global Control Initiative

8. Liaison with other Commissions and Departments

8.1. Terrestrial Animal Health Standard Commission

a) Meeting of the Bureaus of the Code Commission and the Commission
b) Technical working group meeting related to the concept of 'protection zone'
c) Procedure for the evaluation of disease against the listing criteria of *Terrestrial Code* Chapter 1.2.
d) Strategy for placement of the questionnaire for endorsement of official control programme for dog-mediated rabies outside of the *Terrestrial Code*

8.2. Biological Standards Commission

a) Role of carriers in the epidemiology of ASF
b) Use of pen-side tests for ASF

9. Conferences, workshops, meetings, missions

9.1. Kick-off meeting of the Standing Group of Experts on Rabies, Brussels, Belgium, 13 February

9.2. 8th meeting of the GF-TADs Standing Group of Experts for LSD, Paris, France, 28 May

9.3. 12th meeting of the GF-TADs Standing Group of Experts on African swine fever in Europe, Prague, Czech Republic, 11-12 March

9.4. African Swine Fever Forum, Ottawa, Canada, 30 April – 1 May.

9.5. 13th meeting of the GF-TADs Standing Group of Experts on African swine fever in Europe, Paris, France, 29 May

9.6. Launch meeting of the Standing Group of Experts on ASF for Asia, Beijing, China, 10 April

9.7. 2nd Standing Group of Experts on African swine fever in Asia, Tokyo, Japan, 30–31 July

10. **Disease control specific issues**

10.1. Evaluation of diseases against listing criteria

a) Evaluation of pathogenic agent against listing criteria of *Terrestrial Code* Chapter 1.2.:
   a. Low pathogenic avian influenza

10.2. Prion disease in dromedary camels

10.3. Vaccination of animals of high conservation value

10.4. Seasonal freedom

11. **For the Commission information**

11.1. Update on rinderpest activities

11.2. Project update: replacement International Standard Bovine Tuberculin

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

12. **Any other issues**

13. **Programme and priorities**

13.1. Update and prioritisation of the work plan

14. **Adoption of the report**

15. **Date of next meeting**

16. **Meeting review**

Annex 2

MEETING OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

Paris, 9–13 September 2019

_____

List of Participants

MEMBERS

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

Dr Kris De Clercq *(Vice-President)*
Centre d'Etudes et de Recherches
Vétérinaires et Agrochimiques
Department of Virology
Section Epizootic Diseases
CODA-CERVA-VAR
Groeselenberg 99
B-1180 Ukkel
BELGIUM
Tel.: +32 2 379 0400
kris.declercq@sciensano.be

Dr Baptiste Dungu *(2nd Vice-President)*
CEO – Onderstepoort Biological Products
SOUTH AFRICA
Tel.: +27 12 522 1607
Baty@obpvaccines.co.za

Dr Silvia Bellini *(Member)*
Istituto Zooprofilattico Sperimentale della Lombardia e dell'Emilia Romagna 'Bruno Ubertini'
Via Bianchi 9
25124 Brescia
ITALY
Tel: +39 366 588 8774
Silvia.bellini@izsler.it

Dr Misheck Mulumba *(Member)*
Agricultural Research Council
Private Bag X05
Onderstepoort 01110
Pretoria
SOUTH AFRICA
Tel: +27 12 529 9338
mumulbam@arc.agric.za

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

OIE HEADQUARTERS

Dr Gregorio Torres
Head of Science Department
g.torres@oie.int

Dr Stefano Messori
Chargé de mission
Science Department
s.messori@oie.int

Dr Jee Yong Park
Chargé de mission
Science Department
j.y.park@oie.int

Dr Neo Mapitse
Head of Status Department
n.mapitse@oie.int

Dr Min Kyung Park
Deputy Head of Status Department
m.park@oie.int

Dr Anna-Maria Baka
Chargée de mission
Status Department
am.baka@oie.int

_____

Annex 3

Rationale for the amendments to:

CHAPTER 1.6. PROCEDURES FOR SELF-DECLARATION AND FOR OFFICIAL RECOGNITION BY THE OIE
provided by the Scientific Commission

Article 1.6.1. Publication by the OIE of a self-declaration of disease freedom by a Member Country

The Commission suggested that for the purpose of self-declarations, 'disease freedom' should be used rather than 'disease-free status' throughout Article 1.6.1. to avoid confusion with the official status recognition procedure.

The Commission took note of Member comments seeking clarification on the objective of the administrative and technical screening performed by the OIE prior to the publication of self-declarations, considering that self-declarations are not endorsed by the OIE. The procedure, including screening of the self-declaration by the OIE, has been in place since the time when self-declarations of Members were published in the OIE *Bulletin* and the written procedures were mainly developed to clarify the procedure for 'publication' by the OIE. As described in the SOP, the administrative screening performed by the OIE is to check whether the structure of the dossier for self-declaration is in accordance with the SOP, whilst the technical screening involves the assessment of the self-declaration dossier to ensure that sufficient information on the provisions of the specific disease or relevant horizontal chapters of the *Terrestrial Code* is provided. This also ensures a harmonised structure among the self-declarations published on the OIE website as well as consistency with the information reported by the Members to OIE-WAHIS.

The Commission disagreed with Members that proposed the addition of a reference to non-compliances other than an outbreak for the loss of a self-declared disease freedom. Contrary to the OIE procedure on official recognition of disease status, after the publication of a self-declaration there is no formal follow-up on assessing continued compliance with regard to a published self-declaration, and the responsibility for the information contained in a self-declaration lies entirely with the OIE Delegate of the Member concerned. The follow-up is based on the immediate notifications and epidemiological situation reported by the OIE Member to OIE-WAHIS, thus, only an outbreak could lead to the loss of a self-declared disease freedom.

The Commission considered a comment by a Member proposing that to regain a lost self-declared disease freedom, information should be provided on the containment zone and not on the rest of the free country/zone. The Commission emphasised that even though a containment zone is an option to control an outbreak, it is not mandatory. Other measures could be applied to regain disease freedom. The Commission concluded that Members wishing to reclaim a lost self-declared disease freedom should submit a new self-declaration describing in detail the measures applied.

Annex 4

Rationale for the amendments to:

CHAPTER 8.11. INFECTION WITH *MYCOBACTERIUM BOVIS* AND *M. CAPRAE*
provided by the Scientific Commission

Article 8.11.4. Country or zone free from infection with *M. bovis* and *M. caprae* in bovids

The Commission agreed with a Member that the sensitivity of ante and post mortem surveillance is low, and in areas where there is a continuing risk of transmission from infected wildlife species, additional surveillance at the livestock–wildlife interface may be required to assess the effectiveness of the measures intended to prevent transmission of infection.

Article 8.11.5. Country or zone free from infection with *M. bovis* and *M. caprae* in cervids

The Commission recognised that countries could be free from infection in cattle and not in cervids or other susceptible species, and thus, even if requirements for freedom are very similar, separate articles should be provided.

Rationale for the amendments to:

CHAPTER 8.15. INFECTION WITH RIFT VALLEY FEVER VIRUS
provided by the Scientific Commission

Article 8.15.1. General provisions

The Commission agreed with a Member on the point that camels are not considered ruminants.

The Commission was not aware of any information about the susceptibility of South American camelids to Rift Valley fever (RVF). The OIE Reference Laboratory experts on RVF and the chair of the OIE ad hoc Group on camelids were consulted to provide further information.

The Commission took note of a Member comment on the inclusion of indigenous human cases as a definition of an epizootic of RVF. The Commission acknowledged that the occurrence of indigenous human cases would imply virus circulation in the animal population and noted that Article 1.1.2. states "Member Countries shall make available to other Member Countries, through the OIE, whatever information is necessary to minimise the spread of important animal diseases and their pathogenic agents, and to assist in achieving better worldwide control of these diseases". As human cases of RVF are usually preceded or at least accompanied by cases in animals, information on the occurrence of indigenous human cases of RVF would be a useful component of the surveillance system. The occurrence of outbreaks at an incidence substantially exceeding that during an inter-epizootic period should be immediately notified to the OIE. The immediate notification to OIE–WAHIS could also include information on the incidence of RVF in humans

The Commission noted that baseline surveillance data are required to differentiate epizootic from interepizootic periods as defined in point 6. The Commission recommended consulting subject-matter experts to amend Article 8.15.13. in order to provide guidance to countries on how to conduct surveillance to detect variation in the virus activity.

The Commission agreed on the need to clarify the definition of "epizootic of RVF" and proposed a modification reflecting the definition under Article 1.1.3., point 1. d).

The Commission also recommended clarifying the definition of "inter-epizootic period" to highlight that in these periods the rate of virus transmission should be low in animals and humans.

Article 8.15.3. Country or zone free from RVF

With regard to a Member comment on point 2. a), the Commission clarified that the ten-year time span was referring to the duration of the interepizootic period, which is highly variable and could last several years.

The Commission was of the opinion that in case of incursion of the disease into a country that has been historically free, requirements for the recovery of freedom should be provided. The Commission recommended consultations with subject-matter experts on the merit of including provision for the recovery of freedom in the chapterThe Commission recognised that countries could be free from infection in cattle and not in cervids or other susceptible species, and thus, even if requirements for freedom are very similar, separate articles should be provided.

Rationale for the amendments to:

CHAPTER 14.7. INFECTION WITH PESTE DES PETITS RUMINANTS VIRUS (ARTICLES 14.7.3. & 34.) provided by the Scientific Commission

Article 14.7.3. Country or zone free from PPR

The Commission disagreed with Members proposing to add a reference to the questionnaires under Chapter 1.12. considering that these references were already made in Chapter 1.6.

The Commission discussed a comment by a Member seeking clarification on the impact of the importation of animals vaccinated against peste des petits ruminants (PPR) on an officially recognised PPR free status. The Commission highlighted that Article 14.7.10. describes the provisions on safely importing animals from infected countries, including vaccinated animals. However, in accordance with Article 14.7.3., for a country or zone having an official PPR free status, there should be no domestic sheep and goats vaccinated against PPR imported since the cessation of vaccination.

In response to Member comments, the Commission modified the text to distinguish notification obligations from documented evidence to be submitted for annual reconfirmation.

Article 14.7.34. OIE endorsed official control programme for PPR

The Commission disagreed with a Member comment proposing to remove the requirement for the existence of an emergency preparedness plan and emergency response plan for OIE endorsement of official control programmes as it is redundant to measures implemented to prevent the introduction of the pathogenic agent and to ensure the rapid detection of all PPR outbreaks. The Commission indicated that measures for prevention and prompt detection and for emergency preparedness or response plan are different concepts. The Commission updated the text for clarity.

The Commission agreed to maintain the prerequisite of the use of a vaccine compliant with the *Manual of Diagnostic Tests for Terrestrial Animals* (*Terrestrial Manual*) for OIE endorsement of official control programmes, in case vaccination is being implemented as part of the PPR control programme.

Annex 7

Original: English
March 2019

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP
ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT AND SURVEILLANCE
Paris, 18-21 March 2019

———

The OIE *ad hoc* Group on bovine spongiform encephalopathy (BSE) risk assessment and surveillance (hereafter the Group) met from 18 to 21 March 2019 at the OIE Headquarters to complete the revision of the BSE standards initiated by the *ad hoc* Group on BSE risk assessment which met in July and November 2018 and the *ad hoc* Group on BSE surveillance which met in October 2018.

1. Opening

Dr Matthew Stone, OIE Deputy Director General for International Standards and Science welcomed the Group on behalf of Dr Monique Eloit, Director General of the OIE. He noted that all experts had participated in one or both of the previous *ad hoc* Groups on BSE risk assessment and BSE surveillance.

Dr Stone acknowledged the significant achievements made to date in the revision of the BSE standards and emphasised that this meeting aimed to complete the revision of the provisions, including those for which the previous *ad hoc* Groups did not reach a consensus. He underlined the importance of open discussions based of scientific evidence aiming at developing risk-based provisions.

Dr Bernardo Todeschini, representative of the Terrestrial Animal Health Standards Commission (hereafter the Code Commission), emphasised that the revision of the BSE standards was considered a priority for OIE Members.

