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# **REPORT OF THE MEETING**

# OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

# Virtual, 7 to 23 February 2022

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A virtual meeting of the OIE Scientific Commission for Animal Diseases (the Commission) was held from 7 to 23 February 2022.

#### 1. Welcome

Dr Montserrat Arroyo, Deputy Director General (International Standards and Science, DDG ISS) welcomed members of the Commission to this second meeting of the three-year term. She thanked the members for their continued commitment, acknowledging their heavy workload as well as the difficulties associated with conducting the meeting via videoconference. Dr Arroyo extended these thanks to the members' employing institutions and national governments.

Dr Arroyo updated the Commission on the plans for the 89<sup>th</sup> OIE General Session (May 2022) which will now take place with most participants attending remotely. In-person participation will be limited to members of the Council and the Presidents of the Specialist and Regional Commissions, in accordance with the sanitary conditions at the time. The Technical Item at the General Session will be *OIE and Veterinary Services engagement in global, regional, and national Emergency Management Systems.* Dr Arroyo confirmed that a pre-General Session information webinar will be conducted to provide the background and key aspects of the standards being presented for adoption in May 2022.

Dr Arroyo noted that the OIE will concentrate in 2022 on the delivery of the objectives of the OIE 7<sup>th</sup> Strategic Plan, which will increase the focus within the OIE on transversal collaboration, implementation of strategies, digital transformation, agility and efficiency, meeting Member needs, and on development and maintenance of partnerships. She then provided an update on OIE's response to COVID-19, and the progress made against the recommendations of its Interim After-Action Review; information will be shared with the OIE Council and Delegates through the OIE Newsletter. Finally, Dr Arroyo discussed the processes of the Performance Management Framework which is intended to facilitate the work of the Commissions as well as the Secretariat that supports them.

Dr Cristóbal Zepeda, president of the Commission, thanked Dr Arroyo for the information, and extended the Commission's congratulations for her appointment as DDG ISS in October 2021. He thanked the Secretariat for their valuable support and contribution to the Commission's work.

#### 2. Meeting with the Director General

The OIE Director General Dr Monique Eloit met with the Commission on 18 February. She thanked the Commission for their continued commitment to working with the OIE to meet its objectives despite the constraints imposed by the ongoing COVID-19 pandemic. In particular, she noted the challenges of the virtual Commission meeting, and looked forward to September when, sanitary situation permitting, the Commission will meet in person. Dr Eloit provided an update of the preparations for the 89<sup>th</sup> OIE General Session in May 2022, and informed the Commission of the initiative underway to document and review OIE's science system.

The Commission thanked Dr Eloit for making time to meet with its members, and commended the work of the Secretariat in their support of the meeting.

#### 3. Adoption of the agenda

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

#### 4. Terrestrial Animal Health Code

#### 4.1. Member comments received for Commission consideration

#### 4.1.1. Chapter 11.4. Bovine spongiform encephalopathy

The Commission considered specific questions forwarded by the Code Commission in its February 2022 meeting in relation to the official recognition and maintenance of BSE risk status of Members received.

In response to Members requesting the OIE to determine and publish a precise 'starting date' when the risk of BSE agents being recycled within the cattle population could be considered negligible, the Commission maintained its position stated in its last September 2021 meeting report that, for Members already having an officially recognised BSE risk status, the starting date should be determined by the reference year of official recognition. If a Member having negligible BSE risk status wishes to demonstrate that this 'starting date' was earlier than eight years prior to the year of official recognition by the OIE, and earlier than the year of recognition for a Member having controlled BSE risk status, it should be done through bilateral discussions between trade partners, while using the revised questionnaire of Chapter 1.8. as guidance (see Item 5.1.5. regarding the criteria to be used).

Regarding the Members that had a suspension or downgrading of their official BSE risk status due to occurrence of an indigenous classical BSE case, which was subsequently reinstated, the Commission was of the opinion that the year of initial recognition would be used as the reference year provided that the application for recovery or report of the epidemiological investigation evidencing the reinstatement of risk status confirmed that the reason for the suspension or downgrading of risk status was not due to a breach in the control measures or surveillance.

The Commission noted Members' request for the OIE to develop guidelines on BSE surveillance to help Members to revise their surveillance programmes in accordance with the new BSE standards. The Commission recommended the OIE to develop these guidelines as soon as the revised Chapter is adopted and with an aim to make them available to Members by May 2023.

In response to a Member's question on when Members could apply for the official recognition of their BSE risk status using the new provisions after their potential adoption at the General Session in May 2022, the Commission mentioned that, after assessing the implications and different options for better transition and management of the official BSE risk status recognition and maintenance procedure, the new standards will be implemented for official status purposes after the General Session of May 2023. This would not only allow the OIE to develop guidelines on BSE surveillance but also provide time for Members to adapt to the revised standards and procedures for the official recognition and maintenance of official BSE risk status. The opinion of the Commission was shared with the Code Commission that also agreed with the proposed approach.

Regarding a Member comment proposing the maintenance of a controlled BSE risk status after occurrence of an indigenous case of classical BSE and while the epidemiological investigation is ongoing, the Commission agreed that the controlled risk status could be maintained if this case was born after the 'starting date' (from which the risk of BSE agents being recycled within the cattle population has been negligible) and provided that an investigation report is submitted to the OIE within 90 days demonstrating that any identified source of infection has been controlled. The Commission was of the opinion that for consistency a similar approach should be followed in case of occurrence of an indigenous case of classical BSE in Members having an officially recognised negligible BSE risk status. The opinion of the Commission was forwarded to the Code Commission and addressed at its February 2022 meeting.

#### 4.1.2. Chapter 8.8. Infection with foot and mouth disease virus

The Commission addressed the Member comments received on the amended chapter that was circulated for the fourth time after the Specialist Commission meetings in September 2021.

### Article 8.8.1. General provisions

The Commission considered alternative text proposed by a Member for point 3), but disagreed with the proposal to remove viral isolation as a separate option from the case definition, and proposed an editorial change to the text that reduces repetition without omitting the standalone option of isolation of FMDV. The Commission recommended that the *Terrestrial Code* and *Terrestrial Manual* are harmonised.

In response to Member comments seeking clarification regarding the transmission of FMDV from African buffalo to domestic livestock, the Commission explained that in settings where African buffalo and cattle coexist, the predominant transmission route is cattle-to-cattle, whereas buffalo-to-cattle transmission is less frequent<sup>1,2,3,4</sup>.

#### Articles 8.8.2. and 8.8.3. Country or zone free from FMD where vaccination is (not) practised

In response to Member comments questioning the relevance of the provision on the Veterinary Authority having current knowledge of the distribution, habitat and indication of disease occurrence through passive surveillance of wild and feral susceptible animals in the country or zone, the Commission was of the opinion that this requirement should be maintained as an FMD case in wild and feral susceptible animals have an impact on free status. Regarding a Member comment on whether passive surveillance of wild and feral susceptible animals could provide the necessary level of assurance regarding the detection of FMD cases, the Commission explained that the intention of this provision is not to require active surveillance but to ensure that a passive surveillance system is in place to support and maintain the FMD free status of a country or zone.

<sup>&</sup>lt;sup>1</sup> Bengis, R. G., Thomson G. R., Hedger R. S., De Vos V. & Pini A. (1986). - Foot-and-mouth disease and the African buffalo (Syncerus caffer). 1. Carriers as a source of infection for cattle. Onderstepoort Journal of Veterirary Research, 53, 69-73 (1986).

<sup>&</sup>lt;sup>2</sup> Dhikusooka, M.T., Ayebazibwe C., Namatovu A., Belsham G.J, Siegismund H.R., Wekesa S.N, Balinda S.N, Muwanika V.B. & Tjørnehøj K. (2016). Unrecognized circulation of SAT 1 foot-and-mouth disease virus in cattle herds around Queen Elizabeth National Park in Uganda. BMC Veterinary Research (2016) 12:5 DOI 10.1186/s12917-015-0616-1.

<sup>&</sup>lt;sup>3</sup> Maree, F., de Klerk-Lorist L.-M., Gubbins S., Zhang F., Seago J., Pérez-Martín E., Reid L., Scott K., van Schalkwyk L., Bengis R., Charleston B. & Juleff N. (2016). Differential persistence of foot-and-mouth disease virus in African buffalo is related to virus virulence. Journal of virology 2016, 90(10):5132–5140.

<sup>&</sup>lt;sup>4</sup> Jolles A, Gorsich E., Gubbins S., Beechler B., Buss P., Juleff N., de Klerk-Lorist L.-M., Maree F., Perez-Martin E., van Schalkwyk O.L, Scott K., Zhang F., Medlock J. & Charleston B. (2021). Endemic persistence of a highly contagious pathogen: Foot-and-mouth disease in its wildlife host. Science, 2021; 374 (6563): 104 DOI: 10.1126/science. abd2475.

With regard to the maintenance of free status of a country or zone despite an incursion of African buffalo from a neighbouring infected country or zone, the Commission clarified that documented evidence demonstrating that the relevant conditions have been met would be requested and assessed as part of the country's annual reconfirmation. The Commission reiterated its recommendation from the September 2021 meeting that exporting countries should suspend exports of potentially in-contact animals and derived commodities whose certification could have been compromised by an incursion of African buffalo. The Commission noted that it was already the case that most countries suspend exports today when African buffalo incursions occur.

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

The Commission acknowledged Member comments that the time limit of 18 months for achieving recovery of a containment zone's FMD free status may be short, and proposed to extend it to 24 months, which is also harmonised with the time limit for the removal/lifting or the official recognition as a separate zone of a protection zone. The Commission clarified that, should the recovery of the containment zone's FMD free status not be achieved within this time limit, the officially recognised status of the country or zone would be suspended. Nevertheless, the Commission stressed that the establishment of a containment zone is not a requirement, but rather a tool offered to facilitate resumption of trade from the areas outside the containment zone upon its approval by the OIE.

#### Article 8.8.7. Recovery of free status

The Commission took note of a Member comment supporting the work undertaken and encouraging the OIE to continue working on processes to demonstrate freedom to an acceptable level of confidence rather than a specific time period.

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

The Commission addressed a comment regarding serological and virological tests required prior to the importation of domestic ruminants and pigs from countries, zones or compartments free from FMD where vaccination is practiced. The Commission clarified that, whilst using one type of test (serological or virological) has limitations for the purpose of demonstrating freedom from infection at individual animal level, applying two independent tests in parallel (serological and virological) improves the sensitivity of the procedure, providing the necessary level of assurance that the animal is neither currently infected with nor previously exposed to FMDV.

The Commission recognised that the importation of vaccinated animals into an FMD free country or zone without vaccination will have an impact on the design of surveillance and will require identification of vaccinated animals, but did not consider it necessary to maintain the two sub-populations with different vaccination status separately. To further assist Members on this issue, the Commission recommended the OIE to develop FMD surveillance guidelines. Furthermore, in acknowledging the concerns raised by Members on this significant change proposed in allowing importation of vaccinated animals into a country or zone officially recognised free of FMD where vaccination is not practised, the Commission proposed to only allow introduction of vaccinated animals from FMD free countries or zones where vaccination is practised (and not from FMD infected countries or zones) and proposed amendments in Article 8.8.12. 'Recommendations from importation from countries or zones infected with FMDV, where an official control programme exists'.

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

#### 4.2. Other considerations

#### 4.2.1. Chapter 4.4. Zoning and compartmentalisation (Article 4.4.7. Containment zone)

The Commission considered the proposed amended text forwarded by Code Commission, clarifying the time limit for a containment zone, noting that this was in line with the proposal made by the Commission in previous meetings. Regarding the proposal that the areas outside the containment zone would be considered a new zone if the containment zone had not regained its free status within the stated time limit, the Commission highlighted that this was inconsistent with the approach followed for the diseases for which OIE grants official recognition of animal health status. The Commission agreed to further consider the proposed text in its September 2022 meeting and forward its opinion to the Code Commission.

## 5. Ad hoc and Working Groups

#### 5.1. Meeting reports for endorsement

5.1.1. Ad hoc Group on the evaluation of African horse sickness status of Members: 5–7 October 2021

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

The Commission agreed with the conclusions of the *ad hoc* Group and recommended that the Assembly recognise <u>Bahrain</u> as having an AHS-free status. The Commission encouraged Bahrain to take into consideration the recommendations of the *ad hoc* Group and to submit documented evidence of their implementation in the annual reconfirmation.

The Commission considered the recommendations of the *ad hoc* Group on two other applications and concluded that they did not meet the requirements of the *Terrestrial Code* to be officially recognised as free from AHS. The dossiers were referred to the respective applicant Members. Suggestions on actions to be taken to comply with the requirements of the *Terrestrial Code* were provided.

The endorsed report of the *ad hoc* Group is attached as <u>Annex 3</u>.

# 5.1.2. *Ad hoc* Group on the evaluation of contagious bovine pleuropneumonia status of Members: 5–7 October 2021

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

The Commission agreed with the conclusions of the *ad hoc* Group and recommended that the Assembly recognise <u>Ecuador</u> and <u>Mongolia</u> as having a CBPP-free status. The Commission also agreed with the conclusions of the *ad hoc* Group to recommend that the Assembly endorse the official control programme for CBPP of <u>Zambia</u>. The Commission encouraged Ecuador, Mongolia and Zambia to take into consideration the recommendations of the *ad hoc* Group and to submit information on the progress made on them when submitting the annual reconfirmation.

The endorsed report of the ad hoc Group is attached as Annex 4.

# 5.1.3. *Ad hoc* Group on the evaluation of FMD status of Members: 18–20, 22, 25 and 27 October 2021

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

• Evaluation of a request from a Member for the recognition of FMD free zone status where vaccination is not practised

The *ad hoc* Group assessed at its meeting an application by a Member for the recognition of an FMD free zone status where vaccination is not practiced. However, due to a change in the FMD situation since the evaluation by the *ad hoc* Group, the Commission considered that the proposed zone no longer complied with Article 8.8.2. 'FMD free country or zone where vaccination is not practised'. The report of the *ad hoc* Group along with the rationale of the Commission was forwarded to the applicant Member.

• Evaluation of requests from Members for the recognition of FMD free zones where vaccination is practised

The Commission agreed with the conclusions of the *ad hoc* Group and recommended that the Assembly recognise <u>one new zone of Russia</u> as an FMD free zone where vaccination is practised. The Commission encouraged Russia to take into consideration the recommendations of the *ad hoc* Group and to submit documented evidence of their implementation in the annual reconfirmation.

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

• Evaluation of requests from Members for the endorsement of official control programmes for *FMD* 

The Commission agreed with the conclusions of the *ad hoc* Group and recommended that the Assembly endorse the official control programme for FMD of <u>Botswana</u>. The Commission encouraged Botswana to take into consideration the recommendations of the *ad hoc* Group and to submit information on the progress made on them in the annual reconfirmation.

The Commission also considered the recommendations of the *ad hoc* Group on one other application and concluded that it did not meet the requirements of the *Terrestrial Code* for the endorsement of its official control programme for FMD. The dossier was referred to the applicant Member indicating the main aspects that should be improved in order to comply with the requirements of the *Terrestrial Code* before resubmitting its dossier.

• Evaluation of the maintenance of a Member's official recognition of FMD free status

The Commission considered the assessment of the *ad hoc* Group, as well as the report of the virtual interviews carried out in December 2021 between an OIE Expert team and Turkey and recommended the field mission to verify the implementation of the risk mitigation measures, if possible, before the next Kurban festival in July 2022 (see Item 6.3.1.).

The endorsed report of the *ad hoc* Group is attached as <u>Annex 5</u>.

# 5.1.4. *Ad hoc* Group on the evaluation of classical swine fever status of Members: 26 and 28 October 2021

The Commission reviewed and endorsed the report of the *ad hoc* Group on the evaluation of an application from one Member for the recognition of its CSF free status.

The Commission agreed with the recommendations and conclusion of the *ad hoc* Group that it did not meet the requirements of the *Terrestrial Code* to be officially recognised as free from CSF. The dossier was referred to the applicant Member along with the rationale for the Commission's position. Suggestions on actions to be taken to comply with the requirements of the *Terrestrial Code* were provided.

The endorsed report of the *ad hoc* Group is attached as Annex 6.

Based on common shortcomings noted in Members applications, the Commission recommended the OIE to develop guidelines for traceability and surveillance in backyard and small producer livestock farms.

# 5.1.5. Ad hoc Group on the evaluation of bovine spongiform encephalopathy risk status of Members: 16–19 November 2021

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

The Commission agreed with the conclusions of the *ad hoc* Group and recommended that the Assembly recognise <u>France</u> as having a negligible BSE risk and <u>Russia</u> as having a controlled BSE risk. The Commission encouraged Russia to take into consideration the recommendations of the *ad hoc* Group and to submit documented evidence of their implementation in the annual reconfirmation. The Commission recommended a field mission to be deployed in Russia to verify compliance with the relevant provisions of the *Terrestrial Code* for the maintenance of BSE controlled risk status as soon as the sanitary situation related to COVID-19 pandemic improves.

Regarding the criteria for determining the 'starting date' when the risk of the BSE agents being recycled within the cattle population has been demonstrated to be negligible, the Commission acknowledged the recommendation of the *ad hoc* Group to use the exposure assessment of the revised questionnaire of Chapter 1.8. as guidance. The Commission also noted that, depending on the situation of the Member, some elements of the entry assessment and consequence assessment may be necessary to complement the criteria. On the other hand, the Commission maintained its position stated in its September 2021 meeting report that, for Members already having an officially recognised BSE risk status wishing to demonstrate that the 'starting date' is beyond or different from what could be determined by the reference year of initial recognition, this should be done through bilateral discussions between trade partners.

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

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

- Working Group on Wildlife: 14–17 June 2022 (to be confirmed)
- *Ad hoc* Group on the revised BSE standards and impact on official status recognition and maintenance: June-July 2022 (to be confirmed)

- Ad hoc Group on the evaluation of AHS status: 27–29 September 2022 (to be confirmed)
- Ad hoc Group on the evaluation of BSE risk status: 4–6 October 2022 (to be confirmed)
- *Ad hoc* Group on the evaluation of PPR status: 19–21 October 2022 (to be confirmed)
- *Ad hoc* Group on the evaluation of FMD status: 2–4 November 2022 (to be confirmed)
- *Ad hoc* Group on the evaluation of the endorsement of dog-mediated rabies control programmes: 8–10 November 2022 (to be confirmed)
- *Ad hoc* Group on the evaluation of CBPP status: 15–17 November 2022 (to be confirmed)
- *Ad hoc* Group on the evaluation of CSF status: 5–7 December 2022 (to be confirmed)

#### 6. Official animal health status

#### 6.1. Annual reconfirmations for maintenance of status

### 6.1.1. Comprehensive review of annual reconfirmations for pre-selected status and all OIEendorsed official control programmes

The Commission comprehensively reviewed the annual reconfirmations of the Members that were preselected at its last meeting in September 2021. A summary of the Commission discussions and recommendations on this matter can be found in <u>Annex 8</u>.

The Commission raised a general concern regarding the lack of apparent progress made on the OIE endorsed official control programmes. The Commission reminded Members that the overall objective of the OIE endorsed official control programmes is for Members to progressively improve their animal health situation and eventually attain official recognition of animal health status or in the case of dog-mediated rabies to make a self-declaration as a free country or zone. Whilst noting the challenges in recent years related to the COVID-19 pandemic, the Commission regretted the fact that there had not been successful cases of Members with OIE endorsed control programmes where progress had been made in achievement of an official animal health status. The Commission strongly encouraged Members to continue their efforts toward this objective in accordance with Chapter 1.6. of the *Terrestrial Code*.

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

The Commission noted the large volume of annual reconfirmations pre-selected to be comprehensively reviewed by the Commission that also continues to increase annually with the addition of newly recognised official status and endorsement of official control programmes. Moreover, as the work on harmonisation of Chapters progresses, the amount of information to be assessed has increased, creating challenges of time management during its February meetings. The Commission suggested that the OIE reconsider the criteria for the selection of annual reconfirmations for comprehensive review (currently based on percentage) and propose alternative options to the Commission at its September 2022 meeting.

#### 6.1.2. Report of the annual reconfirmation assessments by the Status Department

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

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

The report of all annual reconfirmations, including those comprehensively reviewed by the Commission and those reviewed by the OIE Status Department and reported to the Commission, is attached as <u>Annex 8</u>.

#### 6.1.3. Documented evidence to substantiate annual reconfirmation of CSF and PPR free status

The Commission considered a discussion paper prepared by the OIE Status Department on its experience screening Member's CSF and PPR annual reconfirmations and substantiating documents, following the adoption of the revised Chapters of the two diseases in May 2021, raising the areas of concern and seeking the Commission's opinion on the approach to be followed in the screening of these annual reconfirmations in the next campaign(s).

Regarding the documented evidence provided by Members to demonstrate maintenance of compliance with the provisions of the *Terrestrial Code* for surveillance, the Commission noted that most Members reported CSF-related surveillance activities in place, due to the presence/threat of ASF. With respect to PPR, some Members are conducting PPR-specific surveillance activities due to their proximity to countries where PPR is present, and the majority of countries in regions where the disease is historically absent, no PPR-specific surveillance or activities could be evidenced. The Commission acknowledged that historically free countries are not required to conduct pathogen specific surveillance, however, in these countries, surveillance activities should be based on the risk of disease introduction. In accordance with the relevant surveillance requirements of the *Terrestrial Code*, particularly for Members having an official animal health status recognised by the OIE, the Commission recommended Members in regions of negligible risk of PPR to include PPR in their general awareness activities on exotic diseases targeting at least official veterinarians and veterinary paraprofessionals.

The Commission discussed the issue of Members importing susceptible animals and other commodities from countries with no official CSF or PPR free status (thus, considered 'infected' by default according to the *Terrestrial Code*) but considered disease-free based on their own risk assessment or on the reporting to OIE-WAHIS (e.g., disease never reported or not recently reported) without fully complying with the provisions for importation from infected countries or zones. The Commission noted that this was also the case of other diseases that are part of the OIE procedure for official recognition of animal health status, e.g., AHS and CBPP. The Commission strongly recommended these Members to comply with the relevant requirements of the *Terrestrial Code* for such imports and provide documented evidence demonstrating compliance in the next annual reconfirmation.

The Commission was of the opinion that some of these issues could be resolved by inclusion of additional articles in the disease-specific chapters of the *Terrestrial Code*, e.g., by inclusion of recommendations for importation of domestic small ruminants 'intended for direct slaughter' from countries or zones infected with PPRV under Chapter 14.7., by inclusion of recommendations for importation for domestic bovids and water buffaloes from CBPP infected countries or zones for purposes other than slaughter under Chapter 11.5. The Commission highlighted this to the OIE and requested the secretariat to propose a plan forward to work on this topic with the Code Commission.

#### 6.2. Specific update on official animal health status

#### 6.2.1. Update on situation of countries/zone with suspended status

#### • Kazakhstan (FMD)

The Commission was informed that following the notification of an outbreak of FMD in Shetskiy, Qaraghandy, the 'FMD free zone where vaccination is not practised' status of Zone 5 including central and eastern parts of Karaganda region and southern parts of Akmola and Pavlodar regions of Kazakhstan was suspended with effect from 3 January 2022.

#### • Myanmar (AHS)

The Commission took note that the AHS free status of Myanmar had been suspended for more than three years and, according to the requirements of the *Terrestrial Code*, future recovery of AHS free status would have to follow the provisions of Article 12.1.2.

#### • Thailand (PPR)

The Commission took note that the PPR free status of Thailand had been suspended for more than two years and, according to the requirements of the *Terrestrial Code*, future recovery of PPR free status would have to follow the provisions of Article 14.7.3.

#### 6.3. State of play and prioritisation of expert mission to Members requested by the Commission

#### 6.3.1. Follow-up of past missions/virtual interviews

During its September 2021 meeting, the Commission had suggested that virtual interviews between an OIE expert team and Turkey be organised, followed by a field mission, to verify compliance with the relevant provisions of the *Terrestrial Code* for the maintenance of Turkey's 'FMD free zone where vaccination is practised' status. The Commission reviewed the report of the virtual interviews conducted on 14 and 15 December and commended the work done by the OIE expert team. The Commission concurred with the recommendations provided to Turkey and encouraged the country to produce a formal risk assessment by mid-June 2022 to demonstrate how the measures devised by the country would mitigate the risk of FMD virus introduction through the supply of animals from the FMD-infected zone (Anatolia) for the Kurban festival in the officially recognised FMD-free zone of Turkey (Thrace). The Commission also took note of the recommendations to the OIE expert field mission team and endorsed the Terms of Reference of the field mission to be conducted, if possible, in June 2022 before the 2022 Kurban festival.

#### 6.3.2. State of play and prioritisation

The Commission maintained its list of priority missions regarding Members having an official animal health status and endorsed official control programmes. Considering the ongoing situation with COVID-19, the Commission proposed to closely monitor certain Members' status through the annual reconfirmation campaign until the sanitary situation would allow in-country field missions to take place.

#### 6.4. Standards related to official status recognition

# 6.4.1. Update on SOP: Inclusion of virtual interviews as an alternative or adjunct process to field missions; establishment of a protection zone

The Commission considered the updated text related to the inclusion of the option of virtual interviews in the OIE Standard Operating Procedures (SOP) on official recognition of animal health status and endorsement of official control programmes (<u>Application\_SOP</u>, <u>Mission\_SOP</u>). The Commission reiterated the value of virtual interviews as a complementary tool to field missions, however it reemphasised that they cannot replace field missions and should be used as an alternative or adjunct option on a case-by-case basis.

The Commission also considered the guidelines regarding the establishment of a protection zone proposed as an Addendum to the Application\_SOP.

The Commission agreed that the revised SOP are shared with Members.

# 6.4.2. Follow-up on the impact assessment related to the revised BSE standards and list of countries already having an official risk status by the OIE

In respect to the transition plan with regard to the revision of Chapter 11.4. 'Bovine spongiform encephalopathy' and official BSE risk status, and the recommendations of the *ad hoc* Group on the revision of BSE standards and its impact on the official status recognition (see Item 5.4.1. of the September 2021 meeting report of the Commission), the Commission comprehensively reviewed the annual reconfirmations and additional information submitted by eight Members already having an official BSE risk status by the OIE.

The Commission acknowledged the detailed responses submitted by all eight Members in response to the questions raised by the BSE *ad hoc* Group on the revision of BSE standards and its impact on the official status recognition (June 2021), and endorsed by the Commission. The Commission proposed to refer the information from three Members to a BSE expert Group and agreed to discuss the recommendations of the experts at its September 2022 meeting. The Commission also concurred with the recommendation of the *ad hoc* Group to request two Members to submit an updated risk assessment following the provisions of the new BSE standards once adopted.