Dr Baptiste Dungu, representative of the Scientific Commission for Animal Diseases (hereafter the Scientific Commission), informed the Group that at its February 2019 meeting, the Scientific Commission emphasised the importance for the provisions for atypical BSE to be evidence-based and risk-based. He appreciated that the Group prepared a review on atypical BSE to support its discussions.

The experts were thanked for having signed the forms for undertaking of confidentiality and declaration of conflicts of interest. No potential conflict of interest in the revision of BSE Standards was declared.

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

Dr Stephen Cobb was appointed Chair and Dr Alicia Cloete was the rapporteur with the support of the OIE Secretariat. The Group endorsed the proposed agenda for the meeting.

Dr Stone commended Dr Noel Murray for chairing the *ad hoc* Groups on BSE risk assessment and BSE surveillance.

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

3. Atypical BSE

The Group discussed and endorsed with minor revisions an overview of relevant literature on the risk of atypical BSE being recycled in a cattle population and its zoonotic potential that had been prepared ahead of the meeting by one expert from the Group. This overview is provided as Appendix IV and its main conclusions are outlined below.

With regard to the risk of recycling of atypical BSE, recently published research confirmed that the L-type BSE prion (a type of atypical BSE prion) may be orally transmitted to calves[1]. In light of this evidence, and the likelihood that atypical BSE could arise as a spontaneous disease in any country, albeit at a very low incidence, the Group was of the opinion that it would be reasonable to conclude that atypical BSE is potentially capable of being recycled in a cattle population if cattle were to be exposed to contaminated feed. Therefore, the recycling of atypical strains in cattle and broader ruminant populations should be avoided.

The Group acknowledged the challenges in demonstrating the zoonotic transmission of atypical strains of BSE in natural exposure scenarios. Overall, the Group was of the opinion that, at this stage, it would be premature to reach a conclusion other than that atypical BSE poses a potential zoonotic risk that may be different between atypical strains.

4. Definitions of meat-and-bone meal (MBM) and greaves

The Group discussed and endorsed a document prepared ahead of the meeting by two experts of the Group on the definitions of meat-and-bone meal (MBM) and greaves.

According to the Glossary of the *Terrestrial Animal Health Code* (hereafter the *Terrestrial Code*), MBM currently "*means the solid protein products obtained when animal tissues are rendered, and includes any intermediate protein product other than peptides of a molecular weight less than 10,000 daltons and amino-acids*" and greaves "*means the protein-containing residue obtained after the partial separation of fat and water during the process of rendering*". The Group considered that the rationale to differentiate MBM and greaves was unclear. The Group also emphasised a lack of common understanding in different countries of what greaves are as well as a variety of practices as to how greaves are used.

The Group pointed out that, based on this definition, it was unclear whether greaves could be considered intermediate protein products. If so, it would be relevant to include greaves and MBM in a single definition.

The Group proposed a definition of "*protein meal*" encompassing both MBM and greaves as follows: "*protein meal means any final or intermediate solid protein-containing product, obtained when animal tissues are rendered, excluding blood and blood products, peptides of a molecular weight less than 10,000 daltons and amino-acids*".

The Group noted that MBM (and greaves) were relevant not only for BSE but also for other OIE listed diseases (i.e., Chapter 8.1. on anthrax; Chapter 8.4. on infection with *Brucella abortus, B. melitensis* and *B. suis;* Chapter 8.11. on infection with *Mycobacterium tuberculosis* complex; Chapter 14.8. on scrapie; and Chapter 15.3 on infection with porcine reproductive and respiratory syndrome virus).

The Group recommended the proposed definition of "*protein meal*" should apply, at this stage, for the purpose of Chapters 11.4. and 1.8. of the *Terrestrial Code*. Whether this definition would also be relevant for the other disease-specific Chapters listed above should be further assessed by the OIE. If considered relevant for other diseases, the proposed definition could ultimately replace the definitions of MBM and greaves in the Glossary of the *Terrestrial Code.*

[1] Okada H, Iwamaru Y, Imamura M, Miyazawa K, Matsuura Y, Masujin K, Murayama Y, Yokoyama T. Oral transmission of L-Type bovine spongiform encephalopathy agent among cattle. *Emerging Infectious Diseases*. 2017 Feb; **23**(2):284.

5. Revision of Chapter 11.4. of the *Terrestrial Code*

5.1. Draft Article 11.4.1. General provisions

The Group revised draft Article 11.4.1. to ensure better alignment with the recommended structure of disease-specific Chapters of the Terrestrial Code. To improve clarity, the Group agreed to add definitions of terms applicable to this Chapter, including a case definition.

To address a question raised by the Scientific Commission at its February 2019 meeting, and consistent with the rationale of the ad hoc Group on BSE risk assessment at its November 2018 meeting, the Group concluded that the occurrence of a case of atypical BSE, regardless of the origin (imported or indigenous), would not impact a country's BSE risk status by itself (see section 5.4. of this report). Nevertheless, based on the consideration of recent findings for L-type BSE presented above and provided in Appendix IV, the Group emphasised that the potential recycling of all BSE agents, not only of classical BSE, was important to be considered in the exposure assessment. For this, atypical BSE is not completely disregarded in the recognition of a country's BSE risk status as the existing Article 11.4.1. implies. To avoid misleading statements, the phrase "*For the purposes of official BSE risk status recognition, BSE excludes 'atypical BSE' as a condition believed to occur spontaneously in all cattle populations at a very low rate*" was proposed to be removed from Article 11.4.1. The Group consequently amended draft Articles 11.4.1. and 11.4.2. point 1.b. to indicate the potential for atypical BSE to be recycled in a cattle population if cattle were to be exposed to contaminated feed, and draft Article 11.4.3. points 3.a. and 4. to clarify the impact and the way to address atypical BSE cases (section 5.4. of this report).

5.2. Draft Article 11.4.1.bis. Safe commodities

With regard to safe commodities, the Group took note of the definition provided in the Glossary of the Terrestrial Code (i.e., "means a commodity that can be traded without the need for risk mitigation measures specifically directed against a particular listed disease, infection or infestation and regardless of the status of the country or zone of origin for that disease, infection or infestation") as well as the provisions of the recent Chapter 2.2. of the Terrestrial Code (Criteria applied by the OIE for assessing the safety of commodities, first adopted in May 2017).

The Group noted that for the commodities listed under current Article 11.4.1. points 1.g. and 1.h., measures specifically directed against BSE to mitigate the risk of cross contamination by the BSE agent were explicitly stated. Point 1.g.: "deboned skeletal muscle meat (excluding mechanically separated meat) from cattle which passed ante- and post-mortem inspections; which were not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, prior to slaughter; and which has been prepared in a manner to avoid contamination with tissues listed in Article 11.4.14." ; and point 1.h.: "blood and blood by-products from cattle which were not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, prior to slaughter"). Considering that inclusion of these commodities in an Article specifically listing safe commodities is no longer consistent with either the Glossary or Chapter 2.2., the Group sought advice from the Code Commission and agreed with their recommendation that these commodities should not be listed as safe commodities and would need to be addressed in separate articles of Chapter 11.4. (i.e., Draft Articles 11.4.9. to 11.4.11. and 11.4.13.)

The Group noted that "semen and in vivo derived cattle embryos" were listed as safe commodities in current Article 11.4.1. point 1.b. and discussed whether in vitro derived cattle embryos could also be considered safe commodities. Considering that scientific evidence was only published on in vivo derived cattle embryos[2] the Group could not recommend in vitro derived cattle embryos be specifically listed as safe commodities.

[2] Wrathall AE, Brown KF, Sayers AR, Wells GA, Simmons MM, Farrelly SS, Bellerby P, Squirrell J, Spencer YI, Wells M, Stack MJ. Studies of embryo transfer from cattle clinically affected by bovine spongiform encephalopathy (BSE). *Veterinary Record*. 2002; **150**(12):365-378.

The Group pointed out that "semen and in vivo derived cattle embryos" should not necessarily only be "collected and handled in accordance with the recommendations of the International Embryo Transfer Society" as recommended in current Article 11.4.1. point 1.b., but rather in accordance with relevant Chapters of the *Terrestrial Code*.

To address a request received by the OIE from the European Serum Products association, the Group discussed whether animal serum used in culture media could be considered a safe commodity. The Group pointed out that under current Article 11.4.1. point 1.h., the provisions for BSE pertaining to "blood and blood by-products" applied to "animal serum used in culture media", meaning risks are effectively managed as long as this blood by-product originates from cattle which were not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, prior to slaughter. These requirements are included in draft Article 11.4.13.

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

The Group clarified that the BSE risk status of a cattle population should be determined based on: (i) a comprehensive risk assessment, (ii) the continuous implementation of a passive surveillance programme to detect the emergence or re-emergence of classical BSE, and (iii) the history of occurrence and management of cases of classical or atypical BSE.

The Group reviewed the listed steps of a risk assessment for the purpose of BSE. The Group complemented the provisions on the last step of the assessment (i.e., risk estimation) to better capture the expected outcome of the risk estimation (i.e., "*provide an overall measure of the risk that BSE agents have been recycled in the cattle population through the feeding of ruminant-derived protein meal, with indigenous cases arising as a consequence*").

The Group agreed that consistent with the provisions of current Article 11.4.2., Members should review their BSE risk assessment annually.

5.4. Draft Article 11.4.3. Negligible BSE risk

The Group reviewed draft Article 11.4.3. and addressed unresolved issues from an earlier meeting of the *ad hoc* Group on BSE risk assessment, as well as the questions raised by the Scientific Commission at its February 2019 meeting.

a) Demonstration of the implementation of a ruminant-to-ruminant feed ban

At its November 2018 meeting, the *ad hoc* Group on BSE risk assessment did not decide whether demonstrating that protein meal derived from ruminants have not been fed to ruminants:

- could be considered to be implicitly encompassed in draft Article 11.4.3. point 1.a. as drafted in November 2018 (i.e., "*a risk assessment should demonstrate that the likelihood of cattle population being exposed to BSE agent has been negligible for at least 8 years*"); or

- should be made explicit for the sake of clarity, common understanding by Members, and therefore harmonised implementation of Article 11.4.3.

The Group agreed to complement draft Article 11.4.3. points 1.a. and 1.b. to clearly emphasise that protein meal derived from ruminants should not have been fed to ruminants regardless of the pathway for achieving a negligible BSE risk status (i.e., husbandry practices or effective and continuous mitigation of each identified risk).

b) Impact of the occurrence of case(s) of BSE

Consistent with the approach proposed in section 5.1. of this report, the Group further amended draft Article 11.4.3. point 3.a. to clearly state that the Member could be granted a negligible BSE risk status provided that if there has been a case, this case was either imported or diagnosed as atypical BSE.

At its November 2018 meeting, the *ad hoc* Group on BSE risk assessment noted that draft Article 11.4.3. needed to be further revised to clearly state that if there has been an indigenous case of classical BSE in an animal born 8 or less years ago in a country or zone already recognised as posing a negligible BSE risk, the Member could regain its negligible BSE risk status provided that a subsequent investigation confirmed that the likelihood of the BSE agent being recycled within the cattle population remained negligible. The Group accordingly amended draft Article 11.4.3. point 3.b.ii.

c) Complete destruction or disposal of any cases of BSE

At its February 2019 meeting, the Scientific Commission requested clarifications on whether the last provision of draft Article 11.4.3. (which requested that any cases of BSE have been completely destroyed) also applied to atypical BSE. In accordance with the overview on "Atypical BSE: the risk of being recycled in a cattle population and its zoonotic potential" (section 3 of this report and Appendix IV), the Group re-affirmed its previous position and, to improve clarity, amended draft Article 11.4.3. point 4., indicating that any cases of BSE either classical or atypical that have been detected should be completely destroyed or disposed of in such a way that ensures they do not enter the animal feed chain to prevent the recycling of BSE agents.

5.5. Draft Article 11.4.4. Controlled BSE risk

The Group refined draft Article 11.4.4. to ensure consistency of wording and numbering with draft Article 11.4.3.