The Commission commended the eight Members for acknowledging the purpose of the work conducted by the OIE and for their efforts to collect and provide the requested information in a timely manner.

#### 6.4.3. Procedure for recovery or risk assessment in case of recurrence of rinderpest

The Commission was informed that the draft revised Chapter 8.16. 'Infection with rinderpest virus' will be proposed for adoption at the upcoming General Session in May 2022. According to the revised Chapter, in the event of re-emergence of rinderpest, all OIE Members without a case will be asked to provide a risk assessment to the OIE in order to remain free from rinderpest. The Commission was informed that the OIE has started working on the development of the risk assessment questionnaire, as well as the questionnaire template for recovery of rinderpest-free status and the Standard Operating Procedures describing the guidelines for this process, with the objective to present these documents to the Commission for review and endorsement at its September 2022 meeting and to subsequently make them available on the OIE website.

The Commission agreed with the planned timeline and stressed that the template questionnaire for risk assessment should be simple, considering the short time frame for Members to submit it to the OIE, in the event of re-emergence of rinderpest, and the large number of risk assessments that the OIE will receive and need to promptly evaluate in such short time frame.

The opinion of the Commission was shared with the Code Commission that also agreed with the proposed approach.

#### 7. Global control and eradication strategies

### 7.1. Foot and Mouth Disease. Global Control Strategy

The Commission was updated on the activities that have been conducted in the framework of the Global FMD Control Strategy since its meeting in September 2021. The Strategy was endorsed in 2012 for a 15-year period and it is left with five years of implementation. The goal is to reduce or eliminate FMD virus circulation by 2027. The Strategy is implemented through, the Progressive Control Pathway for Foot and Mouth Disease control (PCP-FMD). There are currently 81 Members and non-Members engaged in the implementation of PCP-FMD. The primary focus is strengthening the capacity for implementation of the strategy by the Members especially those in PCP stages 0-3, through among others, the provision of PCP-FMD tools and the expansion of the PCP-FMD Support Officer programme. Members have identified the development of their strategic plans as a challenge that contributes to lack of progression.

Although the progression along the FMD-PCP has been slow during 2021, countries continue to make more efforts in implementing FMD preventive and control measures as it has been reported during the evaluations made at the virtual roadmap meetings successfully held in the OIE Regions of West Africa in November 2021 and the Middle East in December 2021.

The Commission noted that a Global Framework for the progressive control of Transboundary Animal Diseases (GF-TADs) meeting was held in November 2021 to identify priorities for 2022-2023 for South Asia as it is a region with high priority to revitalise the TADs control activities. A workshop on the "Update on FMD strategic plans and PCP in Arab Organization for Agricultural Development (AOAD) countries" held in June 2021 for the Members in the AOAD regional economic community, provided an opportunity for the collaborative OIE-EuFMD training to take place using the roadmap approach.

The Commission acknowledged the rollout strategy of Phase 6 of the SEACFMD campaign from the SEACFMD 5 Roadmap 2021-2025 that was shared during its meeting of February 2021. The Commission was informed that the rollout strategy includes preparation of regional and country level implementation plans, development of monitoring and evaluation framework which were facilitated through regular SEACFMD Governance meetings and bilateral meetings with Members.

The Commission was concerned about the spread and establishment of some FMD serotypes such as serotypes O and SAT2 in new areas and called for more targeted regional support to be given by the OIE and for the affected Members to control the spread of these new serotypes. The Commission noted the initiatives ongoing regarding technical assistance on the FMDV serotype O outbreaks in southern Africa. The Commission noted reports on the potentially higher than usual virulence and severe clinical manifestation of serotype O in southern and West Africa and raised the need of further investigation to confirm this. Regarding FMDV serotype C, the Commission took note of the assembled FMD Type C Taskforce. Considering that this serotype has not been reported since 2004, and based on Resolution 30 adopted by the World Assembly in May 2017, the Commission encouraged the OIE and its partners to continue to promote actions to reduce risks of recurrence of serotype C.

The Commission was updated on the progress in preparation for the review of the Global FMD Control Strategy and the SEACFMD campaign and the launch of the Global Coordination Committee on FMD (GCC-FMD) and elections of its chair and co-chair (PANAFTOSA6 and GFRA7 respectively) and members. The key objective of GCC-FMD is to offer a platform to exchange experiences, facilitate coordination and align the regional FMD control initiatives and development of a harmonised global FMD action plan towards 2027.

The Commission appreciated the collaborations between OIE and the EuFMD on capacity building programmes that benefit FMD and other TADs control, and private public partnerships in the implementation of OIE standards.

# 7.2. Peste des Petits Ruminants. Global Control and Eradication Strategy

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

The Commission was updated on the progress achieved by the joint FAO/OIE Core Expert Team (CET) which was convened at the beginning of 2021 to undertake the revision of the first five-year PPR Global Eradication Programme (GEP) and the formulation of its second phase (2022-2026). In order to consider the views of relevant stakeholders in the revision process, virtual regional/epizone meetings were held in almost all regions/epizones identified in the PPR GCES. During these meetings, Members provided an overview of their current PPR situation, on the lessons learnt during the first phase of the PPR GEP, including major gaps identified, strategies conducted to address them and priority activities to be undertaken.

<sup>&</sup>lt;sup>5</sup> South-East Asia and China Foot and Mouth Disease (SEACFMD)

<sup>&</sup>lt;sup>6</sup> Pan American Center for Foot-and-Mouth Disease and Veterinary Public Health of the Pan American Health Organization/ World Health Organization (PANAFTOSA/VPH-PAHO/WHO)

<sup>&</sup>lt;sup>7</sup> Global Foot and Mouth (FMD) Research Alliance (GFRA)

Consultations at global level were also organised during the fourth PPR Vaccine Producers Workshop and the fourth PPR Global Research and Expertise Network (GREN) meeting, which were respectively held virtually in November 2021 and in December 2021. On 1st October 2021, a PreCOP26 side event 'Coping with climate change: the key role of livestock ownership' was organised by FAO, OIE and the African Union Commission (AUC-DARBE), which highlighted the contribution of small ruminants to rural households' adaptation to climate shocks and the value of animal health initiatives, such as PPR GEP, to the enhancement of livestock sectors' contribution to climate resilience.

The Commission was also informed about the finalisation process of the in-depth review of the PPR Monitoring and Assessment Tool (PMAT). The revised draft tool was piloted during the aforementioned PPR regional consultation meetings held in the framework of the revision of PPR GEP and is now being fine-tuned by the OIE/FAO revision expert team, based on observations and feedback from participants. The draft revised tool consists of two documents, i) the PMAT Questionnaire, an excel file structured according to the five technical elements of the Global Strategy for the Control and Eradication of PPR (GSCE), and ii) the User Guide, which provides a clear description of the revised tool with detailed instructions on its use and interpretation of results, as well as a description of the role, responsibilities and interaction between key stakeholders involved in the PMAT process.

Finally, the Commission noted the activities implemented by the OIE under the OIE Action plan in support of the PPR GEP.

- The first meeting of the OIE PPR Reference Laboratories Network took place in November 2021, to share experience and best practices among its members. A website dedicated to the network has been developed and was recently launched.
- Eight million PPR vaccine doses were delivered to Mauritania for the implementation of the PRAPS project though the OIE PPR Vaccine Bank in 2021. In addition, the OIE launched a new international call for tender with the support of a Selection Committee composed of OIE and external experts, to renew the manufacturers which will supply the OIE PPR Vaccine Bank for the next four years (2022–2025). Following this call, <u>two manufacturers</u> were selected based on technical and financial criteria. The OIE is now able to provide a thermotolerant PPR vaccine through its PPR Vaccine Bank.
- Two infographics targeting veterinary paraprofessionals of French speaking countries have been developed respectively on PPR diagnosis and on vaccination against PPR and will soon be available in the OIE website.

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

The Commission was informed that the United Against Rabies Forum now encompasses more than 30 institutions in three working groups, working collectively to progress activities that will support countries in their efforts to progress towards the elimination of human deaths from dog-mediated rabies.

Working Group 1 'Effective use of vaccines, medicines, tools and technologies' has identified the minimum data elements for international reporting of human and animal rabies, and is progressing with a tool evaluation process to help stakeholders select and integrate appropriate tools into their rabies activities. This group is also mapping global rabies activities and stakeholders, exploring the benefits of dog identification and vaccination programs, and reviewing available evidence for rapid diagnostic testing of rabies.

Working Group 2, 'Strategic and operational support', has developed a national strategic plan template to help countries develop their own rabies elimination plans and which is now available to countries in both English and French. The group has drafted a proposed roadmap to provide guidance to countries, while linking countries to technical resources, and has identified the main constraints faced by countries in eliminating dog-mediated rabies. This working group is also progressing with the development of a monitoring and evaluation framework, updating the recommendations for the use of oral rabies vaccines in dogs, and has recently started a workstream to explore the possibilities of integrating rabies control with other disease control and prevention programs.

Working Group 3 is focused on 'Resource Mobilisation and Advocacy'. Priority activities for this working group include developing strategies and messaging for the engagement of national resource partners, engaging international resource partners to invest in rabies elimination as part of health system improvement, and creating a toolbox of advocacy and investment materials to engage public and private investors, media, and civil society.

Stakeholders were updated on the progress and outputs of Working Groups during the UAR Forum Stakeholder event, which consisted of three webinars in September and October 2021. Between 200 and 400 participants representing both human and animal health sectors from 92 countries attended each webinar.

The UAR Forum website, which is in development, will provide a central platform where members and other stakeholders can access UAR Forum technical resources, while annual stakeholder events build the networks required to collectively overcome the challenges of achieving zero human deaths from dog-mediated rabies.

The Commission was informed that the UAR Forum had identified six key priority focus areas for 2022: engage local authorities in rabies elimination; maintain rabies in the One Health political agenda; facilitate knowledge transfer; engage, empower and facilitate the work of national stakeholders; expand and engage membership; and engage the wider health development community.

#### 7.4. African swine fever. Global control initiative

The Commission was updated on the activities conducted under the <u>Global Initiative</u> (GI) for the Control of African swine fever (ASF), noting that the GI is managed by the Food and Agriculture Organisation (FAO) and the OIE under the Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TADS). The Commission was advised that the global control of ASF continues to present important challenges. ASF continued to spread, with recent notifications of first occurrence in Thailand, North Macedonia and mainland Italy.

Since the last Commission meeting in September 2021, regional standing group of experts (SGE) meetings were organised in <u>Europe</u>, <u>Asia</u>, and <u>the Americas</u>, and the first meeting of an ASF SGE for the Africa region is in preparation and scheduled for March 2022.

In February 2022, the OIE ASF reference laboratory network published an <u>overview</u> of ASF diagnostic test for field application summarising the current network's knowledge on commercially available field tests, describing the technical details, cost, as well as advantages and disadvantages of each test. This is intended to support diagnosis of ASF in circumstances when the timely submission, processing, and testing of samples using the diagnostic tests described in the OIE Terrestrial Manual are not feasible.

The Commission was also updated on the activities of the GF-TADs ASF Working Group, which was formed in July 2020 to coordinate, monitor, and evaluate the implementation of the GI, and to contribute to the development and support of ASF control strategies at the global and regional levels. It noted that a key focus for 2022 will be the implementation a monitoring and evaluation system for the ASF GI

#### 8. Liaison with other Commissions and Departments

#### 8.1. Terrestrial Animal Health Standards Commission (Code Commission)

At this February 2022 meeting, the Bureaus (i.e. the President and two Vice-Presidents) of the Code Commission and the Scientific Commission held a meeting chaired by Dr Montserrat Arroyo. The purpose of the meeting was to provide an occasion where the two Bureaus could be informed about the planning and coordination of relevant topics of common interest and, where necessary, prioritise them and agree on the process to manage these topics.

The Bureaus discussed the coordination between the OIE Official Status recognition process and the decision to propose for adoption the revised Chapters 11.4., 1.8. (see Items 4.1.1. and 5.1.5.), and 8.16. (see Item 6.4.3.). The Bureaus also discussed the status of the ongoing assessments for listing or delisting of pathogenic agents currently being undertaken by the Scientific Commission (see Item 10.1.1.), and the status of the work to develop or improve, where needed, the case definitions for terrestrial animal listed diseases to support notification being conducted by the Scientific Commission (see Item 10.2.1.). The OIE DDG informed the Bureaus about comments received on the OIE *Standard Operating Procedure for determining if a disease should be considered as an emerging disease* (see Item 8.1.1.) and discussed possible ways to address them.

#### 8.1.1. Implementation of emerging diseases standard operating procedure

In March 2021 the OIE HQ developed a standard operating procedure (SOP) for determining if a disease meets the Terrestrial Code definition of an 'emerging disease' (ED SOP), and an accompanying guidance document. Both documents were published on the OIE website, and an informative article appeared in the June 2021 edition of the OIE Bulletin emphasising that SOPs are implementation tools that the OIE uses to give effect to international standards. During the 2021 GS (and afterwards), some Members expressed concerns about aspects of this SOP, and these were discussed at the meeting of the Bureaus of the Commission and Code Commission. The Bureaus of the Commission and Code Commission extensively discussed the concerns and considered the need to provide further recommendations in the Terrestrial Code to assist the OIE and its Members in the uniform interpretation of evidence in relation to whether an animal health event should be considered an emerging disease. The Bureaus did not agree with the proposal that the Terrestrial Code (Glossary or Chapter 1.1) should be revised, because the SOP describes, standardises, and makes transparent the current emerging diseases notification process. However, they agreed on 1) the need to review the SOP to ensure it is seen as a guidance process for notification, and ensuring the involvement of Delegates in the process; and 2) to improve communications to promote the understanding of Delegates on the identification and notification of emerging diseases (e.g. further disseminate the SOP and the guidance document, both of which are currently available through the OIE website) and on the progress of the work for considering potential emerging diseases.