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

The Group agreed with the opinion of the *ad hoc* Group on BSE which met in August 2016 which emphasised that provisions of current Article 11.4.6. were not applicable to commodities listed as safe commodities (current Article 11.4.1.) or to commodities for which recommendations were prescribed in other articles of Chapter 11.4. (i.e., current Articles 11.4.7., 11.4.10., and from 11.4.13. to 11.4.18.). The Group reviewed the list of commodities addressed in the other relevant articles of Chapter 11.4. and could not identify any remaining commodities which were not covered. The Group therefore recommended Article 11.4.6. be removed.

5.7. Draft Article 11.4.6. Recommendations for importation of cattle from a country, zone or compartment posing a negligible BSE risk

The Group noted that current Article 11.4.7. provided 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. The Group considered that in light of the provisions of draft Article 11.4.3., which clearly define the conditions related to the occurrence of an indigenous case, it was no longer relevant to provide such recommendations. The same recommendations would apply for the importation of live cattle from any country, zone or compartment posing a negligible BSE risk. The title of the draft article was amended accordingly.

The Group noted that current Article 11.4.7. point 1. on the permanent identification of cattle required measures to be taken on same feed cohort or birth cohort animals when an indigenous case of classical BSE was identified. Consistent with the recommendations of the *ad hoc* Group on BSE risk assessment at its July 2018 meeting, the Group agreed that the measures for cohort animals would not provide a significant gain in risk reduction as long as the likelihood of BSE being recycled within the cattle population continues to be negligible. As a result, the Group concluded that current Article 11.4.7. point 1. was no longer necessary.

Regarding the requirement of current Article 11.4.7. point 2. that cattle were born "*after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants had been effectively enforced*", the Group advised that rather the cattle were born in the country, zone or compartment *"during the period when the likelihood of the BSE agent being recycled in the cattle population has been demonstrated to be negligible*", consistent with Draft Article 11.4.3. point 1.

The Group discussed the provisions for trade that should apply to cattle older than the period for which the likelihood of the BSE agent being recycled in the cattle population has been assessed to be negligible. The Group noted that a country or zone applying for the official recognition of a negligible BSE risk status may be able to demonstrate that the likelihood of the BSE agent being recycled in the cattle population has been negligible for more than 8 years. In that case, this should be acknowledged in the report of the *ad hoc* Group on BSE Risk Status Evaluation of Members. This would allow countries or zones newly recognised as having a BSE negligible risk status to export cattle older than 8 years based on the provisions of draft Article 11.4.6. The Group emphasised that it should be possible for an applicant Member to document the BSE risk assessment for a period of more than eight years and that it would be necessary to make it explicit in the relevant sections of the BSE questionnaire.

5.8. Draft Article 11.4.7. Recommendations for importation of cattle from a country, zone or compartment posing a controlled BSE risk

Consistent with the approach proposed in draft Article 11.4.6., the Group advised that the provisions on the permanent identification of cattle were no longer necessary and that the cattle selected for export should be born in the country, zone or compartment during the period when the likelihood of the BSE agent being recycled in the cattle population has been demonstrated to be negligible. Consequently, this period should be acknowledged in the report of the *ad hoc* Group on BSE Risk Status Evaluation of Members.

5.9. Draft Article 11.4.8. Recommendations for importation of cattle from a country, zone or compartment posing an undetermined BSE risk

The Group reviewed the recommendations listed in current Article 11.4.9. (Recommendations for the importation of cattle from a country, zone or compartment posing an undetermined BSE risk) and pointed out that compliance with the provisions listed in points 1 ("*the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been banned and the ban has been effectively enforced*") and 3.b. (cattle selected for export "*were born at least two years after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants was effectively enforced*") would be difficult to institute and assess considering that a feed ban may not have been implemented in countries, zones or compartments posing an undetermined BSE risk.

The Group therefore recommended that draft Article 11.4.8. should focus on the demonstration that an individual animal has never been fed with feed containing ruminant-derived protein meal (see section 4 of this report). The Group acknowledged that this would be difficult to certify and that a permanent individual identification, recording and traceability system from birth and throughout the lifetime of the animal prior to export would be a pre-requisite to allow such a demonstration to be made. This option would, however, allow for bilateral negotiations of such trade.

5.10. Draft Article 11.4.9. Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a negligible BSE risk

The Group reviewed the recommendations listed in current Article 11.4.10., and, consistent with the proposed approach in draft Article 11.4.6., the Group recommended that meat and meat products imported from a country, zone or compartment posing a negligible BSE risk should be derived from cattle that passed ante-mortem inspection and were born during the period when the likelihood of the BSE agent being recycled in the cattle population has been assessed to be negligible. The Group proposed alternative provisions for meat and meat products derived from cattle that were not born during this period.

The Group reviewed the recommendation made by the *ad hoc* Group on BSE which met in August 2016 proposing that the fresh meat and meat products imported from a country, zone or compartment posing a negligible BSE risk should be produced and handled in a manner which ensures that such products do not contain and are not contaminated with skull, brain, eyes and spinal cord and mechanically separated meat from the skull from cattle over 60 or 72 months of age. Considering that, based on the provisions of draft Article 11.4.3., the likelihood of the BSE agents (atypical and classical) being recycled in the cattle population would have been demonstrated to be negligible, and acknowledging that atypical BSE would remain at a very low level and with a potential uniform presentation in any cattle population, the Group considered that specific recommendations targeting atypical BSE for international trade from a country, zone or compartment posing a negligible BSE risk would be disproportionate to the likely level of risk. As a result, the Group did not fully endorse the proposal made by the 2016 *ad hoc* Group on BSE.

The Group emphasised that *post-mortem* inspection is not considered relevant for BSE and recommended any reference to *post-mortem* inspection to be removed throughout draft Chapter 11.4.

5.11. Draft Article 11.4.10. Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing a controlled BSE risk

The Group reviewed the recommendations listed in current Article 11.4.11. and only made editorial changes for the sake of clarity and harmonisation with draft Article 11.4.11.

5.12. Draft Article 11.4.11. Recommendations for importation of fresh meat and meat products from a country, zone or compartment posing an undetermined BSE risk

The Group reviewed the recommendations listed in current Article 11.4.12. and agreed with the opinion of the *ad hoc* Group on BSE which met in August 2016 that point 2.b. of current Article 11.4.12., should be removed. Point 2.b. currently recommends that fresh meat and meat products should be produced and handled to ensure that such products do not contain and are not contaminated with nervous and lymphatic tissues exposed during the deboning process. The Group agreed that these measures would have been implemented out of an abundance of caution based on a comparison with scrapie. Indeed, pathogenesis studies have subsequently confirmed that BSE in cattle amplifies almost exclusively in the CNS and the ileal Peyer's patches, with later limited centrifugal spread of infectivity along nerve fibres into the periphery in the clinical stages of the disease[3, 4]. As a result, the Group concluded that the removal of these tissues is not relevant to mitigate the BSE risk.

The Group noted that current Article 11.4.12. point 2.c. required that fresh meat and meat products should be produced and handled in a manner which ensures that such products do not contain and are not contaminated with mechanically separated meat from the skull and from the vertebral column from cattle over 12 months of age. The Group discussed the age limit of 12 months and agreed that it was originally implemented out of an abundance of caution in the early 2000s when there was significant uncertainty. However, experiences gained since then have confirmed that the occurrence of clinical cases in cattle less than three years of age is a rare event. For example, even in Great Britain, the country with the highest levels of exposure to BSE, only 0.15% of almost 137,000 BSE cases, for which there was reliable age data, were less than 36 months of age over the course of the entire epidemic [5]. In addition, experimental oral challenge studies in cattle with a one-gram dose of highly infectious brain material indicate that the detection of infectivity in central nervous system (CNS) in the majority of animals likely occurs only after 42 months-post-exposure (Arnold *et al.*, 2007). The one-gram dose used in this study is likely to represent a reasonable worst-case exposure scenario for naturally infected cattle. Considering that the average

[3] Espinosa JC, Morales M, Castilla J, Rogers M, Torres JM. Progression of prion infectivity in asymptomatic cattle after oral bovine spongiform encephalopathy challenge. *Journal of General Virology*. 2007; **88**, 1379-1383.

[4] Balkema-Buschmann A, Fast C, Kaatz M, Eiden M, Ziegler U, McIntyre L, Keller M, Hills B, Groschup MH. Pathogenisis of classical and atypical BSE in cattle. *Preventive Veterinary Medicine*. 2011; **102** (2):112-117.

[5] Animal and Plant Health Agency (March 2019). (1) Age related statistics, available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/795724/pub-tse-stat-age.pdf, and (2) General statistics on BSE cases in Great Britain, available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/795723/pub-tse-stat-gen.pdf

incubation period of cattle infected in the field is in the range of 5.0 to 5.5 years, these authors considered that their findings *"offer considerable scope for modulation of current regulations".* The Group concluded that maintaining an age limit of 12 months would be disproportionate to the level of risk and recommended it be aligned with the age limit suggested for the importation of meat and meat products from a country, zone or compartment posing a controlled BSE risk (i.e., 30 months).

5.13. Draft Article 11.4.12. Recommendations for importation of cattle-derived protein meal from a country, zone or compartment posing a negligible BSE risk

Current Article 11.4.13. was revised consistent with the change in definition presented in section 4 of this report (i.e., from "meat-and-bone meal or greaves" to "protein meal").

The Group recommended revising the scope from "ruminant-derived meat-and-bone meal or greaves" to "cattle-derived protein meal" as cattle (*Bos taurus* and *B. indicus*) are the species of relevance for BSE as defined in draft Article 11.4.1. Furthermore, as stated in draft Article 11.4.1., the recommendations in this chapter are intended to mitigate the human and animal health risks associated with the presence of the BSE agents in cattle only. As a result, the recommendations in draft Articles 11.4.6. to 11.4.18. are all about mitigating the BSE risks associated with the trade of commodities derived from cattle. Including "ruminants" more broadly in draft Article 11.4.14. would be beyond the scope of the BSE Chapter. It's worth noting that Article 14.8.11., concerning scrapie, recommends to not trade MBM containing any sheep or goat protein from countries not considered free from scrapie, and does not impose restrictions for trade of ruminant-derived MBM.

Consistent with the revision proposed in draft Article 11.4.6., the Group recommended revising current Article 11.4.13. point 1. which provides recommendations for importation from negligible BSE risk countries where there has been an indigenous case of BSE. Indeed, provisions regarding the occurrence of an indigenous case of BSE, in a country, zone or compartment posing a negligible BSE risk were no longer considered relevant in light of the provisions of draft Article 11.4.3. The Group emphasised that the age of the cattle should be taken into consideration to ensure that they were born during the period when the likelihood of the BSE agent being recycled in the cattle population was assessed to be negligible.

The Group discussed whether recommendations could be developed for the importation of cattle-derived protein meal from countries, zones or compartments posing a controlled or undetermined BSE risk provided these protein meals are free from those commodities listed in draft Article 11.4.14. that are associated with the vast majority of BSE infectivity. However, the Group determined that the proper implementation of this requirement would be difficult to verify and stressed that the BSE risk associated with any improper implementation of this requirement would be significant considering the importance of protein meal in the recycling of BSE. The Group therefore concluded that it was not appropriate to develop recommendations for the importation of cattle-derived protein meal from countries, zones or compartments posing a controlled or undetermined BSE risk.

5.14. Draft Article 11.4.13. (New Article). Recommendations for importation of blood and blood products

Considering that the Group recommended that blood and blood products should no longer be listed as safe commodities (see section 5.2. of this report and draft Article 11.4.1.bis.) to comply with the recently adopted Chapter 2.2. of the *Terrestrial Code*, the Group drafted a new article to provide recommendations for the importation of blood and blood products.

The Group clarified that the provisions in this Article relate to blood and to blood products rather than to blood by-products. A blood by-product refers to one that is not intended to be produced but that results from processing of blood when a different final product is intended (which would be a blood product). Blood product refers to derived product from blood, which, together with blood are the scope of this Article.