Dr Arroyo emphasised that the current SOP does not represent a change in the policy for managing emerging disease notification, but streamlines the existing process according to mandated roles and responsibilities of the different players. The OIE Delegates remain responsible for notifying the OIE of emerging diseases as defined in Article 1.1.4. while the Commission provides scientific guidance to the OIE on the development of policies relating to the assessment and control of diseases, including emerging diseases. In addition, the emerging disease register will be created with the sole purpose of facilitating access to relevant information concerning emerging diseases and will ensure no confusion with the OIE List of Chapter 1.3. She also noted the SOP and associated guidance document are 'living documents' that should be reviewed regularly to improve the clarity and efficiency of the process.

#### 8.2. Biological Standards Commission

# 8.2.1. Follow-up General Session: emerging recombinant lumpy skin disease virus strains, their correct diagnosis and notification

At the OIE General Session in May 2021, concerns were raised on behalf of the EU about the DIVA PCR methods used to distinguish vaccine strains from field strains of lumpy skin disease virus (LSDV), and the challenges encountered in recent years with correctly identifying new recombinant field strains that have emerged in certain parts of the world. Correct identification of LSDV strains has wide implications for disease notification, country status and international trade.

The Biological Standards Commission (BSC) obtained feedback from OIE Reference Laboratory experts on this matter. BSC accepted the experts' recommendations on the need to identify LSDV strains, including recombinant viruses, by whole genome sequencing at the start of an outbreak and rapid publication of the sequence data to facilitate research efforts to develop better tests. In addition, they suggested that the *Terrestrial Manual* Chapter 3.4.12 be amended to describe the impact of emerging recombinant field strains and the need to sequence the virus to identify emerging and novel strains.

The Commission agreed with the BSC, and (in addition), emphasized the need for infected countries to engage with OIE Reference Laboratories to facilitate the process of whole genome sequencing, and also the need for improving the DIVA PCR methods to allow for the distinction between a LSDV classical field strain, a recombinant strain and a vaccine strain.

### 9. Conferences, workshops, meetings, missions

### 9.1. Second lumpy skin disease (LSD) coordination meeting for South-East Asia

The Commission was informed about the second LSD coordination meeting held in South-East Asia on 16 December 2021. The meeting, organised by the OIE Sub-Regional Representation for South-East Asia, was attended by 70 participants from the ASEAN countries, FAO RAP, and the OIE.

The objectives of the meeting were to: provide an update on the current LSD situation in the affected countries; provide updates and share experiences in implementation of LSD vaccination by those countries implementing LSD vaccination; provide an update on the LSD Preventive Vaccination Plan by those countries at risk of LSD incursion; provide a platform to the member countries for discussion on various issues related to LSD vaccination and in particular access to quality LSD vaccines. Vietnam, Thailand, Malaysia, Lao PDR, Philippines and Indonesia shared their various countries experiences. The final report of the meeting can be found <u>here</u>.

### 10. Disease control: specific issues

#### 10.1. Evaluation of pathogenic agent against listing criteria of *Terrestrial Code* Chapter 1.2.

#### 10.1.1. Update on (de)listing assessments of pathogenic agents

The Commission noted the progress made since February 2021 on (de)listing assessments of pathogenic agents against the criteria defined in the *Terrestrial Code* Chapter 1.2.

The Commission was informed that at its September 2021 meeting, the Code Commission requested that an assessment be presented to the OIE DDG ISS in line with the Standard Operating Procedure for listing decisions for pathogenic agents of terrestrial animals, and that, in implementing step 2-2 of the *Standard operating procedure for listing decisions for pathogenic agents of terrestrial animals* (listing SOP), the OIE DDG ISS considered the request and concluded that an assessment was not justified by any scientific evidence that would question the current status of scrapie on the OIE List, noting that available information shows that the disease has been spread internationally by trade in sheep, that there are countries which claim freedom, it can be diagnosed, and it has significant impact in livestock populations.

The Commission considered whether the listing SOP should be adjusted to remove the requirement that the Biological Standards Commission is consulted for its opinion regarding the assessment of criterion 3 or Article 1.2.2. (Steps 3.2-6 and 3.3-7) when the assessment to be conducted is for the delisting of a currently listed terrestrial animal disease. The rationale is that, as all OIE-listed terrestrial animal diseases have a chapter in the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, this indicates that a reliable means of detection and diagnosis exists, and the remaining component of criterion 3 (that a precise case definition is available) can be addressed by the Commission. Although acknowledging this point, the Commission noted that it appreciated the opportunity to work with other Commissions and receive their advice, and recommended that this step in the listing SOP be maintained for both listing and delisting assessments.

The Commission then discussed several issues raised by subject-matter experts undertaking the (de)listing assessments against the criteria of Chapter 1.2. For criterion 1 ('international spread of the pathogenic agent (via live animals or their products, vectors, or fomites) has been proven'), the Commission remarked that it would be difficult to identify pathogenic agents for which this would not be met, making questionable the relevance and utility of this criterion. In addition, the Commission noted the difficulties in assessing the disease against criterion 2 ('At least one country has demonstrated freedom or impending freedom from the disease'), and challenged its relevance as a listing criterion. The Commission emphasised that the criteria need to be interpreted in the context of OIE's mandates to facilitate safe international trade, and to improve animal welfare and improve disease control (or eradication) measures. The Commission discussed the difficulties in assessing diseases against the criteria and recommended convening an *ad hoc* group to update them. The Commission forwarded this opinion to the Code Commission and requested that this topic be added to its work plan.

# 10.1.2. Consideration of expert consultation report and BSC opinion (SOP 3.2-8)

#### 10.1.2.1. Paratuberculosis

At their September 2021 meeting, the Commission had reviewed the assessments for the (de)listing of paratuberculosis prepared by subject-matter experts, but had requested that additional information pertaining to criterion 2 ('at least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the provisions of Chapter 1.4.') be provided before making their decision. The supplementary expert opinion was considered by the Commission at this meeting.

The Commission concurred with the experts' opinions that criterion 1 was met.

The Commission considered the additional material pertaining to criterion 2 ('at least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the provisions of Chapter 1.4') and noted the continued difficulty experienced by the experts in responding to this item. The Commission again expressed their reservation about this criterion being fit for purpose. Although there is evidence suggesting that cattle in Sweden may be free from paratuberculosis<sup>8</sup>, doubts have been expressed about this claim<sup>9</sup>. The Commission considered that paratuberculosis does not meet this criterion as currently written.

<sup>&</sup>lt;sup>8</sup> Frössling J., Wahlström H., Ågren E.C.C., Cameron A., Lindberg A. & Sternberg Lewerin S. (2013). – Surveillance system sensitivities and probability of freedom from Mycobacterium avium subsp. paratuberculosis infection in Swedish cattle. *Preventive Veterinary Medicine*, 108 (1), 47–62. doi:10.1016/j.prevetmed.2012.07.010.

<sup>&</sup>lt;sup>9</sup> EFSA Panel on Animal Health and Welfare (AHAW), More S., Bøtner A., Butterworth A., Calistri P., Depner K., Edwards S., Garin-Bastuji B., Good M., Gortázar Schmidt C., Michel V., Miranda M.A., Nielsen S.S., Raj M., Sihvonen L., Spoolder H., Stegeman J.A., Thulke H.H., Velarde A., Willeberg P., Winckler C., Baldinelli F., Broglia A., Zancanaro G., Beltrán-Beck B., Kohnle L., Morgado J. & Bicout D. (2017). – Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): paratuberculosis. *EFSA Journal*, 15 (7), e04960. doi:10.2903/j.efsa.2017.4960

The Commission observed that although all subject-matter experts and the Biological Standards Commission agreed that paratuberculosis satisfied criterion 3 (that 'reliable means of detection and diagnosis exist, a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections or infestations'), as noted in the September 2021 meeting, this is not the same as confirming that the available means of detection and diagnosis are appropriate for use to prevent the transboundary spread of paratuberculosis. They recommended that revisions to this criterion reflect this need.

The experts differed in their assessments of criteria 4a and 4c; however, they were unanimous in their opinion about 4b, that 'the disease has been shown to have a significant impact on the health of domestic animals at the level of a country or a zone taking into account the occurrence and severity of the clinical signs, including direct production losses and mortality'. The Commission agreed, and thus concluded that paratuberculosis meets criterion 4.

The experts were unanimously firm in their opinion that paratuberculosis should be maintained as an OIE-listed terrestrial animal disease. The Commission noted that if the criteria were strictly applied as (currently) written, paratuberculosis would **not** remain on the OIE list of terrestrial animal diseases because it would not meet criterion 2. However, the Commission does not recommend delisting paratuberculosis at this time and instead recommends that it be reassessed after the criteria of Chapter 1.2 of the *Terrestrial Code* have been reviewed.

This conclusion and the experts' summary assessment were forwarded to the Code Commission, and the experts' summary assessment appended to this report (Annex 9).

#### 10.1.2.2. Strangles (infection with Streptococcus equi)

The Commission was advised that subject-matter experts had conducted their assessments of *Streptococcus equi* against the listing criteria of *Terrestrial Code* Chapter 1.2 as requested, and the expert consultation report had been provided to the Biological Standards Commission for their opinion regarding the assessment of criterion 3 of Article 1.2.2. as per item 3.2-6 of the *Standard Operating Procedure for Listing Decisions for Pathogenic Agents of Terrestrial Animals*. However, due to time constraints, the Commission did not discuss this item at its February 2022 meeting, so no conclusion was possible at this time.

#### 10.2. Development of case definitions

#### 10.2.1. Case definition process and progress update

The Commission noted the progress made with development of case definitions to date, and appreciated the opportunity to review this with Code Commission at the meeting of the Bureaus of the two Commissions. As the work involves consideration and incorporation (where relevant) of the current and best-available scientific evidence for each topic, the Commission noted that inconsistencies may arise between a newly developed or revised case definition and the existing OIE standards.

The Bureaus agreed on the need to better integrate the Code Commission earlier in the process for prioritisation and to seek advice for if possible conflicts with the standards are identified, and that if experts recommend a change in the case definition that is considered by the DDG to conflict with the current standards (such as different hosts or pathogenic agents with sound rationale), it should be considered by the Code Commission as a driver to review the current standards before the definition is published.

#### 10.2.1.1. Infection with bovine pestiviruses (bovine viral diarrhoea)

The Commission considered the opinion of Code Commission that the case definition (endorsed by the Scientific Commission at its September 2021 meeting), went beyond the current notification obligations stated in the Code, and considered that if the opinion of the experts concerns a modification of the pathogenic agent or the host species, the disease should be reassessed for listing before producing a new case definition. Subsequently, the Commission reconsidered its decision of September 2021 to endorse the proposal made by subject-matter experts to include swine and camelids in the case definition for infection with bovine pestiviruses. While agreeing that these species are susceptible to infection with bovine pestiviruses, the Commission considered that they do not play a significant role in the epidemiology of the disease in the context of international trade. The Commission decided to remove swine and camelids from the case definition developed for the purposes of notification to the OIE, and defined the animal hosts as Bos taurus, Bos indicus, and Bubalus bubalis. The Commission recommended that scientific evidence regarding susceptible species and their roles in the epidemiology of the disease be reassessed when a disease-specific Terrestrial Code chapter is developed. During this discussion, the Commission noted that the existing categorisation in Terrestrial Code Chapter 1.3 may have been developed for administrative convenience and is not necessarily a science-based and comprehensive indication of species susceptibility for the purpose of notification to the OIE.

In addition, the Commission removed the words 'and characterised' from the recommendation to 'isolate and characterise' bovine pestiviruses (excluding vaccine strains) from a sample collected from an animal host, which had been proposed as the first option to confirm a case of infection with bovine pestiviruses. The Commission reviewed its consideration after subsequent discussions including at the February 2022 meeting of the Bureaus of the Commission and the Code Commission indicated that the word 'characterisation' may not consistently be understood, and might be applied with different levels of complexity and thoroughness, perhaps down to the molecular level, when this was not intended. Therefore, the Commission advised that the requirement to confirm the identity of an organism is implied using its name in the option, and that 'and characterised' should not be included.

The Commission concluded that the revised case definition for infection with bovine pestiviruses (bovine viral diarrhoea) does not conflict with existing OIE standards.

#### 10.2.2. Case definitions

#### 10.2.2.1. Infection with Coxiella burnetii (Q fever)

The Commission reviewed the draft case definition for infection with *Coxiella burnetii* (Q fever) prepared by an expert group, along with their report and the opinion of the Biological Standards Commission on the case definition. The Commission commended the work of the experts, noting that Q fever is a complex zoonotic disease and recognising the difficulty experienced in developing a case definition for the purposes of notification to the OIE.

The Commission noted that the experts recommended three options (any one of which is sufficient) for confirming a case of infection with *Coxiella burnetii* (Q fever) for the purposes of notification to the OIE. The first option included isolating and characterising the organism; however, consistent with its decision regarding use of the term 'and characterise' (see Item 10.2.1.1.), the Commission removed 'and characterise' from the case definition.

The Commission noted the Biological Standards Commission's opinion concerning the second proposed option, for the detection of nucleic acid specific to *C. burnetii*, and agreed that additional supplementary evidence (that the animal host is epidemiologically linked to a suspected or confirmed case) is required. However, the Commission disagreed with the Biological Standards Commission's recommendation to add a requirement that the detection of nucleic acid specific to *C. burnetii* is confirmed by sequencing. They considered that this is implicit in the requirement to detect nucleic acid **specific to the pathogen** (i.e. that sufficient testing to distinguish between *C. burnetii* and Coxiella-like organisms is implied) noting also that this can be achieved by molecular methods other than sequencing.

Finally, the Commission considered the third proposed option that encompasses serological testing, and discussed the Biological Standards Commissions concerns that a single positive antibody test result in an individual animal could confirm infection with *C. burnetii*, even when this is accompanied by supporting evidence. The Commission decided to retain the option for serological testing, as there are circumstances when it may be useful and appropriate. However, noting the opinion of the experts that, due to the possibility of cross-reaction with *C. burnetii*, the Commission (alone) does not confirm active infection with *C. burnetii*, the Commission did not agree to include a requirement for seroconversion in this option.

The Commission considered that the endorsed case definition for infection with *Coxiella burnetii* (Q fever) does not conflict with OIE standards. The experts' report is appended (<u>Annex 10</u>), and the case definition as endorsed will be published on the OIE website in due course.

#### 10.2.2.2. Infection with camelpox virus (camelpox)

The Commission reviewed the draft case definition for infection with camelpox virus (camelpox) prepared by an expert group, along with their report and the opinion of the Biological Standards Commission on the case definition. The Commission commended the work of the experts.

The Commission noted that the experts recommended four options (any one of which is sufficient) for confirming a case of infection with camelpox virus (camelpox) for the purposes of notification to the OIE. As outlined previously in this report for bovine pestiviruses (Item 10.2.1.1.) and *Coxiella burnetii* (Item 10.2.2.1.), the Commission removed the expression 'and characterised' from 'isolated and characterised' in this option.

The Commission then considered the option that proposed requirements for identification of antigen or genetic material specific to camelpox. For consistency with other case definitions, the Commission replaced 'genetic material' with 'nucleic acid' in the case definition. In both cases, additional supporting evidence is required to confirm a case.

An option for confirming a case based on the typical appearance of orthopox virions as observed by transmission electron microscopy in conjunction with additional supporting evidence (characteristic clinical signs or epidemiological link to confirmed case) was then discussed and accepted. However, the Commission noted that many Members may not have the ability to perform this examination, and further, the skills involve a degree of subjectivity, making the process difficult to accredit under ISO 17025 which is the OIE quality standard for veterinary laboratories. The final option considered by the Commission included the detection of antibodies that are not the consequence of vaccination, in conjunction with supporting evidence. The Commission agreed with the experts and the Biological Standards Commission that this option would have very limited utility in an endemic country where vaccination is practiced and infection may be widespread. However, noting that at least one country with a significant camel population free from camelpox exists, and for consistency with other case definitions, the Commission opted to include this option but disagreed with the Biological Standards Commission's suggestion to include text limiting its applicability to non-endemic countries.

The experts' report is appended (<u>Annex 11</u>), and the case definition as endorsed will be published on the OIE website in due course.

#### 10.2.2.3. Infection with avian metapneumovirus (turkey rhinotracheitis)

The Commission was informed that an expert group has prepared a draft case definition for infection with avian metapneumovirus, and that the Biological Standards Commission considered this along with the experts' report at its February 2022 meeting. The Commission thanked the Biological Standards Commission for their inputs and plans to consider these along with the experts' report and the draft case definition in the September 2022 meeting.

#### 10.3. Update on the foot-and-mouth disease reference laboratory network and disease global situation

Dr Donald King (OIE FMD Reference Laboratory, Pirbright Institute, United Kingdom) updated the Commission on the activities of the OIE/FAO FMD Reference Laboratory Network and on significant FMD-related events that occurred globally in recent years, with emphasis on the past 12 months.

He noted that FMD epidemiology is very dynamic with new unpredictable patterns in Asia (East and West) and North Africa, posing threats to FMD-free countries and affecting the selection and deployment of vaccines. Dr. King discussed the endemic pool concept which is peculiar to FMD noting that sampling of field outbreaks is critical particularly in these endemic pools. COVID-19 had an impact on sample collection with lower numbers collected in 2020 than in previous years, but sampling has started to increase again in 2021.

Serotype O remains the dominant serotype followed by serotype A. No outbreaks of serotype C have been reported since 2004. Between 30 and 50% of samples received by laboratories are of low quality that do not allow virus detection, or where typing is not possible. O/ME-SA/Ind-2001 continues to represent a potential source for future spread as the source of multiple escapes from Pool 2 with many events involving long distance spread.

Dr King highlighted that gathering information on the distribution of the FMD virus lineage in each of the seven pools of virus circulation is fundamental for vaccine matching in these regions. He emphasised that sampling of field outbreaks is critical particularly in the endemic pools where COVID-19 has reduced field surveillance activities. He also stressed the importance of an active FMD Reference Laboratory Network to facilitate sample collection from FMD outbreaks in the field to feed real-time laboratory data back to FMD control programmes.

Recent efforts have focused on developing heterologous multivalent vaccines, and on establishing standardised FMDV antigen panels representative of a particular region and standard reference sera to calibrate assays for measuring vaccine induced responses. Dr. King also described a new (2021) openaccess system for FMD sequences (FMDbase) addressing problems with accessibility of FMDV genomic data. The Commission commended the FMD Reference Laboratory Network for their efforts.

# 11. For Commission information

### 11.1. Update on OFFLU

The OIE continued coordination of the OIE/FAO Network of expertise on animal influenza (OFFLU). From October 2021 to the time of this report, the avian influenza epidemic continued with a high number of detections reported in poultry and wild birds resulting in the death and slaughter of millions of affected poultry throughout the continents of Europe, Asia, and Africa. In response to these outbreaks, OFFLU network experts held teleconferences to share epidemiological and molecular data on currently circulating viruses and released situation updates and statements needed to inform surveillance and control policies.

OFFLU and WHO shared data to update risk assessments and establish consensus on issues related to the animal-human interface, including pandemic preparedness. OFFLU participated in the February and September 2021 WHO Vaccine Composition Meetings providing 298 H5, 1 H7 and 17 H9 avian influenza virus sequences representing more than 30 countries globally. In addition, 495 H1 and 304 H3 swine influenza virus sequences were contributed. Equine influenza experts updated the vaccine recommendations for 2021 based on current surveillance and outbreak data.

OFFLU <u>technical activities</u> continued to deliver concrete outputs that contribute to the mitigation of risks posed by zoonotic animal influenza viruses to public and animal health.

## 11.2. Update on the STAR-IDAZ International Research Consortium

The Commission was informed about the activities of the scientific secretariat (SIRCAH, which is cohosted by the OIE) of the Global Strategic Alliances for the Coordination of Research of Major Infections Diseases of Animals and Zoonosis (STAR-IDAZ) International Research Consortium (IRC). In December 2021 SIRCAH was favourably evaluated by an external panel of independent experts of the European Commission (EC) and is currently working to secure additional funding for its continuation.

The twice-yearly meeting of the STAR-IDAZ IRC Executive Committee was held in October to update members on the status of the Network and to discuss coordination activities relating to influenza, alternatives to antibiotics (ATA), vaccine platform and vector borne diseases. In addition, information on members' research activity was shared.

Five regional virtual meetings were held between September 2021 and January 2022 for the networks of Africa, the Middle East (AMERN), the Americas, Asia, Australasia, and Europe (CWG AHW). Regional members were updated on current activities and opportunities for sharing resources (including access to samples and strains of organisms, specialised facilities, and expertise) were explored, as well as international funding opportunities. In the AMERN meetings, external funding organisations (e.g. GALVmed, IDRC, ILRI, World Bank) were invited to present their research programmes. In addition, SIRCAH provided support to the activities of the European Regional Network (CWG AHW) for the identification of animal health and welfare research needs for the next European Strategic Research and Innovation Agenda (SRIA).

Two Scientific Committee virtual meetings were held to discuss the activities of the Working Groups (WGs) on the current priorities, and the <u>state-of-the-art report 2021</u> was made available. Despite delays due to COVID restrictions, the WGs and affiliated experts continued their networking activities, delivering the outputs on ATA, ASF, emerging diseases, influenza, platform Technologies for veterinary Vaccinology, one Health and vector transmission and control.

#### 11.3. Update on OIE antimicrobial resistance activities

The Commission was informed about the meeting of the Working Group on Antimicrobial Resistance (AMR WG, held 26 to 28 October 2021) during which the AMR WG discussed the progress made by a subgroup on a technical reference document that lists antimicrobial agents of veterinary importance for swine, which will be completed in April 2022. In addition, AMR WG considered the work of the OIE *ad hoc* Group on Technical References for Aquatic Animals, which will be completed in October 2022. Another AMR WG subgroup has been created, and they will be working on revisions to be proposed to the *Terrestrial Code* Chapter 6.10. 'Responsible and prudent use of antimicrobial agents in veterinary medicine'; their next meeting will take place from 27 to 29 April 2022.

The Commission was updated on the activities of the OIE Electronic Expert Group on Antiparasitic Resistance (EEG APR), and advised that the EEG APR had prepared a document on 'Responsible and prudent use of anthelmintic chemicals to help control anthelmintic resistance in grazing livestock species' which was informed by responses to questionnaires on antiparasitic resistance that were sent to Focal Points for Veterinary Products in all OIE Regions in 2020 and 2021. This work was <u>published</u> on the OIE website in December 2021 and will be presented to the AMR WG in April 2022 to discuss how the work of the EEG APR could be progressed given AMR WG priorities and context.

# 11.4. Update on the Global Burden of Animal Diseases programme (GBADS) and the OIE Collaborating Centre for the Economics of Animal Health

The Commission was updated on the GBADs programme which continues to work on developing methodologies to assess the economic burden of animal diseases in a systematic manner to include net loss of production, expenditure, and trade impacts. The focus to date has been on gathering data, advancing work on the prototype of an analytics platform, and refining methodologies to enable initial estimates of disease burden. Processes have also been initiated to start validation of the methods.

#### 11.5. Update on 'international trade of insects: potential impact on animal health'

The Commission was provided with a preprint of a paper entitled 'The World Organisation for Animal Health – current and potential roles in safe international trade of bees and other insects' which was prepared by OIE staff for the upcoming *OIE Scientific and Technical Review* (Vol. 41 (1)) on 'Safety, regulatory, and environmental issues related to breeding and international trade of insects'. The paper recognises that insects, including bees, are crucially important for the global ecosystem and that preserving the health of insects can pose a One Health challenge. The paper noted that the OIE is well placed to contribute to discussions on developing or reviewing standards or guidance for the safe international trade of insects and their products, but the development of specific recommendations for evaluating and preserving the health of insects entering trade (other than bees) would require changes to the current scope of the OIE international standards.

The Commission expressed its continued interest in this topic and looks forward to the publication of upcoming *OIE Scientific and Technical Review* (Vol. 41 (1)).

# 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 will be accessible to Members on the OIE website.

The updated work programme is attached as Annex 12.

## 14. Adoption of the meeting report

The Commission adopted the report that was circulated electronically after the meeting

# 15. Date of the next meeting

The next meeting of the Scientific Commission is scheduled to take place between 19 and 23 September 2022 (or between 12 and 23 September, if held virtually).

#### 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

# Virtual, 7 to 23 February 2022

#### Agenda

# 1. Welcome

- 2. Meeting with the Director General
- 3. Adoption of the agenda
- 4. Terrestrial Animal Health Code
  - 4.1. Member comments received for Commission consideration
    - 4.1.1. Chapter 11.4. Bovine spongiform encephalopathy
    - 4.1.2. Chapter 8.8. Infection with foot and mouth disease virus
  - 4.2. Other considerations
    - 4.2.1. Chapter 4.4. Zoning and compartmentalisation (Article 4.4.7. Containment zone)

#### 5. Ad hoc and Working Groups

- 5.1. Meeting reports for endorsement
  - 5.1.1. Ad hoc Group on the evaluation of African horse sickness status of Members: 5-7 October 2021
  - 5.1.2. *Ad hoc* Group on the evaluation of contagious bovine pleuropneumonia status of Members: 5–7 October 2021
  - 5.1.3. Ad hoc Group on the evaluation of FMD status of Members: 18-20, 22, 25 and 27 October 2021
  - 5.1.4. *Ad hoc* Group on the evaluation of classical swine fever status of Members: 26 and 28 October 2021
  - 5.1.5. *Ad hoc* Group on the evaluation of bovine spongiform encephalopathy risk status of Members: 16–19 November 2021
- 5.2. Planned ad hoc Groups and confirmation of proposed agendas

#### 6. Official animal health status

- 6.1. Annual reconfirmations for maintenance of status
  - 6.1.1. Comprehensive review of annual reconfirmations for pre-selected status and all OIE-endorsed official control programmes
  - 6.1.2. Report of the annual reconfirmation assessments by the Status Department
  - 6.1.3. Documented evidence to substantiate annual reconfirmation of CSF and PPR free status
- 6.2. Specific update on official animal health status
  - 6.2.1. Update on situation of countries/zone with suspended status
- 6.3. State of play and prioritisation of expert mission to Members requested by the Commission
  - 6.3.1. Follow-up of past missions/virtual interviews
  - 6.3.2. State of play and prioritisation