The recommendations provided for blood and blood products derived from ruminants which were not born in a country, zone or compartment posing a negligible BSE risk during the period when the likelihood of the BSE agent being recycled in the cattle population has been demonstrated to be negligible ensure that cross contamination with nervous tissue is avoided.

5.15. Draft Article 11.4.14. Recommendations regarding commodities associated with the vast majority of BSE infectivity

The Group considered the recommendation made by the *ad hoc* Group on BSE which met in August 2016 proposing that the restriction applicable to tonsils be removed and reviewed the scientific evidence[6] supporting this proposal. The Group concurred with the *ad hoc* Group that the restriction applicable to tonsils should be removed.

As emphasised in section 5.12. of this report, the Group agreed that current scientific evidence does not support an age limit of 12 months. The Group therefore recommended removing point 3. of current Article 11.4.14.

Consistent with current Article 11.4.13. point 2., and with the rationale presented in section 5.13. of this report, the Group emphasised that cattle-derived protein meal, or any commodities containing such products, which originate from a country, zone or compartment posing a controlled or undetermined BSE risk should not be traded. Therefore, the Group proposed to move this recommendation to draft Article 11.4.14. point 3.

The Group reviewed the recommendation made by the ad hoc Group on BSE which met in August 2016 proposing that the commodities "*from cattle that were at the time of slaughter over 60 or 72 months of age originating from a country, zone or compartment defined in Article 11.4.3., the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord and skull. Protein products, food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities (unless covered by other Articles in this chapter) should also not be traded.*" This provision and age limit were proposed to mitigate the risk associated with atypical BSE. Consistent with the rationale presented in section 5.10. of this report, the Group determined that the proposal made by the ad hoc Group in 2016 was disproportionate to the level of risk and did not endorse it.

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

The Group reviewed the steps that bones should be subjected to for the preparation of gelatine and collagen as described in current Article 11.4.15. point 2.b. The Group considered a report from EFSA[7] and agreed that the steps listed in point 2.b. were sufficient to ensure that *"the relative human exposures due to gelatine produced from bones including the skull and vertebral column sourced from cattle of any age are very low (< 10^{-5}) and do not support the continuation of the restriction prohibiting the inclusion of skull and vertebral column".* The Group therefore determined that the provision of exclusion in current Article 11.4.15. point 2.a. (i.e., "*vertebral columns from cattle over 30 months of age at the time of slaughter and skulls have been excluded*") could not be justified.

---

6 EFSA Panel on Biological Hazards. Scientific Opinion on the revision of the quantitative risk assessment (QRA) of the BSE risk posed by processed animal proteins. *The EFSA Journal*. 2011; **9**(1):1947 doi:10.2903/j.efsa.2011.1947. The infectivity of tonsils is estimated 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 that it would be in fact 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 and it is not classified as a high risk tissue. As a result, it is reasonable to conclude that the risk posed by tonsillar tissue is insignificant.

7 EFSA Panel on Biological Hazards. Opinion of the Scientific Panel on biological hazards (BIOHAZ) on the "Quantitative assessment of the human BSE risk posed by gelatine with respect to residual BSE [1]". *The EFSA Journal*. 2006; **4**(1):312, 1–29 doi:10.2903/j.efsa.2006.312

Furthermore, the Group considered that the steps of the process described in point 2.b. were common industrial practices and were not specifically directed against BSE. Therefore, the Group contemplated whether, in light of the definition of safe commodities provided in the Glossary of the *Terrestrial Code* and of the provisions of Chapter 2.2. of the *Terrestrial Code,* gelatine and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices could be considered safe commodities provided they are subjected to the processes currently described in point 2.b. of Article 11.4.15. After seeking advice from the Code Commission, the Group remained uncertain whether or not this would be fully consistent with Chapter 2.2. As a result, the Group proposed to maintain this provision in draft Article 11.4.15. at this stage and to refer the proposal to include it in the list of safe commodities to the Code Commission for further deliberation.

The Group reviewed the recommendation made by the *ad hoc* Group on BSE which met in August 2016 proposing that the commodities should come from a country, zone or compartment posing a negligible BSE risk and should be derived from cattle which have passed *ante-* and *post-mortem* inspections and the skull from cattle over 60 or 72 months of age at the time of slaughter should be excluded. Consistent with the rationale presented in section 5.10. of this report, the Group determined that this proposal was disproportionate to the level of risk and did not endorse it.

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

The Group considered the opinion of the *ad hoc* Group on BSE that met in August 2016 which recommended that tallow coming from a country, zone or compartment posing a negligible BSE risk should not have been prepared using tissues listed in current Article 11.4.14. Consistent with the rationale presented in section 5.10. of this report, the Group determined that this proposal was disproportionate to the level of risk and did not endorse it.

The Group reviewed a recent study undertaken by Fast *et al.*[8] where BSE infectivity was detected in tallow produced by standard rendering methods (20 minutes at 95° C) using mesentery with embedded nervous tissue from the celiac and mesenteric ganglion complex from a clinical case of classical BSE that had been experimentally infected by the oral route. While this provides proof of principle that prion infectivity in adipose tissue is associated with the nervous tissue attached to the mesentery, it is important to note that the level of infectivity (tested by transgenic mouse bioassay) was extremely low with positive findings in only 1 out of 6 mice. This indicates that the levels of infectivity would likely have been less than that detected in semitendinosus muscle where 9 out of 13 transgenic mice were positive (Kaatz *et al.*, 2012[9]). In the latter study, the level of infectivity was estimated to be at least 6 logs less than the brain. In light of these findings, the Group was of the opinion that the level of infectivity in tallow derived from mesenteric fat would be negligible.

The Group agreed that, based on the evidence available to date, the exclusion of those materials listed in point 1. of draft Article 11.4.14. in the preparation of tallow, ensures the effective mitigation of potential BSE risks regardless of whether the country, zone or compartment of origin has controlled or undetermined BSE risk status. As a result, the Group proposed to remove the specific reference to controlled BSE risk in point 2 of current Article 11.4.16. With this change, tallow would be eligible for trade from a country, zone or compartment posing a controlled or undetermined BSE risk as long as it derived from cattle that passed *ante-mortem* inspection and had not been prepared using the commodities listed in point 1 of draft Article 11.4.14.

---

8 Fast C, Keller M, Kaatz M, Ziegler U, Groschup MH. Low levels of classical BSE infectivity in rendered fat tissue. *Veterinary Research*. 2018; **49**(1):122.

9 Kaatz M, Fast C, Ziegler U, Balkema-Buschmann A, Hammerschmidt B, Keller M, Oelschlegel A, MacIntyre L, Groschup MH (2012) Spread of classic BSE prions from the gut via the peripheral nervous system to the brain. *Am. J. Pathol*., **181**:515–524.

5.18. Draft Article 11.4.17. Recommendations for importation of dicalcium phosphate (other than as defined in Article 11.4.1.bis) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

As dicalcium phosphate can be considered a co-product of bone gelatine, the Group concurred with the opinion of the *ad hoc* Group on BSE which met in August 2016 which recommended that dicalcium phosphate should originate from products compliant with the requirements of the relevant article within Chapter 11.4. (i.e., draft Article 11.4.15.). However, the Group emphasised that this provision should only apply to countries, zones, or compartments posing a controlled or undetermined BSE risk.

Furthermore, the Group clarified that dicalcium phosphate is rather a co-product than a by-product of bone gelatine as it is produced along with gelatine when the material of origin is bone. Both gelatine and dicalcium phosphate share the initial production steps (i.e., decreasing and demineralization) and are both intended outputs of the process.

5.19. Draft Article 11.4.18. Recommendations for importation of tallow derivatives (other than those made from tallow as defined in Article 11.4.1.bis) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

The Group considered the provisions of current Article 11.4.18. point 3. which recommend that tallow derivatives should have been produced by hydrolysis, saponification or transesterification using high temperature and pressure. The Group considered that these measures were common industrial practices and were not specifically directed against BSE. Therefore, the Group contemplated if in light of the definition of safe commodities provided in the Glossary of the *Terrestrial Code* and of the provisions of Chapter 2.2. of the *Terrestrial Code,* tallow derivatives could be considered safe commodities provided they are subjected to the process described in current Article 11.4.18. point 3. However, after receiving preliminary advice from the Code Commission, the Group proposed to maintain the corresponding provision in draft article 11.4.15. at this stage, and to refer the proposal to include it in the list of safe commodities to the Code Commission for further consideration.

5.20. Draft Article 11.4.19. Procedures for the reduction of BSE infectivity in protein meal

The Group did not propose any revision to the procedures for the reduction of BSE infectivity in protein meal.

5.21. Draft Article 11.4.20. Passive surveillance

The Group reviewed and endorsed the revised Article on BSE surveillance drafted by the *ad hoc* Group on BSE surveillance in October 2018 and made only minor editorial changes.

6. Revision of Chapter 1.8. of the *Terrestrial Code*

The Group reviewed and edited draft Chapter 1.8. (the BSE "questionnaire") which was only initially drafted by the *ad hoc* Group on BSE risk assessment at its November 2018 meeting and completed electronically by the experts ahead of this meeting. Major edits in the structure of the BSE questionnaire were done to ensure full consistency between this document and revised Chapter 11.4.

6.1. General considerations

At its November 2018 meeting, the *ad hoc* Group on BSE risk assessment did not reach a consensus regarding whether or not applicant Members should undertake and document a BSE risk assessment, or alternatively, if the BSE "questionnaire" should facilitate the compilation of sufficient data to enable the *ad hoc* Group on BSE Risk Status Evaluation of Members to undertake the BSE risk assessment. The Group discussed these options and agreed that applicant Members should document the necessary body of

evidence and undertake the risk assessment. In addition, the Group recommended that likelihood estimates for each step of the risk assessment process as well as the final risk estimate should be consistent with and based on the guidance provided in the OIE *Handbook on Import Risk Analysis for Animals and Animal Products*.

The Group acknowledged that "questionnaires" for the official recognition of status for other diseases (i.e., Chapters 1.7. and 1.9. to 1.12.) do not justify why certain information is necessary nor offer detailed guidelines on how it should be provided. However, the Group was of the opinion that applicant Members for the official recognition of a BSE risk status would benefit from detailed guidance to assist them in undertaking a comprehensive risk assessment. Furthermore, the Group was of the opinion that Chapter 1.8. should, as much as possible, be designed to be a "user friendly", standalone document without extensive cross-references to other Chapters of the *Terrestrial Code*.

Consistent with the recommendations for trade applicable to various commodities, applicant Members would have the option of providing evidence for a different period of time (more than eight years if applying for negligible risk status, or for the time they have it if applying for a controlled risk status) in support of a determination, by the *ad hoc* Group on BSE Risk Status Evaluation of Members, of the actual period when the likelihood of the BSE agent being recycled in the cattle population has been assessed to be negligible. See sections 5.7. and 5.8. of this report.

6.2. Draft Article 1.8.5. point 1. Entry assessment

Based on the experience of the OIE *ad hoc* Group on BSE Risk Status Evaluation of Members, applicant Members tend to provide extensive amounts of data, information, tables, and figures in their applications which do not necessarily inform the risk assessment. The Group re-affirmed its previous position that detailed quantitative information (e.g., volume, statistics, etc.) on imported commodities was not informative for the entry assessment as long as either the commodities were imported under conditions consistent with the recommendations laid out in Chapter 11.4. or it can be demonstrated that an equivalent level of assurance was provided. The emphasis should be on documenting the measures applied to imported commodities depending on the BSE risk status of the country or zone of origin together with how the Competent Authority verifies compliance through supporting legislation, certification, and regulations.

6.3. Draft Article 1.8.5. point 2. Exposure assessment

The Group discussed how an applicant Member should determine which pathway (i.e., either livestock industry practices or effective and continuous mitigation of each identified risk) to follow during the application for official recognition of its BSE risk status. The Group indicated that it would be based on the conclusions arising from livestock industry practices and the associated likelihood that the cattle population has been exposed to either classical or atypical BSE agents. If the applicant Member concluded that the likelihood has been non-negligible, an evaluation of BSE specific mitigation measures should be performed. The Group agreed that the applicant should provide information on livestock industry practices regardless of the pathway chosen as this provides indispensable background information.