- 6.4. Standards related to official status recognition
  - 6.4.1. Update on SOP: Inclusion of virtual interviews as an alternative or adjunct process to field missions; establishment of a protection zone
  - 6.4.2. Follow-up on the impact assessment related to the revised BSE standards and list of countries already having an official risk status by the OIE
  - 6.4.3. Procedure for recovery or risk assessment in case of recurrence of rinderpest

#### 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 Standards Commission (Code Commission)
  - 8.1.1. Implementation of emerging diseases standard operating procedure
- 8.2. Biological Standards Commission
  - 8.2.1. Follow-up General Session: emerging recombinant lumpy skin disease virus strains, their correct diagnosis and notification
- 9. Conferences, workshops, meetings, missions
  - 9.1. Second lumpy skin disease (LSD) coordination meeting for South-East Asia
- 10.Disease control: specific issues
  - 10.1. Evaluation of pathogenic agent against listing criteria of Terrestrial Code Chapter 1.2.
    - 10.1.1. Update on (de)listing assessments of pathogenic agents
    - 10.1.2. Consideration of expert consultation report and BSC opinion (SOP 3.2-8)
      - 10.1.2.1 Paratuberculosis
      - 10.1.2.2 Strangles (infection with Streptococcus equi)
  - 10.2. Development of case definitions
    - 10.2.1. Case definition process and progress update
      - 10.2.1.1 Infection with bovine pestiviruses (bovine viral diarrhoea)
    - 10.2.2. Case definitions
      - 10.2.2.1 Infection with Coxiella burnetii (Q fever)
      - 10.2.2.2 Infection with camelpox virus (camelpox)
      - 10.2.2.3 Infection with avian metapneumovirus (turkey rhinotracheitis)

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

#### 11. For Commission information

- 11.1. Update on OFFLU
- 11.2. Update on the STAR-IDAZ International Research Consortium
- 11.3. Update on OIE antimicrobial resistance activities
- 11.4. Update on the Global Burden of Animal Diseases programme (GBADS) and the OIE Collaborating Centre for the Economics of Animal Health

 $\underline{Annex 1}$  (contd)

11.5. Update on 'international trade of insects: potential impact on animal health'

12.Any other issues

13. Programme and priorities

13.1. Update and prioritisation of the work plan

- 14. Adoption of the meeting report
- 15.Date of the next meeting
- 16.Meeting Review

# Annex 2

# MEETING OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

# Virtual, 7 to 23 February 2022

### List of participants

#### **MEMBERS**

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Original: English October 2021

# REPORT OF THE VIRTUAL MEETING OF THE OIE *AD HOC* GROUP ON THE EVALUATION OF AFRICAN HORSE SICKNESS (AHS) STATUS OF MEMBERS 5 - 7 October 2021

A virtual meeting of the OIE *ad hoc* Group on the Evaluation of African Horse Sickness (AHS) Status of Members (hereafter the Group) was held from 5 to 7 October 2021.

# 1. Opening

Dr Montserrat Arroyo, Deputy Director General for International Standards and Science of the OIE, welcomed and thanked the Group for its commitment and the extensive support towards the OIE mandates. She extended her appreciation to the institutions that kindly allowed the experts to participate in the meeting. She highlighted that the official recognition of animal health status was an important activity for the OIE and acknowledged the amount of work before, during and after the *ad hoc* Group meeting in reviewing the dossiers and documenting the Group's assessment in the report.

Dr Arroyo reminded the Group of the confidentiality of the dossiers received for official recognition and thanked the experts for abiding by the undertaking of confidentiality. She mentioned that the OIE has recently updated the confidentiality agreement forms and kindly asked the experts to submit the updated forms. She underlined the OIE procedures for protecting the confidentiality of information and for declaring potential conflicts of interest; the experts would withdraw themselves from the discussion and conclusion in case of a potential conflict of interest.

Dr Arroyo also highlighted the importance of the quality of the report which would be scrutinised by Members before the proposal of the list of Members free from AHS to be adopted by the World Assembly. She also encouraged the Group to provide detailed feedback to Members with a negative outcome to support them in identifying the main gaps and points for improvement, as well as providing informative recommendations to those Members with positive outcomes for further improvement in maintenance of their AHS free status.

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

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

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

### 3. Evaluation of applications from Members for official recognition of AHS free status

### a) Bahrain

In August 2021, Bahrain submitted a dossier for the official recognition of its AHS free status based on historical grounds. The Group requested additional information and received clarifications from Bahrain.

#### *i)* Animal disease reporting

The Group acknowledged that Bahrain has a record of regular and prompt animal disease reporting and that AHS is a notifiable disease for at least the past ten years.

#### *ii)* Veterinary Services

The Group acknowledged that Bahrain had relevant legislation in place with regard to AHS. The Group also acknowledged that equestrian sport, especially endurance and racing, is an essential part of the country's heritage and is supported by many members of the royal families and the horse industry. Bahrain described that the Horse Welfare Affaire provides and operates the equine services in the country. Furthermore, an emergency Equine Disease Control Committee trains veterinarians on reporting equine diseases including AHS as part of continuing professional development. Bahrain also described the responsibilities of private veterinarians in notifying AHS as well as in contingency planning activities in emergency situations. The Horse Welfare Affaire, in coordination with the Animal Wealth Resources in Bahrain, publishes and distributes updated awareness material on horse diseases, including on AHS, based on the publicly available reports and information provided by the OIE. Whilst the Group noted the distribution of information on horse diseases by Bahrain, the Group encouraged Bahrain to develop AHS and equine infectious disease related educational materials that are locally significant and continue to conduct training sessions for all veterinarians and veterinary paraprofessionals to enhance the early detection and diagnosis of the disease.

The Group considered that the Horse Welfare Affaire in Bahrain had current knowledge of, and authority over equids in the country.

#### iii) Situation of AHS in the past 24 months

The Group noted that AHS has never been reported in the country and that this is consistent with the information in OIE-World Animal Health Information System (WAHIS) and in the public domain.

*iv)* Absence of systematic vaccination in the past 12 months:

The Group noted that systematic vaccination against AHS was never carried out in the country and acknowledged the regulatory framework on the prohibition of AHS vaccination.

#### v) Importation of equids and their semen, oocytes or embryos in accordance with Articles 12.1.6. to 12.1.9.

The Group took note that all imported equids are kept in isolation in vector-protected facilities at the Equine Veterinary Quarantine and under official veterinary supervision. Horses in isolation are allocated specific time slots for training without coming into contact with local equids. The Group noted that Kingdom of Bahrain Horse Welfare Authority Order No (1) of 2021 lists the countries Bahrain may import horses from and the list includes two countries of undetermined AHS status. Import conditions from these two countries include a minimum 30-day pre-export quarantine with AHS testing as well as post arrival quarantine and testing. The Group encouraged Bahrain to pay particular attention to ensuring import conditions for equids from countries of undetermined AHS status is in strict compliance with Article 12.1.7. of the *Terrestrial Animal Health Code (Terrestrial Code)*.

The Group noted that Bahrain does not import equine oocytes or embryos and the importation of equine semen is only permitted from countries officially recognised free from AHS by the OIE.

The Group noted a discrepancy between a statement in Bahrain's dossier that import of vaccinated horses against AHS into Bahrain is not allowed, and the additional information provided by Bahrain regarding seropositive equids which were investigated, and it was concluded that they were previously vaccinated horses imported into Bahrain. The Group strongly encouraged reconciling the underlying legislation with current import practices.

The Group agreed that the regulations in place for importation of equids and equine semen are compliant with Articles 12.1.6. and 12.1.8. of the *Terrestrial Code*.

vi) Surveillance if adjacent to an AHS infected country or zone if relevant

The Group acknowledged that Bahrain does not share land borders with any other country, and that there is a border inspection post at King Fahad Causeway that links Bahrain to Saudi Arabia.

vii) Surveillance in accordance with Articles 12.1.11. to 12.1.13.

The Group noted that passive clinical surveillance was in place, and serological surveillance is only carried out on horses prior to exportation. Bahrain described that between 300-400 samples are tested annually for export purposes using an enzyme-linked immunosorbent assay (ELISA) test performed at the Central Veterinary Research Laboratory (CVRL), in United Arab Emirates. A small percentage of animals tested positive, all of which up to now have been described as having a history of previous vaccination.

The Group noted the relatively small population of equids in Bahrain (approximately 5,000 equids) and the absence of wild equids (except for a very small number of captive wild equids). Bahrain stated that identification and registration of all equids are mandatory by law. Bahrain indicated that the Animal Wealth Resources monitors private veterinary clinics and hospitals, and the Horse Welfare Affaire inspects the stables periodically.

The Group acknowledged that the majority of horses and properties are registered, and horses are individually identified with microchips and passports.

viii) Regulatory measures for the prevention and early detection and control of AHS

Regarding the prevention of AHS introduction, a regulatory framework was in place and no illegal import of equids was reported in Bahrain.

Considering the naïve equid population, and identification of all horses in Bahrain, the Group considered that introduction of AHS would be easily and promptly detected by the authorities and prompt actions for follow-up could be undertaken.

*ix)* Compliance with the questionnaire in Article 1.7.1

The Group agreed that Bahrain's dossier was compliant with the questionnaire in Article 1.7.1. of the *Terrestrial Code*.

#### Conclusion

Considering the information submitted in the dossier and the answers received from Bahrain to the questions raised, the Group concluded that the application was compliant with the requirements of Chapter 12.1., as well as with Article 1.4.6. and the questionnaire in Article 1.7.1. of the *Terrestrial Code*. Therefore, the Group recommended the official recognition of Bahrain as a country free from AHS.

The Group would draw the attention of Bahrain to the following recommendations and to provide updates when Bahrain reconfirms its AHS free status in 2022:

- Whilst the Group commended the transparency of Bahrain in providing information on the sero-reactors and interpretation of the source, it noted the discrepancy with Bahrain's statement under item 9. b) of the core dossier stating that import of vaccinated horses against AHS into Bahrain is not allowed. In this regard, the Group strongly encouraged reconciling the underlying legislation with current import practices and subsequently informing the OIE of the actions taken.
- The Group encouraged Bahrain to develop AHS educational material that is locally relevant and conduct training sessions for all veterinarians and veterinary paraprofessionals to enhance the early detection and diagnosis of the disease.

Please also consider the following recommendations based on the assessment of the information provided:

- The Group took note that imported horses are sprayed with an approved insect repellent prior to leaving and re-entering the quarantine station. The Group highlighted the fact that the chemical substance used

does not have repellent properties against *Culicoides* vectors and advised Bahrain to reconsider the selection of adequate repellent for use.

- The Group encouraged Bahrain to include horses other than those destined for trade purposes, as part of the surveillance programme, e.g., a suspect case where a horse with a fever was investigated.
- The Group recommended using the appropriate serological tests (e.g., virus neutralisation test-VNT) for ensuring the absence of an increased in antibody titre in a paired test as recommended by Chapter 3.6.1 of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)*.
- The Group recommended Bahrain to amend relevant plans and policy documents specifying that tissue sampling for AHS diagnosis should include samples from lung, spleen, and lymph nodes.

#### b) Other applications

The Group assessed two other requests from Members for the official recognition of AHS free status. The Group concluded that the applications did not meet the requirements of the *Terrestrial Code*.

## 4. Adoption of report

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

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Appendix I

# VIRTUAL MEETING OF THE OIE *AD HOC* GROUP ON THE EVALUATION OF AFRICAN HORSE SICKNESS (AHS) STATUS OF MEMBERS 5 - 7 October 2021

# **TERMS OF REFERENCE**

## Purpose

The purpose of the *ad hoc* Group on the evaluation of African Horse Sickness (AHS) of Members is to evaluate applications for official recognition of AHS free status of Members.

#### Background

In accordance with the <u>OIE procedure for official recognition of animal health status</u>, OIE Members can be officially recognised by the OIE as having a AHS free status through the adoption of a resolution by the World Assembly of Delegates of the OIE (the Assembly) in May every year. A Member wishing to apply for the official recognition of its AHS free status should complete and submit the <u>questionnaire</u> laid out in Chapter 1.7 of the OIE *Terrestrial Animal Health Code (Terrestrial Code)* and comply with all requirements specified in the *Terrestrial Code*. The OIE Scientific Commission for Animal Diseases (<u>Scientific Commission</u>) is responsible for undertaking, on behalf of the Assembly, the assessment of OIE Members' applications for their compliance with OIE standards. The assessment carried out by the Scientific Commission is based on the recommendations formulated by a relevant *ad hoc* Group. *Ad hoc* groups are convened under the authority of and report to the OIE Director General.

#### Specific issues to be addressed

The Group will evaluate Members' applications in detail on their compliance with the requirements specified in the *Terrestrial Code* for AHS. Based on the evaluations, the Group will provide its conclusions and recommendations to the Scientific Commission.

# Prerequisites

The Group members should:

- Sign the OIE Undertaking on Confidentiality of information (if not done already);
- Complete the Declaration of Interest Form;
- Understand that the membership of the Group may be retained between its meetings to ensure continuity of the work.

## Actions to deliver

## Before the meeting

Upon reception of an application from a Member, the Status Department (SD) conducts a preliminary screening to check the conformity of the dossier (structure of the dossier in accordance with the SOP and with the questionnaire under Chapter 1.7 of the *Terrestrial Code*, main sections of the questionnaire, regular notification to the OIE, payment of the fee, OIE Performance of Veterinary Services (PVS) report, etc.). If an information gap is identified, the SD requests additional information from the Member.

As the PVS reports are bound by the OIE rules on confidentiality of information, the SD and experts will consider for the evaluation the available PVS report(s) if not obsolete (PVS reports from more than five years ago) or confidential.

The SD will send the working documents to the Group, including the dossiers received from applicant Members, at least one month before the Group meeting (i.e., 03 September 2021).

# Annex 3 (contd)

The experts can request support from the SD at any time.

The SD suggests the nomination of a Chair and Rapporteur for the Group's consideration.

The SD can suggest a preparatory meeting with the Chair, the Rapporteur or all experts to address specific points in advance, if needed.

The experts are expected to:

- Be familiar with Chapters <u>1.7</u> and <u>12.1</u> of the *Terrestrial Code*;
- Evaluate and study in detail all dossiers provided by the OIE;
- Take into account any other information available in the public domain that is considered pertinent for the evaluation of the dossiers;
- Summarise the dossiers according to the *Terrestrial Code* requirements by completing the summary tables provided by the SD (the summary tables will be provided at a later stage along with the working documents for the meeting). <u>Experts are expected to capture and summarise in each corresponding section of the summary table the main gaps as well as strengths identified during the assessment of the dossiers, using extracted texts or reference to pages/annexes from the application;</u>
- Draft questions to the applicant Members whenever the analysis of the dossiers identifies incomplete or unclear information;
- Submit to the SD the completed summary tables for each application together with possible questions for the applicant Members at least 10 days before the teleconference and preferably by **24 September 2021**;

The SD will compile the summary tables and the questions to be forwarded to the applicant Members before the teleconference. All subsequent information and material provided by a Member will be forwarded to the Group.

# During the meeting

- Agree on the appointment of the Chair and Rapporteur of the meeting (the Chair will lead the discussion and the Rapporteur will ensure that the report reflects the discussion and captures the detailed assessment of the dossiers);
- Mention any potential conflict of interest and, if relevant, withdraw him/herself from the discussion;
- Contribute to the discussions;
- Provide a detailed report in order to recommend, to the Scientific Commission, the Member(s) to be
  recognised (or not) as free from AHS and to indicate any information gaps or specific areas that should be
  addressed in the future by the applicant Members.

If during the teleconference the Group decides that additional information should be requested from an applicant Member before an informed conclusion can be drawn, the SD can request it and forward the additional information to the Group at a later date. The Chair is responsible for coordinating the finalisation of the assessment and for ensuring that the views of all members of the Group are taken into consideration.

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 if needed.

# After the meeting

The SD will circulate the draft report after the teleconference is over. Experts are expected to contribute to the finalisation of the report within approximately one week.

The SD will circulate the final version of the report to the Group once endorsed by the Scientific Commission and is published online.

# Annex 3 (contd)

## Deliverables

A detailed report to recommend to the Scientific Commission whether an applicant Member(s) should be (or not) recognised with an official AHS free status. The report should indicate any information gaps or specific areas that should be addressed in the future by the Members.

# **Reporting / timeline**

The OIE will circulate the draft report no more than seven days after the teleconference (no later than 15 October 2021) and the Group will finalise its report within ten days (indicative deadline: 22 October 2021).

# AHG Evaluation of AHS status of Members/October 2021

# Appendix II

# VIRTUAL MEETING OF THE OIE *AD HOC* GROUP ON THE EVALUATION OF AFRICAN HORSE SICKNESS (AHS) STATUS OF MEMBERS 5 - 7 October 2021

# AGENDA

- 1. Opening
- 2. Adoption of the agenda and appointment of chairperson and rapporteur
- 3. Evaluation of applications from Members for official recognition of AHS free status
  - a. Bahrain
  - b. Other applications
- 4. Adoption of report

## Appendix III

# OIE AD HOC GROUP ON THE EVALUATION OF AFRICAN HORSE SICKNESS (AHS) STATUS OF MEMBERS 5 - 7 October 2021

# List of participants

#### MEMBERS

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#### Dr John Grewar

Veterinary epidemiologist Research and Innovation Manager South African Equine Health and Protocols (SAEHP) NPC Cape Town South Africa

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#### REPRESENTATIVE OF THE SCIENTIFIC COMMISSION

#### Dr Baptiste Dungu

CEO – Onderstepoort Biological Products Onderstenpoort Pretoria South Africa

## **OIE HEADQUARTERS**

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Original: English October 2021

# REPORT OF THE VIRTUAL MEETING OF THE OIE *AD HOC* GROUP ON THE EVALUATION OF CONTAGIOUS BOVINE PLEUROPNEUMONIA STATUS OF MEMBERS 5 – 7 October 2021

A virtual meeting of the OIE *ad hoc* Group on the Evaluation of Contagious Bovine Pleuropneumonia (CBPP) Status of Members (hereafter the Group) was held from 5 to 7 October 2021.

# 1. Opening

Dr Montserrat Arroyo, Deputy Director General for International Standards and Sciences of the OIE, welcomed the Group. She thanked the experts for their availability and contribution to the work of the OIE and extended her appreciation to their institutes and national governments for allowing their participation in this meeting. Dr Arroyo acknowledged the amount of work before, during and that would be done after the *ad hoc* Group meeting in reviewing the dossiers and writing the report. Dr Arroyo thanked the Group for its commitment and support to the OIE in fulfilling the mandates given by Members.

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

Dr Arroyo highlighted the sensitivity and confidentiality of the dossiers received for official recognition and thanked the experts for having signed the updated forms for undertaking of confidentiality. She also mentioned that if any members of the Group had any conflict of interest in the evaluation of a dossier, the expert(s) should withdraw from the discussions and decision making of the particular application.

The experts and the OIE welcomed Dr Lucía Manso-Silván as a new member of the Group.

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

The Group was chaired by Dr Flavio Sacchini. Dr Chandapiwa Marobela-Raborokgwe acted as rapporteur, with the support of the OIE Secretariat. The Group endorsed the proposed agenda.

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

# 3. Evaluation of applications from Members for official recognition of CBPP free status

#### a) Ecuador

In August 2021, Ecuador submitted a dossier to apply for the official recognition of its CBPP free status based on historical grounds.

The Group requested additional information and received clarifications from Ecuador.

#### *i.* Animal disease reporting

The Group acknowledged that Ecuador has a record of regular and prompt animal disease reporting and that CBPP has been a notifiable disease for at least the past ten years according to the Andean Community of Nations legislation and in accordance with Article 1.4.6. of the *Terrestrial Code*.

#### ii. Veterinary Services

The Group noted that the relevant legislation was in place and that the Veterinary Services of Ecuador were part of the Phytosanitary and Zoosanitary Regulation and Control Agency and comprised the General coordination of animal health, which has three technical offices, being Office of Animal Health Surveillance, Office of Animal Health Control, and Office of Animal Health Certification.

The Group further noted that CBPP related activities were supervised by the Office of Animal Health surveillance. The Veterinary Services of Territory of the Galapagos Islands (TIG) falls under the responsibility of the Galapagos Biosafety and Quarantine Regulation and Control Agency. The Group noted the close coordination between the Veterinary Services in continental Ecuador and those in the TIG.

The Group noted that Ecuador has in place an Animal Health Information System for notification and reporting of animal health events.

The Group appreciated the comprehensive information provided on demographics of livestock and noted that animal identification was mandatory, and that the animals were identified individually and at a group level at the mainland. Ecuador explained that having these two methods of animal identification in place, together with the issuance of the "Animal Health Certificate of Production and Mobility – Movement", allows the traceability of such animals to a final destination such as a congregation centre, a farm or a slaughterhouse. The Group took note that the method of identification of animals at TIG was individual, through the placement of an electronic ear tag, in compliance with the requirements implemented at the national level. The traceability and control of bovine movements was undertaken through the issuance of animal health certificates for the movement of animals from farm to farm, and from farm to slaughterhouse/abattoir.

The Group took note of the several control posts in continental Ecuador, as well as on each of the islands in the TIG, where the inspection and monitoring of shipments of products and by-products of animal and plant origin are carried out to reduce the risk of entry of any pathogen.

Whilst the Group noted that an awareness programme was in place for veterinarians and other stakeholders for disease notification, it was not evident whether a regular and sustainable programme targeting CBPP was in place. Therefore, the Group recommended to Ecuador to implement more specific awareness and training activities focusing on CBPP disease recognition and, in particular, on the lesions suggestive of CBPP.

The Group concluded that the Veterinary Services had current knowledge of and authority over the livestock population in the country.

#### *iii.* Situation of CBPP in the past 24 months

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

## iv. Absence of vaccination in the past 24 months

The Group noted that the importation of CBPP vaccine is prohibited by the regulations of the organic law of agricultural health, which prohibits import or use in the country of biological vaccines for exotic diseases, including CBPP, and that vaccination against CBPP had never been carried out in Ecuador.

#### v. Surveillance in accordance with Articles 11.5.13. to 11.5.17.

The Group acknowledged that Ecuador has a passive surveillance and early detection system in place based on field notifications and post-mortem inspections at slaughterhouses/abattoirs.

From the information in the dossier, the Group concluded that a targeted CBPP surveillance system was not in place since the disease had never been reported in the country. While acknowledging that pathogen-specific surveillance was not required in accordance with Article 1.4.6. Point 2. of the *Terrestrial Code*, the Group expressed its concern about the follow-up investigations of CBPP suspect cases that were only based on the epidemiological analysis and did not include any laboratory testing to confirm or exclude CBPP.

The Group noted that the CBPP laboratory diagnosis was not carried out in the country. However, the Group was informed that there was a formal agreement in place with the OIE Reference Laboratory for CBPP in Portugal for sending the samples in case of strong CBPP suspicion. The country has established the guidelines that describe responsibilities, tasks, sampling procedures, sample management, storage and shipping of samples as well as the time frame for reporting results.

#### vi. Regulatory measures for the prevention and early detection of CBPP

The Group was of the opinion that regulatory measures to prevent and control foreign animal diseases in general, including CBPP, were in place. The Group took note of Ecuador's membership in the Andean Community of Nations that has common regulations in relation to reporting, importation, movement and transit of domestic cattle and their products, including genetic material.

The Group noted that Ecuador imported semen from countries not officially recognised free from CBPP by the OIE. Upon the Group's request, Ecuador provided the information on the import conditions/requirements for such a commodity. Nevertheless, the Group underlined that the import conditions should comply with the recommendations of Chapter 11.5. of the *Terrestrial Code*.

The Group noted that there was a generic contingency plan in place. The Group emphasized that the particular actions to be taken in case of a CBPP suspect case and a specific CBPP sample collection and procedures for disease diagnosis should be developed Therefore, the Group recommended to Ecuador to adjust the contingency plan with the more specific actions targeting CBPP. The Group noted that there was no information on CBPP simulation exercises conducted in Ecuador and encouraged the country to organise a simulation exercise to reinforce the CBPP outbreak response plan.

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

The Group found that the content of Ecuador's dossier was compliant with the questionnaire in Article 1.10.1. of the *Terrestrial Code*.

#### Conclusion

Considering the information submitted in the dossier and the answers received from Ecuador to the requests for additional information, the Group considered that the application was compliant with the requirements of Chapter 11.5., Article 1.4.6., and with the questionnaire in Article 1.10.1., of the *Terrestrial Code*. The Group therefore recommended that Ecuador be recognised as country free from CBPP on historical grounds.

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

- Implementation of specific awareness and training activities focusing on CBPP disease recognition at abattoirs, including simulation exercises on CBPP control actions;

- An adjusted contingency plan including the chain of actions specifically targeted to CBPP, from the point of detection of a clinical suspicion, necropsy and submission of samples for laboratory confirmation of disease and differential diagnosis.

#### b) Mongolia

In August 2021, Mongolia submitted a dossier to apply for the official recognition of its CBPP free status based on historical grounds.

The Group requested additional information and received clarifications from Mongolia.

#### i. Animal disease reporting

The Group acknowledged that Mongolia has a record of regular and prompt animal disease reporting and that CBPP has been a notifiable disease for at least the past 10 years according to national legislation and in accordance with Article 1.4.6. of the *Terrestrial Code*.

#### *ii. Veterinary Services*

The Group noted that the new Animal Health Law (AHL) of 2018 together with subsequent Ministerial Decrees and Government resolutions provide the legal framework and ensure that the financial resources fully supported all activities of the Veterinary Services in Mongolia.

The Group acknowledged that Mongolia has well-structured Veterinary Services with three levels of veterinary authorities. At national level, the General Authority of Veterinary Services (GAVS) of the Ministry of Food, Agriculture and Light Industry is the Government Implementing Agency in charge of animal disease control, food safety and veterinary public health, as well as international trade of animal and animal products. At the province/municipal level, provincial veterinary service departments cover animal health and food safety issues; and within each soum and district, the state veterinary service unit and private veterinary units are the ones in charge to deliver veterinary support. The Group took note about the five departments under the GAVS authority: Veterinary hygiene and assurance, Animal health protection, Veterinary inspection and risk management, Administration, and Finance and investment. Mongolia informed the Group that the main duties of the GAVS are animal health protection, rapid response measures to animal diseases, ensuring the quality of animal products, prevention of zoonotic diseases, certification of exportations, inspection of animal health, animal movement control, quarantine, and inspection in slaughterhouses.

The Group appreciated the comprehensive information provided on livestock demographics. The Group took note that livestock owners identify an individual animal by signs and marks (ear notches, painting horns of cloven-hoofed animals etc.) and that all livestock owners are responsible for identifying and registering all animals individually in accordance with Article 7 of the AHL. Nevertheless, the Group emphasized that the current livestock identification system poses challenges with tracing animal movements which might affect a rapid and effective control during an outbreak.