If an applicant Member concluded that the likelihood that the cattle population has been exposed to either classical or atypical BSE agents has been negligible as a result of its livestock industry practices, but the *ad hoc* Group on BSE Risk Status Evaluation of Members reached a different conclusion, the application for a BSE risk status would be rejected. The applicant Member would then be invited to apply for the recognition of its BSE risk status based on the effective and continuous mitigation of each identified risk.

Current Article 11.4.2. point 1.b. recommends that "*if the entry assessment identifies a risk factor, an exposure assessment should be conducted*". Consistent with the provisions of draft Article 11.4.2., the Group stressed that in the revised framework for BSE, an exposure assessment should be undertaken regardless of the outcome of the entry assessment. Indeed, in accordance with the findings of the overview on "*Atypical BSE: the risk of being recycled in a cattle population and its zoonotic potential*" (section 3 of this report and Appendix IV), the potential recycling of atypical BSE in any cattle population should be considered and, if necessary, mitigated.

6.4. Draft Article 1.8.5. point 3. Consequence assessment

The Group explained the circumstances that could lead to the recycling of BSE agents in a cattle population. In particular, the Group outlined the series of events that could initiate a cycle of BSE infectivity within a cattle population and made clear that recycling would arise when this cycle is repeated one or more times.

The Group emphasised that any level of recycling within a given period was sufficient to conclude that the consequences of exposure to contaminated feed for that period within the cattle population was non-negligible.

6.5. Draft Article 1.8.5. point 4. Risk estimation

The risk estimation is the final step of the BSE risk assessment, and should provide an overall measure of the risk that the BSE agents have been recycled in the cattle population through the feeding of cattle with ruminant-derived protein meal, with indigenous cases arising as a consequence.

6.6. Draft Article 1.8.6. BSE surveillance

Current Article 1.8.4. on BSE surveillance was revised to reflect the new provisions for BSE surveillance defined in draft Article 11.4.20.

6.7. Draft Article 1.8.7. Recovery of a BSE risk status

The Group provided some guidance for Members applying for the recovery of a previously recognised negligible BSE risk status suspended following non-compliance with any of the 4 provisions of Article 11.4.3, including the occurrence of an indigenous case of classical BSE in an animal born within the preceding 8 years.

7. Potential impact of the revision of the BSE standards on the official BSE risk status currently recognised

Based on the provisions of draft Chapter 11.4. an exposure assessment should be undertaken regardless of the outcome of the entry assessment. However, in accordance with the provisions of current Chapter 11.4. (Article 11.4.2. point 1.b.), some Members have had an official BSE risk status recognised by the OIE based on a negligible likelihood of entry despite a non-negligible likelihood of exposure at the time of the assessment.

The OIE Secretariat pre-identified 18 Members which may be impacted by the revision of the BSE standards, if a negligible likelihood of exposure cannot be demonstrated.

The Group agreed that updated information should be gathered on the likelihood of exposure to the BSE agents, including through the 2019 annual reconfirmation campaign as necessary. The Group recommended that based on the updated information collected, the likelihood of exposure to the BSE agents should be (re)assessed under the responsibility of the Scientific Commission with the support of the *ad hoc* Group on BSE Risk Status Evaluation of Members if necessary.

If based on the updated assessment, the likelihood of exposure is assessed to be non-negligible for some Members, the Scientific Commission would have to determine how the recognised status would be impacted. The Group emphasised that the BSE risk posed by a Member's cattle population has not changed as a result of the proposed changes to the Chapter and a pragmatic approach would be required to ensure against any disproportionate impact on individual Members.

8. Retention on the list of negligible or controlled BSE risk status

The Group discussed the level of evidence that should be provided by Members annually to confirm compliance with the relevant provisions of draft Articles 11.4.3. and 11.4.4. to be retained on the list of countries or zones with negligible or controlled BSE risk status.

The Group advised that Members should annually:

- confirm that the risk assessment for BSE has been reviewed indicating whether or not the conclusion has changed and when it has, provide the updated risk assessment to the OIE;

- provide documented evidence that passive surveillance for BSE has been implemented in accordance with the provisions of draft Article 11.4.20;

- confirm that there have not been any cases of classical BSE in indigenous cattle born less than 8 years ago;

- confirm, in addition to the information provided through notifications made in accordance with the requirements of Chapter 1.1. of the *Terrestrial Code*, that any BSE cases detected have been completely destroyed or disposed of.

The Group agreed that based on these provisions, an annual reconfirmation form would be drafted by the OIE Secretariat and circulated to the Group for its review.

In addition, to increase confidence in the annual review of the BSE risk assessment and its conclusions, the Group suggested that Members could be requested to provide an updated risk assessment either at a given frequency (e.g., every 10 years), or when selected for comprehensive review by the Scientific Commission (i.e., 10% of the official BSE risk status each year). The Group recommended this proposal be referred to the Scientific Commission for its consideration.

9. Recommendations for the consideration of the OIE

The Group recommended the overview on "*Atypical BSE: the risk of being recycled in a cattle population and its zoonotic potential*" (Appendix IV) be referred to the Biological Standards Commission in support of the update of Chapter 3.4.5. of the *Terrestrial Manual* (section 5.1. of this report). The Group also recommended that consistency should be ensured between the list of behavioural or clinical signs related to BSE defined in draft Article 11.4.20. and those listed in Chapter 3.4.5. of the Terrestrial Manual.

The Group recommended that when assessing applications for the recognition of a BSE risk status, the ad hoc Group on BSE Risk Status Evaluation of Members should specify the date from which likelihood of the BSE agent being recycled in the cattle population is assessed to be negligible. This period could be longer than 8 years for Members applying for a negligible risk status, or for the time there is sufficient evidence for Members applying for a controlled risk status (sections 5.7. and 5.8. of this report).

The Group noted that whether the definition of "protein meal" proposed for the purpose of Chapters 11.4. and 1.8. is relevant for other disease-specific Chapters (i.e., Chapter 8.1. on anthrax; Chapter 8.4. on infection with *Brucella abortus, B. melitensis* and *B. suis*; Chapter 8.11. on infection with *Mycobacterium tuberculosis complex*; Chapter 14.8. on scrapie; and Chapter 15.3. on infection with porcine reproductive and respiratory syndrome virus) should be further assessed by the OIE. See Section 4 of this report.

The Group recommended that the following commodities be further considered by the Code Commission for inclusion as safe commodities:

- gelatine and collagen prepared from bones subjected to the process described in draft Article 11.4.15. point 2. and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices (section 5.16. of this report); and

- tallow derivatives produced by hydrolysis, saponification or transesterification using high temperature and pressure (section 5.19. of this report).

The Group recommended that the potential impact of revisions of the BSE standards on the currently recognised BSE risk status should be further assessed by the Scientific Commission with the support of the *ad hoc* Group on BSE Risk Status Evaluation of Members as necessary. See section 7 of this report.

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

The Group noted that due to the nature of BSE, OIE standards are likely to need to be reassessed in the future in light of emerging scientific evidence and the evolution of the global situation for BSE.

10. Finalisation and adoption of the report

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

_____

…/Annexes

Annex I

MEETING OF THE OIE *AD HOC* GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT AND SURVEILLANCE

Paris, 18-21 March 2019

———————

Terms of Reference

Purpose

The purpose of this *ad hoc* Group is to provide independent analysis and advice to OIE on the surveillance and risk-based provisions applicable to the recognition and maintenance of BSE risk status as well as on recommendations applicable for international trade.

Functions

This *ad hoc* Group will report to the Director General of the OIE, and approved reports will be considered by the relevant Specialist Commissions (the Scientific Commission or the Terrestrial Animal Health Standards Commissions) when necessary, in accordance with the OIE Basic Texts.

- Experts' contributions will be solicited in preparation of this meeting under the coordination of the OIE Secretariat.

- During this meeting, this *ad hoc* Group will:

1. Finalise the revision of Chapter 11.4.:

   a. Further consider atypical BSE, including:

      - Review and endorse a draft paper on the risk of atypical BSE being recycled in a cattle population and its zoonotic potential;

      - Ensure that the terms 'atypical', 'classical', and 'BSE agent(s)/strains' are clearly stated to avoid ambiguity about the applicability of each provision to either atypical BSE only, classical BSE only, or both, in Chapters 1.8. and 11.4., and in the annual reconfirmation form.

   b. Article 11.4.3. (Negligible BSE risk), considering in particular:

      - whether the need for a Member to demonstrate the implementation of a ruminant-to-ruminant feed ban should be explicitly stated as an independent point (point 1.b.) (i.e., a separate point to the provision on risk assessment) or if it would be sufficient to rather implicitly consider it within the risk assessment (point 1.a.) (i.e., by indicating that the risk assessment should demonstrate a negligible likelihood of recycling);

      - proper wording to clearly state that if there has been an indigenous case of classical BSE in an animal born 8 or less years ago in a country or zone already recognised with a negligible BSE risk status, the Member could retain the status as long as an investigation confirms that the likelihood of the BSE agent being recycled within the cattle population remained negligible (point 2.b.ii.).

   c. Articles 11.4.6. to 11.4.19 (recommendations for trade commodities) taking into consideration the proposals made by the *ad hoc* Group on BSE which met in August 2016;

   d. Article 11.4.1. (safe commodities) taking into consideration the proposals made by the *ad hoc* Group on BSE which met in August 2016 as well as the recent scientific knowledge;

e. Article 11.4.14. (commodities that should not be traded) taking into consideration the proposals made by the *ad hoc* Group on BSE which met in August 2016, the opinion of the Scientific Commissions on these proposals, as well as the recent scientific knowledge;

f. Article 11.4.20. (BSE Surveillance).

2. Finalise the revision of Chapter 1.8. (BSE questionnaire):

a. Address any remaining matters based on comments to the Draft Questionnaire. In particular:

- Determine whether the BSE risk assessment should be performed by the applicant Member or by the ad hoc Group on BSE risk status evaluation of Members. This will impact the type, amount and granularity of the data and information to be included in the questionnaire.

- Clarify BSE risk status recognition of compartments.

- Agree on the steps to follow after a pathway for achieving negligible risk status is selected and how to reflect this on the Questionnaire. Should information on specific risk mitigation measures be provided after selecting the first pathway (i.e., livestock industry practices)?

- Agree whether a ruminant-to-ruminant feed ban is compulsory regardless of its presence or absence in a country's legislation.

b. Discuss whether an Article on Conclusions is needed.

c. Ensure full consistency between the questionnaire and draft revised Chapter 11.4.

3. Address any remaining issues, including:

a. Review the definitions of meat-and-bone meal and greaves within Chapters 1.8. and 11.4. and assess whether updated definitions should be proposed and whether the revised definitions would only apply to Chapters 1.8. and 11.4., or throughout the *Terrestrial Code* (i.e., revision of the Glossary).

b. Assess the impact of the proposed revised requirements for the categorisation of BSE risk status on the countries or zones already having an officially recognised BSE risk status.

c. Revise the form in support of the annual reconfirmation of BSE risk status

- Ensure full consistency between the reconfirmation form and draft revised Chapter 11.4.

d. Consider a request from the European Serum Products Association.

➢ Should the Group not be able to complete its Terms of reference during this meeting, experts' contributions will be solicited after the meeting, including by teleconference(s) if needed.

_____

Annex II

MEETING OF THE OIE *AD HOC* GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT AND SURVEILLANCE

Paris, 18-21 March 2019

_____

Agenda

1. Opening
2. Adoption of the agenda and appointment of chairperson and rapporteur
3. Atypical BSE
4. Definitions of meat-and-bone meal (MBM) and greaves
5. Revision of Chapter 11.4. of the *Terrestrial Code*
6. Revision of Chapter 1.8. of the *Terrestrial Code*
7. Potential impact of the revision of the BSE standards on the official BSE risk status currently recognised
8. Recommendations for the consideration of the OIE
9. Retention on the list of negligible or controlled BSE risk status
10. Finalisation and adoption of the report

_____

Annex III

MEETING OF THE OIE *AD HOC* GROUP ON BOVINE SPONGIFORM ENCEPHALOPATHY RISK ASSESSMENT AND SURVEILLANCE

Paris, 18-21 March 2019

_____

List of participants

MEMBERS

Dr Stephen Cobb
Manager (New Organisms)
Environmental Protection Agency
NEW ZEALAND
Tel.: +64 474 55 22
stephen.cobb@epa.govt.nz

Dr Alicia Cloete
State Veterinarian
Sub-Directorate: Disease Control
Department of Animal Health
Department of Agriculture, Forestry and Fisheries
SOUTH AFRICA
Tel.: 012 319 7518
AliciaC@daff.gov.za

Dr Eric Thévenard
Head of Unit
European Commission
BELGIUM
Tel.: +32 2 296 99 66
Eric.Thevenard@ec.europa.eu

Dr Toshiyuki Tsutsui
(invited, but could not attend)
Director
Department of Planning and General Administration
National Institute of Animal Health
National Agriculture and Food Research Organization
JAPAN
Tel.: +81-29-838-7704
tsutsui@affrc.go.jp

Dr Noel Murray
Senior Advisor on Risk Analysis
Canadian Food Inspection Agency
CANADA
Tel.: +1 613 773 5904
noel.murray@canada.ca

Dr Ximena Melón
Directora de Comercio Exterior Animal
Servicio Nacional de Sanidad y Calidad Agraolimentaria (SENASA)
ARGENTINA
Tel.: +54 11 41 21 5425
xmelon@senasa.gob.ar

Dr Ángel Ortiz-Pelaez
Senior Scientific Officer
European Food Safety Authority (EFSA)
ITALY
Tel.: +39 0521 036 640
angel.ortizpelaez@efsa.europa.eu

Representatives from the Specialist Commissions

Dr Baptiste Dungu
(By teleconference)
Member of the Scientific Commission for Animal Diseases.
CEO - Onderstepoort Biological Products
SOUTH AFRICA
Tel.: +27 (0)12 522 1607
Baty@obpvaccines.co.za

Dr Bernardo Todeschini
Member of the Terrestrial Animal Health Standards Commission.
Federal Superintendent of Agriculture for Rio Grande do Sul - Ministry of Agriculture, Livestock and Food Supply
BRAZIL
Tel.: +598 2 4101676
bernardo.todeschini@agricultura.gov.br

OIE HEADQUARTERS

Dr Neo J. Mapitse
Head of the Status Department
n.mapitse@oie.int

Dr Francisco D'Alessio
Deputy Head of the Standards Department
f.dalessio@oie.int

Dr Morgane Dominguez
Project officer
Status Department
m.dominguez@oie.int

Dr Kiyokazu Murai
Chargé de mission
Standards Department
k.murai@oie.int

Dr Fernanda Mejía-Salazar
Chargée de mission
Status Department
f.mejia-salazar@oie.int

_____

Annex IV

Atypical bovine spongiform encephalopathy (BSE) – transmissibility among cattle and its zoonotic potential

OIE *ad hoc* Group on BSE risk assessment and surveillance – March 2019

This overview of relevant literature was prepared by Dr N. Murray on behalf of the OIE *ad hoc* Group on BSE risk assessment and surveillance, and was edited and endorsed by this *ad hoc* Group. It aims to gather current scientific literature to support the assessment of the risk of recycling of atypical BSE in a cattle population and its zoonotic potential to support an informed risk-based revision of the provisions for atypical BSE outlined in Articles 11.4.2. and 11.4.3. of the *Terrestrial Animal Health Code*.

I. Implications for the cattle population of a country (risk of recycling)

Atypical BSE is a neurological disease of cattle caused by misfolded prion proteins with different conformations than those of the classical BSE (C-BSE). Two phenotypes of atypical BSE have been recognised, designated H-type or L-type based on Western Blot characteristics of the unglycosylated PrP following proteinase-K (PK) digestion (Casalone *et al.*, 2004, Biacabe *et al.*, 2004), both are transmissible to cattle following intracerebral inoculation (Lombardi *et al.*, 2008; Fukuda *et al.*, 2009; Konold *et al.*, 2012; Balkema-Buschmann *et al.*, 2011; Okada *et al.*, 2011).

As discussed in a previous report from an OIE *ad hoc* Group on BSE (August 2016), epidemiological data from Europe as well as from Brazil, Canada, Israel, Japan and the United States of America (USA) all support the contention that atypical BSE is likely to arise spontaneously in all cattle populations at a very low rate.

Simmons *et al.* (2017) highlighted the fact that in experimental inoculation models in cattle, the incubation periods of H- and L-BSE were similar to or shorter than those observed with C-BSE (Balkema-Buschmann, Ziegler, *et al.*, 2011; Fukuda *et al.*, 2009; Konold *et al.*, 2012; Lombardi *et al.*, 2008). Based on pooled data for 110 atypical cases for which the age is known from the European Union (EU) and the OIE for countries outside the EU from 2001 to 2019, most cases (>91.7%) have been detected in animals 8 years or older[10] (European Commission, 2016; EFSA 2016, 2017, 2018). The youngest case reported to date was almost 67 months old (5.6 years) (World Organisation for Animal Health, 2019).

In recently published research work, Okada and colleagues, 2017, confirmed that the L-type BSE prion can be orally transmitted. Of 16 calves challenged with various amounts of infectious brain material, only 1 animal, which was given a high dose (50 grams), developed clinical signs after a lengthy incubation period of 88 months (7.3 years). The rest of the calves (1 that received the same dose, and 15 that received lower doses) did not show clinical signs and results were negative by Western blot and immunohistochemistry analyses after 51-94 months post inoculation. Although this study is limited, its results suggest a low likelihood of oral transmission of L-BSE agent among calves. Moreover, based on the dose-response curve estimated by Wells *et al.* (2007), for a comparable amount of infectivity for C-BSE, the corresponding incubation period would be approximately 55 months, indicating that C-BSE would be more infectious.

In contrast, there have not been any substantiated reports of the successful oral transmission of H-BSE in cattle. Initial reports from Dudas *et al.*, 2014 based on RT-QuIC pointed to the possibility of oral transmission following a very high dose (100 grams of brain material), although the individual did not display clinical signs and the findings from standard molecular or immunohistochemical assays were all negative. Investigations are ongoing in an attempt to clarify these findings.

Although significant uncertainty remains regarding the origin of C-BSE, several studies involving the serial passage of H-BSE and L-BSE in transgenic and wild-type mice have revealed their potential to lead to the emergence of a C-BSE-like phenotype (Baron *et al.*, 2011; Torres *et al.*, 2011; Bencsik *et al.*, 2013) or other novel strains (Masujin *et al.*, 2016). Whether or not one or both of these atypical strains led to the emergence of C-BSE remains speculative; however, the similarities between transmissible mink encephalopathy (TME), first reported in the USA in 1947 (Hartsough and Burger, 1965), and L-BSE indicate that TME may have been a surrogate indicator for the presence of L-BSE in cattle populations in those countries such as the USA, Canada, Germany, Finland and Russia where outbreaks of TME had been reported decades before C-BSE was first recognised in the

[10] Pulled data from 110 atypical cases: 49 H-BSE, 58 L-BSE and 3 of unknown atypical type. The mean age at diagnosis was 11.6 years (from 5.5 to 18 years). 78.2% were between 10 and 15 years old.

United Kingdom in 1986 (Hadlow and Karstad, 1968; Marsh *et al.*, 1991; McKenzie *et al.*, 1996; Baron *et al.*, 2007; Comoy *et al.*, 2013). Although TME was originally thought to have occurred as a result of feeding mink with scrapie infected sheep carcases, oral challenge studies did not confirm this (Marsh *et al.*, 1991). Importantly, in an outbreak reported in the USA in 1985, mink had never been fed sheep products; instead they had been fed on products derived from dead and sick dairy cattle (March *et al.*, 1991). Similarly, from an outbreak in Canada in 1963, mink had reportedly been fed with products derived from cattle but not sheep (Hadlow and Karstad, 1968).

Although, as discussed above, the passage of H-BSE or L-BSE has been proposed as a possible explanation for the origin of C-BSE, transformation of L-BSE or H-BSE to C-BSE has not been observed so far in transmission studies in cattle. That being said, it is likely that, compared to various rodent models, an insufficient number of passages have been undertaken.

It is worth noting that sheep and goats are susceptible to L-BSE following intracerebral inoculation without lymphoid involvement in most individuals (Simmons *et al.*, 2016; Gielbert *et al.*, 2018; Vallino-Costassa *et al.*, 2018). As discussed by Houston and Andreoletti (2018), C-BSE appears to increase in virulence for humans if it is first passaged in sheep. Whether or not this is the same for atypical strains remains to be determined.

Conclusions on transmissibility of atypical BSE among cattle

Given that cattle have been successfully infected by the oral route, at least for L-BSE, it is reasonable to conclude that atypical BSE is potentially capable of being recycled in a cattle population if cattle are exposed to contaminated feed. In addition, based on reports of atypical BSE from several countries that have not had C-BSE, it appears likely that atypical BSE would arise as a spontaneous disease in any country, albeit at a very low incidence in old cattle. In the presence of livestock industry practices that would allow it to be recycled in the cattle feed chain, it is likely that some level of exposure and transmission may occur. As a result, since atypical BSE can be reasonably considered to pose a potential background level of risk for any country with cattle, the recycling of both classical and atypical strains in the cattle and broader ruminant populations should be avoided.

II. Zoonotic potential

Experimental studies

There are tremendous challenges in demonstrating the zoonotic transmission of atypical strains of BSE in natural exposure scenarios based on experimental studies involving:

- *In vivo* models including non-human primates (macaques and lemurs) (Comoy *et al.*, 2008; Ono *et al.*, 2011; Mestre-Frances *et al.*, 2012), humanised transgenic mice that either overexpress human PrP or express it at normal physiological levels (Béringue *et al.*, 2007; Béringue *et al.*, 2008; Kong *et al.*, 2008; Wilson *et al.*, 2012)
    - artificial routes of challenge such as intracerebral inoculation;
    - large doses of infectious material whether administered parenterally or orally.
- *In vitro* models including PMCA (protein misfolding cyclic amplification) reactions where brain homogenates from humans or transgenic mice containing PrP^c are used as a substrate (Barria *et al.*, 2014a; Barria *et al.*, 2014b);

In addition, not all studies are in agreement, for example:

- PMCA results suggest that atypical BSE poses a lower zoonotic risk than C-BSE since neither L-BSE nor H-BSE produced detectable human PrP^{res} when brain homogenates from humans or transgenic mice representative of human prion protein genotypes (codon 129 MM and VV) were used as substrates. In contrast, both C-BSE and variant Creutzfeldt-Jacob disease (vCJD) successfully converted human PrP^{c} to PrP^{res} in a codon 129 (M allele) dependent manner (Barria *et al.*, 2014a; Barria *et al.*, 2014b).

- Using humanized transgenic mice (tg650) overexpressing human PrP, H-BSE failed to transmit indicating the existence of a robust transmission barrier whereas the potential zoonotic risk from L-BSE appeared to be higher than C-BSE with attack rates on first passage of 100% and 30%, respectively. An attack rate of 100% for C-BSE was only achieved on third passage (Béringue *et al.*, 2008).

- Initial findings using transgenic mice expressing physiological levels of the human PrP representative of the three genotypes correlating with human susceptibility to TSEs (codon 129 MM, MV, VV) were suggestive of a significant transmission barrier between both L-BSE and H-BSE and humans (Wilson *et al.*, 2012). However, on subsequent passage into bovinized transgenic mice (Bov6), some of the mice originally challenged with L-BSE were found to harbour low levels of infectivity in their brains (Wilson *et al.*, 2013). Interestingly, in an earlier study, C-BSE was not transmitted to the same lines of humanized transgenic mice (Bishop *et al.*, 2006), whereas vCJD was successfully transmitted to all three lines. This is likely to be indicative of a significant cattle to human barrier for C-BSE, but a substantially reduced barrier for human-to-human transmission once that barrier is overcome. It is worth noting that an important limitation of these studies is the lifespan of mice that is much shorter than the incubation period of humans having only a single copy of the allele.

- Studies involving the intracerebral challenge of non-human primates (cynomolgus macaques) indicate that L-BSE is more virulent than C-BSE with shorter incubation periods (~20 months *vs* 38 months) (Comoy *et al.*, 2008; Ono *et al.*, 2011). While a similarly short incubation period was observed in mouse lemurs challenged through the oral route with L-BSE (Mestre-Frances *et al.*, 2012), transmission of C-BSE was only observed after initially being passaged in macaques (Bons *et al.*, 2002). This finding would also support the contention that L-BSE is more virulent than C-BSE. L-BSE has reportedly been transmitted to macaques by the oral route although a direct comparison with C-BSE does not appear to have been made (Comoy 2010; BIOHAZ, 2011). The results of this work have yet to be formally published (Comoy E, pers comm, 2019).

Tissue distribution of atypical BSE in cattle

The uncertainty associated with the actual route of acquiring the disease, if any, limits the implementation of appropriate studies investigating the pathogenesis of atypical BSE and the accumulation, progression and detection of PrP^{Sc} and infectivity in different tissues. Nevertheless, a limited number of studies have been undertaken (Appendix A of EFSA, 2014). PrP^{res} has been detected in the peripheral nervous system (PNS) of cattle intracerebrally inoculated with L-BSE (Iwamaru *et al.*, 2010) and H-BSE (Okada *et al.*, 2013) as calves. As with C-BSE, PrP^{res} from animals challenged with L-BSE was found to accumulate in both central and peripheral nerve tissues in a time-dependent manner suggesting that propagation was initially in the central nervous system (CNS) followed by spread into the PNS (Iwamaru *et al.*, 2010). The levels of infectivity in the PNS were approximately 1,000 times lower than those in the CNS. PrP^{res} was not detected in lymphoid tissues. Infectivity was detected in the skeletal muscle from a 14-year-old natural case of L-BSE as well as from an experimentally infected cow that had been inoculated intracerebrally as a calf (Suardi *et al.*, 2012). In this study, infectivity was not found in the spleen, cervical lymph nodes or kidneys of either the natural or experimentally infected cows.

Potential link between atypical BSE and sporadic Creutzfeldt-Jacob disease (sCJD)

It has been reported that the biochemical signature of L-BSE in an intracerebrally inoculated macaque was similar to that of the MM2 cortical subtype of human sCJD (Comoy *et al.*, 2013) raising the possibility that if L-BSE crossed the species barrier into humans it could present as sCJD. In a study involving humanized transgenic mice, Kong *et al.*, 2008, also reported that similarities between L-BSE and sCJD where the electrophoretic pattern of L-BSE and that of Type 2 PrP^{res} from sCJD patients were indistinguishable. The possibility that the two diseases are causally linked was subsequently investigated by Jaumain *et al.*, 2016, who compared the phenotypic traits of

L-BSE isolates with those from representative human sCJD cases. Although evidence of an aetiological link was not found, they nevertheless cautioned that an unrecognised form of CJD may emerge from the accidental transfer of L-BSE to humans.

Conclusions on the zoonotic potential of atypical BSE

Given the findings to date, the associated uncertainties and challenges in drawing inferences from studies involving surrogate models such as non-human primates, transgenic mice and molecular techniques, some tentative conclusions can nevertheless be drawn that inform potential zoonotic risks:

- While L-BSE poses a potentially greater zoonotic risk than C-BSE, the risk associated with H-BSE is likely to be less.

- Consistent with C-BSE, both H and L-BSE are likely to be essentially restricted to the CNS with involvement of the PNS at substantially lower levels arising later in the disease process.

- It is highly unlikely that lymphoid and other tissues outside the CNS and PNS are involved in the pathogenesis of H and L-BSE.

- It would be reasonable to assume based on the limited evidence available to date that the distribution of atypical BSE is similar to C-BSE with the exception of the distal ileum and tonsils.

- Potential human exposure to atypical BSE would be by the oral route that is unlikely to be repeated at an individual level considering that atypical BSE is a rare disease that is likely to arise spontaneously in old cattle.

- If atypical BSE were to break the species barrier, a form of CJD may emerge with the potential for a substantially reduced barrier for subsequent human-to-human transmission.

- Although the likelihood of human exposure to atypical BSE with the species barrier being breached may be considered to be extremely low, the consequences as experienced with C-BSE would be high if exposure results in infection.

At this stage it would be premature to reach a conclusion other than that atypical BSE poses a potential zoonotic risk that although may be different between atypical strains, nevertheless justifies a consideration of measures to prevent recycling in the cattle population to protect both the human food supply and the ruminant feed chain.

———————

References

Balkema-Buschmann A, Ziegler U, McIntyre L, Keller M, Hoffmann C, Rogers R, Hills B and Groschup MH. Experimental challenge of cattle with German atypical bovine spongiform encephalopathy (BSE) isolates. Journal of Toxicology and Environmental Health, Part A. 2011 Jan; 74(2-4):103-109.

Baron T, Bencsik A, Biacabe A-G, Morignat E, and Bessen R. Phenotypic similarity of transmissible mink encephalopathy in cattle and L-type bovine spongiform encephalopathy in a mouse model. Emerging Infectious Diseases. 2007 Dec; 13(12):1887.

Baron T, Vulin J, Biacabe A-G, Lakhdar L, Verchere J, Torres J-M, and Bencsik A. Emergence of classical BSE strain properties during serial passages of H-BSE in wild-type mice. PLoS One. 2011 Jan; 6(1): e15839.

Barria MA, Balachandran A, Morita M, Kitamoto T, Barron R, Manson J, Knight, Ironside JW, and Head MW. Molecular barriers to zoonotic transmission of prions. Emerging Infectious Diseases. 2014a; 20(1):88.

Barria MA, Ironside JW and Head MW. Exploring the zoonotic potential of animal prion diseases. Prion. 2014b; 8(1):85-91.

Bencsik A, Leboidre M, Debeer S, Aufauvre C and Baron T. Unique properties of the classical bovine spongiform encephalopathy strain and its emergence from H-type bovine spongiform encephalopathy substantiated by VM transmission studies. Journal of Neuropathology & Experimental Neurology. 2013 Mar;72(3):211-218.

Béringue V, Andréoletti O, Le Dur A, Essalmani R, Vilotte JL, Lacroux C, Reine F, Herzog L, Biacabé AG, Baron T, Caramelli M. A bovine prion acquires an epidemic bovine spongiform encephalopathy strain-like phenotype on interspecies transmission. Journal of Neuroscience. 2007 Jun; 27(26):6965-6971.

Béringue V, Herzog L, Reine F, Le Dur A, Casalone C, Vilotte J-L and Laude H. Transmission of atypical bovine prions to mice transgenic for human prion protein. Emerging Infectious Diseases. 2008 Dec; 14(12):1898.

Biacabe AG, Laplanche JL, Ryder S, Baron T. Distinct molecular phenotypes in bovine prion diseases. EMBO Reports. 2004 Jan; 5(1):110–115.

Bishop MT, Hart P, Aitchison L, Baybutt HN, Plinston C, Thomson V, Tuzi NL, Head MW, Ironside JW, Will RG and Manson JC. Predicting susceptibility and incubation time of human-to-human transmission of vCJD. The Lancet Neurology. 2006 May; 5(5):393–398.

Bons N, Lehmann S, Nishida N, Mestre-Frances N, Dormont D, Belli P, Delacourte A, Grassi J and Brown P. BSE infection of the small-lived primate *Microcebus murinus*. Comptes Rendus Biologies. 2002 Jan;325(1):67-74.

Casalone C, Zanusso G, Acutis P, Ferrari S, Capucci L, Tagliavini F, Monaco S, Caramelli M. Identification of a second bovine amyloidotic spongiform encephalopathy: molecular similarities with sporadic Creutzfeldt-Jakob disease. Proceedings of the National Academy of Sciences. 2004 Mar 2;101(9):3065-3070.

Comoy EE, Casalone C, Lescoutra-Etchegaray N, Zanusso G, Freire S, Marcé D, Auvré F, Ruchoux MM, Ferrari S, Monaco S, Salès N. Atypical BSE (BASE) transmitted from asymptomatic aging cattle to a primate. PLoS One. 2008; 3(8):e3017.

Comoy E. Transmission studies in primates. Workshop on the epidemiology of human and animal TSEs. 30 April 2010, Torino, Italy.

Comoy E, Mikol J, Ruchoux M-M, Durand V, Luccantoni-Freire S, Dehen C, Correia E, Casalone 2, Richt JA. Greenlee JJ, Torres J-M, Brown P and Deslys J-P. Evaluation of the zoonotic potential of transmissible mink encephalopathy. Pathogens. 2013 Sep; 2(3):520-32.

Dudas S, Gray JG, Clark R and Czub S. Potential detection of oral transmission of H-type atypical BSE in cattle using in vitro conversion. Prion. 2014 Apr; 8:105.

EFSA Panel on Biological Hazards (BIOHAZ). Joint scientific opinion on any possible epidemiological or molecular association between TSEs in animals and humans. EFSA Journal. 2011 Jan; 9(1):1945.

European Commission (2016). Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathies (TSEs) in the EU in 2014.

EFSA - European Food Safety Authority. Protocol for further laboratory investigations into the distribution of infectivity of atypical BSE. EFSA Journal 2014; 12(7):3798. Appendix A.

EFSA - European Food Safety Authority. The European Union summary report on surveillance for the presence of transmissible spongiform encephalopathies (TSEs) in 2015. EFSA Journal. 2016 Nov; 14(12):4643.

EFSA - European Food Safety Authority. The European Union summary report on surveillance for the presence of transmissible spongiform encephalopathies (TSEs) in 2016. EFSA Journal. 2017 Nov; 15(11):e05069.

EFSA - European Food Safety Authority. The European Union summary report on surveillance for the presence of transmissible spongiform encephalopathies (TSEs) in 2017. EFSA Journal. 2018 Nov; 16(11):e05492.

Fukuda S, Iwamaru Y, Imamura M, Masujin K, Shimizu Y, Matsuura Y, Shu Y, Kurachi M, Kasai K, Murayama Y, Onoe S, Hagiwara K, Sata T, Mohri S, Yokoyama T and Okada H. Intraspecies transmission of L-type-like bovine spongiform encephalopathy detected in Japan. Microbiology and Immunology. 2009 Dec; 53(12):704-707.

Gielbert A, Thorne JK, Plater JM, Thorne L, Griffiths PC, Simmons MM and Cassar CA. Molecular characterisation of atypical BSE prions by mass spectrometry and changes following transmission to sheep and transgenic mouse models. PLoS One. 2018; 13(11):e0206505.

Hadlow W and Karstad L. Transmissible encephalopathy of mink in Ontario. Canadian Veterinary Journal. 1968; 9(8):193.

Hartsough GR, Burger D. Encephalopathy of mink: I. Epizootiologic and clinical observations. The Journal of Infectious Diseases. 1965:387-392.

Houston F and Andreoletti O. The zoonotic potential of animal prion diseases, Handbook of Clinical Neurology. 2018; 153:447-462.

Iwamaru Y, Imamura M, Matsuura Y, Masujin K, Shimizu Y, Shu Y, Kurachi M, Kasai K, Murayama Y, Fukuda S, Onoe S, Hagiwara K, Yamakawa Y, Sata T, Mohri S, Okada H, and Yokoyama T. Accumulation of L-type bovine prions in peripheral nerve tissues. Emerging Infectious Diseases. 2010; 16(7):1151-1154.

Jaumain E, Quadrio I, Herzog L, Reine F, Rezaei H, Andréoletti O, Laude H, Perret-Liaudet A, Haïk S, Béringue V. Absence of evidence for a causal link between bovine spongiform encephalopathy strain variant L-BSE and known forms of sporadic Creutzfeldt-Jakob disease in human PrP transgenic mice. Journal of Virology. 2016; 90(23):10867–10874.

Konold T, Bone GE, Clifford D, Chaplin MJ, Cawthraw S, Stack MJ and Simmons MM. Experimental H-type and L-type bovine spongiform encephalopathy in cattle: observation of two clinical syndromes and diagnostic challenges. BMC Veterinary Research. 2012; 8(1):22.

Kong Q, Zheng M,1 Casalone C, Qing L, Huang S, Chakraborty B, Wang P, Chen F, Cali I, Corona C, *et al.* Evaluation of the human transmission risk of an atypical bovine spongiform encephalopathy prion strain. Journal of Virology. 2008 Apr; 82(7):3697–3701.

Lombardi G, Casalone C, d'Angelo A, Gelmetti D, Torcoli G, Barbieri I, Corona C, Fasoli E, Farinazzo A, Fiorini M, Gelati M. Intraspecies transmission of BASE induces clinical dullness and amyotrophic changes. PLoS Pathogens. 2008; 4(5):e1000075.

Marsh RF, Bessen RA, Lehmann S, Hartsough GR. Epidemiological and experimental studies on a new incident of transmissible mink encephalopathy. Journal of General Virology. 1991; 72(3):589-94.

Masujin K, Okada H, Miyazawa K, Matsuura Y, Imamura M, Iwamaru Y, Murayama Y, Yokoyama T. Emergence of a novel bovine spongiform encephalopathy (BSE) prion from an atypical H-type BSE. Scientific reports. 2016; 6:22753.

McKenzie D, Bartz JC, Marsh RF. Transmissible mink encephalopathy. In: Seminars in Virology. 1996 Jun; 7(3):201-206. Academic Press.

Mestre-Frances N, Nicot S, Rouland S, Biacabe A-G, Quadrio I, Perret-Liaudet A, Baron T, and Verdier JM. Oral transmission of L-type bovine spongiform encephalopathy in primate model. Emerging Infectious Diseases. 2012 Jan; 18(1):142.

Okada H, Iwamaru Y, Imamura M, Masujin K, Matsuura Y, Shimizu Y, Kasai K, Mohri S, Yokoyama T and Czub S. Experimental H-type bovine spongiform encephalopathy characterized by plaques and glial- and stellate-type prion protein deposits. Veterinary Research. 2011; 42(1):79.

Okada H, Iwamaru Y, Yokoyama T, Mohri S. Immunohistochemical detection of disease-associated prion protein in the peripheral nervous system in experimental H-type bovine spongiform encephalopathy. Veterinary Pathology. 2013 Jul; 50(4):659-563.

Okada H, Iwamaru Y, Imamura M, Miyazawa K, Matsuura Y, Masujin K, Murayama Y, Yokoyama T. Oral transmission of L-Type bovine spongiform encephalopathy agent among cattle. Emerging Infectious Diseases. 2017 Feb; 23(2):284.

Ono F, Tase N, Kurosawa A, Hiyaoka A, Ohyama A, Tezuka Y, Wada N, Sato Y, Tobiume M, Hagiwara KI, Yamakawa Y. Atypical L-type bovine spongiform encephalopathy (L-BSE) transmission to cynomolgus macaques, a non-human primate. Japanese Journal of Infectious Diseases. 2011 Jan; 64(1):81-84.

Simmons MM, Chaplin MJ, Konold T, Casalone C, Beck KE, Thorne L, Everitt S, Floyd T, Clifford D and Spiropoulos J. L-BSE experimentally transmitted to sheep presents as a unique disease phenotype. Veterinary Research. 2016; 47(1):112.

Suardi S, Vimercati C, Casalone C, Gelmetti D, Corona C, Iulini B, Mazza M, Lombardi G, Moda F, Ruggerone M, Campagnani I. Infectivity in skeletal muscle of cattle with atypical bovine spongiform encephalopathy. PLoS One. 2012; 7(2):e31449.

Torres J-M, Andréoletti O, Lacroux C, Prieto I, Lorenzo P, Larska M, Baron T and Espinosa J-C. Classical bovine spongiform encephalopathy by transmission of H-type prion in homologous prion protein context. Emerging Infectious Diseases. 2011; 17(9):1636.

Vallino Costassa E, D'Angelo A, Mazza M, Meloni D, Baioni E, Maurella C, Colussi S, Martinelli N, Lo Faro M, Berrone E, Favole A, Crociara P, Grifoni S, Gallo M, Lombardi G, Iulini B, Casalone C, Corona C. Clinical, pathological, and molecular features of classical and L-type atypical-BSE in goats. PLoS One. 2018; 13(5):e0198037.

Wells GAH, Konold T, Arnold ME, Austin AR, Hawkins SAC, Stack M, Simmons MM, Lee YH, Gavier-WidenD, Dawson M and Wilesmith JW. Bovine spongiform encephalopathy: the effect of oral exposure dose on attack rate and incubation period in cattle. Journal of General Virology. 2007; 88(4):1363–1373.

Wilson R, Plinston C, Hunter N, Casalone C, Corona C, Tagliavini F, Suardi S, Ruggerone M, Moda F, Graziano S, Sbriccoli M, Cardone F, Pocchiari M, Ingrosso L, Baron T Richt J, Andreoletti O, Simmons M, Lockey R,. Manson JC and Barron RM. Chronic wasting disease and atypical forms of bovine spongiform encephalopathy and scrapie are not transmissible to mice expressing wild-type levels of human prion protein. Journal of General Virology. 2012; 93(7):1624–1629.

Wilson R, Dobie K, Hunter N, Casalone C, Baron T and Barron RM. Presence of subclinical infection in gene-targeted human prion protein transgenic mice exposed to atypical bovine spongiform encephalopathy. Journal of General Virology. 2013; 94(12):2819–2827.

World Organisation for Animal Health (OIE). WAHIS Interface. Bovine spongiform encephalopathy, Spain. Consulted 4 March 2019. Available from: http://www.oie.int/wahis_2/public/wahid.php/Reviewreport/Review?page_refer=MapFullEventReport&reportid=29656

WORK PROGRAMME FOR
THE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES (SEP 2019)

Issue and priority order (1-3; 1 being highest priority)		Status and action
Update of OIE standards		
1	Glossary	Proposed amendments and sent to TAHSC.
2	Ch. 1.3. Diseases, Infections and Infestations listed by the OIE	Proposed amendments and sent to TAHSC.
2	Ch. 1.4. Animal Health Surveillance	Proposed amendments on the definition of epidemiological unit and sent to TAHSC.
1	Ch. 1.6. Procedures for self-declaration and official recognition by the OIE	Proposed amendments and sent to TAHSC.
1	Chapter 14.7. Infection with PPR virus - Harmonisation of the requirements in the *Terrestrial Code* Chapters for official disease freedom	Proposed amendments and sent to TAHSC.
2	Ch. 4.4. Zoning and compartmentalisation	See section on liaison with other Specialist Commissions.
3	Ch 4.Y. Official control of listed and emerging diseases	Not applicable
1	Ch.8.8. Infection with foot and mouth disease	Not applicable
2	Chapter 8.11. Infection with *Mycobacterium bovis* and *M. caprae*	Proposed amendments and sent to TAHSC. Recommended reassessing M. tuberculosis against the criteria described in Chapter 1.2. of the *Terrestrial Code* in September 2020.
1	Ch. 8.14. Infection with rabies virus	Not applicable
3	Chapter 8.15. Infection with Rift Valley Fever virus	Proposed amendments and sent to TAHSC. Consulted with experts and waiting for replies.
3	Ch. 8.16. Infection with rinderpest virus	Revised ToR of the *ad hoc* Group that will revise the chapter.
3	Ch 8.X. *Trypanosoma evansi (not equine surra)*	Not applicable
1	Ch. 8.Y. Animal African Trypanosomoses	Assessment of the risk of movement of live animals. Opinion sent to TAHSC.
1	Ch.10.4. Infection with avian influenza virus	Considered the opinion of the *ad hoc* Group on avian influenza. Considered the assessment of low pathogenic avian influenza (LPAI) against the criteria described in Chapter 1.2. of the *Terrestrial Code*, and recommended amending Chapter 1.3. accordingly. Suggested adding references to the *Terrestrial Manual* in the case definition of LPAI /.
1	Ch. 11.4. Bovine spongiform encephalopathy	*Ad hoc* Group report on BSE risk assessment and surveillance and draft chapters 11.4. and 1.8. were considered. Draft chapters and report summarising rationale
3	Ch. 11.9. Infection with lumpy skin disease virus	Not applicable.
3	Ch. 11.12. infection with *T. anulata, T. orientalis, T. parva*	Not applicable.
3	Ch. 12.3. Infections with Trypanozoon in equids	Not applicable

2	Ch. 12.6. Infection with equine influenza virus	Not applicable.
3	Ch. 14.X. infection with *T. lestoquardi, T. luwenshuni, T. uilenbergi*	Not applicable.
1	Ch 15.1. African Swine Fever	Not applicable.
1	Ch 15.2. Classical Swine Fever	Proposed amendments and sent to TAHSC.
Official disease status recognition		
1	Evaluation of Member dossiers	[Each February meeting] SCAD will consider the report of the ad hoc Groups for evaluation of Members' status, analysis of the dossiers and other findings and recommend the final outcome for adoption by the World Assembly.
2	Experts missions to Member Countries	[Continuous process] SCAD prioritised in-country missions to be deployed to monitor continuous compliance with the *Terrestrial Code* requirements for maintenance of official status. Follow-up on action plan(s) submitted by Members on the implementation of recommendations of the expert mission.
2	Follow up of Member Countries with official disease status or with suspended status	[Continuous process] Situation in the listed countries reviewed and follow-up on recommendation of SCAD for certain countries; on-going process.
1	Review of annual reconfirmations	[Each February meeting] SCAD evaluated the annual reconfirmations of selected countries' disease status and endorsed official control programmes [Each September meeting] SCAD selected 10% of countries' disease status for comprehensive review at its February meeting.
1	Harmonisation of the requirements in the *Terrestrial Code* Chapters for official disease freedom	- Chapter 1.6.: Proposed amendments and sent to TAHSC. - Chapter 14.7. (PPR): Proposed amendments and sent to TAHSC. - Chapter 15.2.(CSF): Proposed amendments and sent to TAHSC. - Considered the need for harmonisation of other articles (e.g. containment zone, recovery of free status, of disease-specific chapters for official status recognition)
Disease control issues		
2	Advise on Global Control and eradication strategies (FMD, PPR, rabies, ASF)	Update on the progress made.
1	Assess and endorse non-disease-Status and non-standard-setting *ad hoc* Groups reports falling into the SCAD remit	Not applicable.
1	Assess recent developments in the practical problems of control and eradication of infectious diseases and the impact of these developments	Consideration and proposed recommendations on the following: - Prion disease in dromedary camels; - Vaccination of animals of high conservation value; - Seasonal freedom; - Update on the SIRCAH STAR-IDAZ International Research Consortium; - Update on the project on replacement of International Standard Bovine Tuberculin.
1	Define a procedure for the evaluation of diseases against the listing criteria of Chapter 1.2.	Review the draft SOP for the evaluation of disease against the listing criteria of *Terrestrial Code* Chapter 1.2. Proposed update to guidance document to the application of the criteria for listing terrestrial animal diseases.

Liaison with other Specialist Commissions		
1	Terrestrial Animal Health Commission	Meeting of the two bureaus to discuss topic of common interest Technical meeting to discuss the discuss the modified concept of protection zone
1	Biological Standards Commission	Consideration and proposed recommendations on the following: - Role of carriers in the epidemiology of ASF; - Use of penside test for ASF.
Working Groups		
1	Antimicrobial resistance Working Group	Update on the progress made for the institution go the AMR WG.
1	Wildlife Working Group	Advise on the activities. Agenda for the next meeting reviewed.
Other activities that could impact SCAD work programme		
1	Evaluation of applications for OIE Collaborating Centre status	Not applicable.
3	Update on the main conclusion/ recommendations of meetings relevant for the work of the Commission	The Commission was updated on the outcomes of the most relevant meetings organised since February 2019.
	Any other business	Not applicable