The Group took note that the GAVS has developed an information technology called Mongolian animal health information system - MAHIS - which allows monitoring of animal health and food safety, identification of the origin of animals, movement control of livestock and products in the entire country. The Group noted that veterinary certificates for the movement of animals were issued by official veterinarians when the animals cross the borders of the soum or district. The Group was informed that a digital platform to issue veterinary certificates for movement of livestock has been introduced countrywide in December 2019 and it has been fully operational since 1 February 2020.

The Group noted that an OIE Performance of Veterinary Services (PVS) evaluation follow-up mission was conducted in 2019 and one of the key findings was the need to accompany the Veterinary Services to check the development of human resources, programmes and management systems of the Veterinary Services. The Group acknowledged that the PVS follow-up mission report clearly demonstrated the significant improvement of Veterinary Services at all levels.

The Group took note that the General Agency for Specialized Inspection is responsible for any export and import controls and implements these through its Export, Import and Border Quarantine Inspection Department. In addition, the Group noted that Mongolia has a risk management strategy for uncontrolled movements of susceptible animals and that most illegal movements are associated with stolen animals. The Group acknowledged that the GAVS was collaborating with the National Police Agency to reduce the number of illegal movements. Nevertheless, the Group regretted that information on the number of susceptible animals moved illegally within the country in the past 24 months was not provided.

The Group noted that a CBPP simulation exercise was conducted in 2019, and that training, and awareness activities related to many transboundary animal diseases (TADs) including CBPP, were carried out between 2018-2020. Nevertheless, the Group considered that Mongolia should target training and awareness campaigns related to CBPP, particularly for recognition of pneumonic lesions suggestive of CBPP at abattoirs.

The Group concluded that the Veterinary Services had current knowledge of and authority over the livestock population in the country.

#### *iii.* Situation of CBPP in the past 24 months

The Group acknowledged that the last CBPP cases were reported in Mongolia in 1972 and therefore, Mongolia could be eligible for historical freedom from CBPP as described in Article 1.4.6. of the *Terrestrial Code*.

#### iv. Absence of vaccination in the past 24 months

The Group noted that the last vaccination against CBPP was recorded in 1974. The Group highlighted that, based on the information in the dossier and the additional information submitted by Mongolia, vaccination is not prohibited by law, although Mongolia's CBPP contingency plan (2019) and the prevention strategy (2021) both state that CBPP control will be achieved without the use of vaccines. However, the Group took note that according to the legislation in place, and as confirmed by Mongolia, production of CBPP vaccine and emergency vaccination in case of a CBPP outbreak shall be approved by the central authority. Furthermore, the Group noted that, according to the requirements for live cattle import into Mongolia, it is stated in the CBPP prevention strategy (2021) that animals must originate from a CBPP-free country or zone, which implies that vaccinated animals may no longer be imported.

#### v. Surveillance in accordance with Articles 11.5.13. to 11.5.17.

The Group noted that Mongolia has a passive and active surveillance system at the national level. The passive surveillance system is based on post-mortem inspection at slaughterhouses by trained veterinarians under the Veterinary Authority. The Group took note that between 2019 and 2020, 176 samples were submitted for laboratory testing, from which seven mycoplasma cultures were isolated, but *Mycoplasma mycoides* subsp. *mycoides* (*Mmm*) was ruled out by conventional PCR. However, the Group regretted that information on the timeframe for laboratory confirmation of samples from suspect cases was not provided in the dossier. The Group took note that Mongolia's active surveillance system is based on serological surveys, and regretted that these surveillances were not targeted, which would have been much more effective. The Group commended Mongolia for its efforts to demonstrate CBPP absence by the serological surveys conducted. The Group was of the opinion that considering the epidemiological situation of CBPP in the country, strengthening of the abattoir surveillance including differential diagnosis should be paramount.

The Group took note that, besides official veterinarians, farmers and other personnel in the livestock industry are involved in surveillance activities and disease reporting. The Group was informed that veterinarians are accredited every five years through the renewal of veterinary licenses and that in order to renew their accreditation, veterinarians are required to attend and pass a continuous professional development course which includes early detection, control and prevention of TADs.

The Group noted that Mongolia has a laboratory network with a State Central Veterinary Laboratory (SCVL) that acts as national reference laboratory for diagnosis and surveillance of infectious diseases of livestock. The SCVL is supported by a laboratory network composed of provincial and municipal laboratories. In addition, the Group took note that the Institute of Veterinary Medicine (IVM) carries out diagnosis and research on animal health related issues such as Mycoplasma infection. The Group acknowledged that laboratory diagnosis of CBPP is done at provincial and municipal veterinary laboratories, IVM and SCVL in Mongolia. The Group noted that according to the regulation for laboratory network, final confirmation of laboratory diagnosis should be done at SCVL; however, according to the information provided, IVM actually conducts laboratory confirmation for CBPP. Based on the information on CBPP diagnostic tests provided in the dossier, the Group was of the opinion that Mmm PCR testing procedure should be revised and positive reference material for Mmm should be included as positive control. In addition, the Group was concerned about the scope of the accreditation provided by Mongolia and regretted that Mongolia did not show any evidence of participation in CBPP proficiency tests. Therefore, the Group considered that Mongolia should improve the capacity of the confirmatory laboratory for CBPP and participate in proficiency tests for CBPP diagnosis organised by an OIE Reference Laboratory for CBPP.

#### vi. Regulatory measures for the prevention and early detection of CBPP

The Group took note that the Mongolian Veterinary Services work in cooperation with Russia, China and Japan through a constant exchange of animal disease information.

The Group acknowledged and commended Mongolia for its animal health agreement on import control procedures with other countries. The Group took note that there are 13 border ports for import of live breeding animals and appreciated the information provided on penalties for illegal imports of animals and animal products. The Group noted that imported live cattle must originate from countries/zones officially recognised as CBPP free or countries/zones where cases have not been reported in the past 12 months. In addition, the Group took note that all imported animals are subjected to clinical examination at the border port or at the place of destination, and that quarantine and laboratory testing for a number of infectious diseases are implemented.

The Group acknowledged that a contingency plan for CBPP has been included in the veterinary legislation. The Group noted that livestock owners are compensated in case of culling of animals due to disease control policy. In addition, the Group noted that a more recent national preparedness plan for TADs has been drafted and included in the national legislation in 2021. The Group appreciated that such plan clearly outlines the roles, responsibilities, timelines and actions to be undertaken in case of TADs occurrence, including CBPP.

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

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

#### Conclusion

Considering the information submitted in the dossier and the answers received from Mongolia to the requests for additional information, the Group considered that the application was compliant with the requirements of Chapter 11.5., Article 1.4.6., and with the questionnaire in Article 1.10.1., of the *Terrestrial Code*. The Group therefore recommended that Mongolia be recognised as country free from CBPP on historical grounds.

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

- Improvement of the capacity of the confirmatory laboratory for CBPP diagnosis under Good Laboratory Practices and towards quality assurance, particularly regarding mycoplasma culture and molecular identification, using appropriate positive reference material;

- Participation in proficiency tests for CBPP diagnosis organised by an OIE Reference Laboratory for CBPP;

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- Strengthening of abattoir surveillance for lesions suggestive of CBPP and establishing the cause of pneumonic lesions through laboratory investigation;
- Updating the legislation to include a formal prohibition both for the use of vaccines and for the importation of vaccinated animals

# 4. Evaluation of an application from a Member for the endorsement of official control programme for contagious bovine pleuropneumonia (CBPP)

#### a) Zambia

In August 2021, Zambia submitted a dossier for the endorsement of its official control programme for CBPP.

The Group requested additional information and received clarifications from Zambia.

*i.* Animal disease reporting

The Group noted that CBPP is a notifiable disease per legislation and that Zambia has a record of CBPP outbreaks occurrence.

*ii.* Capacity of the Veterinary Services to control CBPP

The Group noted that the Department of Veterinary Services (DVS) is responsible for animal health, welfare and veterinary public health. The Group acknowledged that Zambia has a well-structured DVS with the offices at provincial, and district levels. The DVS undertakes the responsibility to conduct different CBPP related activities such as active and passive surveillance in the infected and high-risk zones, vaccinations in the infected and protection zones with vaccinations, in addition to movement controls, testing and slaughter, sensitisation and awareness creation, stakeholder involvement and community participation.

From the dossier, the Group was informed that the slaughterhouses were supervised by the DVS. Clinical surveillance is conducted at farm level, abattoirs and slaughter slabs all over the country and post-mortem inspections are conducted on all carcasses to check for pathognomonic lesions. However, the Group noted that data on abattoir surveillance provided with the dossier only refers to CBPP infected provinces while no information was displayed for the other provinces, particularly for "CBPP free zones". The Group considered that CBPP surveillance activity of the control program should cover the entire country and encouraged Zambia to provide evidence that these activities are also carried out in the "CBPP free zones".

The Group took note of a tailored capacity building programme targeting different stakeholders from the national to the field level.

The Group noted that Zambia reported the information on notification of disease outbreaks and the measures taken to prevent the spread of diseases, which might include quarantine measures and restrictions applied to the movement of animals, animal products and biological products.

*iii.* Applicability of the official control programme for CBPP to the entire territory

The official control programme is applicable to the whole territory of Zambia while following a zonal approach for CBPP control.

#### iv. The detailed plan of the programme to control and eventually eradicate CBPP in the country or zone

The Group noted that Zambia is demarcated into five epidemiological zones (infected zone, protection zone with vaccination, protection zone without vaccination, high surveillance zone and free zone) based on the level of risk of CBPP. The Group took note of the control measures implemented in each of the zones depending on the epidemiological situation of CBPP. These measures include mass vaccination, clinical and serological surveillance, movement control, slaughter of infected herds, regular and timely reporting, and abattoir and slaughter-slab monitoring of cattle. The Group noted that cattle in the different epidemiological zones are identified by a unique brand (different for each zone) in addition to owner brand. Zambia informed that in order to enhance the cattle identification and registration system, the DVS has been piloting a web-based system since 2017. The main goal of this system would be to identify cattle at individual level and enhance their traceability. The Group also noted that according to the timeline and performance indicators provided with the dossier, the national rollout of the electronic system will be completed within 5 years starting from year 2 to 5 of the control program.

The Group took note that currently cattle are only allowed to move with veterinary permission from the free zone, high surveillance zone, and protection zone without vaccination, and that movement of cattle from the infected and protection zones with vaccination are not allowed into the other zones. The Group noted that Zambia plans to progressively achieve disease freedom status by 2026. The high surveillance zones will progress to free zones, the protection zone without vaccination to high surveillance zones, the protection zone without vaccination and finally the infected zones will progress to protection zones with vaccination. Upon request, Zambia provided an updated five-year workplan compiling the different performance indicators to show how the planned activities would be strengthened year by year to achieve the desired goal. The Group considered the submitted workplan as ambitious and questioned whether it will reach its full implementation over the five-year period. Zambia indicated that the funds for the first year of implementation had been secured through the Enhanced Smallholder Livestock Investment Programme funded by the International Fund for Agricultural Development. From the second year to year five, funds from the Animal Disease Control Fund will be used for implementation with the remaining gaps to be funded by the Central treasury.

#### v. Epidemiology of CBPP in the country

The Group took note that the first recorded outbreak of CBPP in Zambia was in 1915 in the Western Province. This was followed by another outbreak in 1969 which was eradicated in 1973. A third outbreak was recorded in 1997. The infected zone includes parts of Western Province that borders Angola and Muchinga and Northern Provinces that border Tanzania. CBPP is endemic in areas of Western Province that borders Angola. From the dossier, the Group was informed that the disease was spread by husbandry practices such as transhumance, communal grazing and watering and some customary practices that promote congregation of animals from different areas. Regarding the situation in Northern and Muchinga Provinces, the Group was informed that normally, cattle are moved from some neighbouring countries into Zambia for sale, which precipitates outbreaks of CBPP in the locality where these animals are destined. The low cattle density in these provinces results in slow spread of the disease and usually does not affect larger areas. The epidemiological risk levels have been identified similar to those of the Western Province. Zambia informed the Group that most of the CBPP outbreaks experienced in the North-Western Province are extensions of the disease from the Western Province.

Zambia described the illegal movements of susceptible animals from some neighbouring countries as sources and routes of the disease introduction. While acknowledging the information on risk assessment made and cross-border coordination with some of the neighbouring countries, the Group considered that this risk assessment of CBPP incursions should be referring to all bordering countries and that the country should enhance a cross-border collaboration and put in place stronger control measures to reduce the risk of such disease introduction.

## vi. CBPP surveillance

The Group noted that a CBPP surveillance system in the country is under the responsibility of the DVS. The Group acknowledged that a procedure was in place for the rapid collection of information, collection and transportation of samples from suspect cases of CBPP to the Central Veterinary Research

Institute (CVRI) for rapid diagnoses. Suspect cases of CBPP are reported to the District Veterinary Officer within 24 hours and they are investigated immediately. The Group took note that where suspicion cannot be resolved by epidemiological and clinical investigation, samples are taken and submitted to CVRI. Zambia described that a CBPP suspicion is raised following any cattle showing signs of coughing, pain and difficulty in breathing, inactivity, sudden death, high morbidity within a short period of time, high mortality in naïve populations or identification of gross lesions on postmortem examination that are consistent to those described for the disease in the National Animal Disease Control Standard Operating Procedures.

The Group took note that the procedure to notify the authorities is well-described in the same standard operating procedures for animal disease control. The Group took note of the following surveillance methodologies in place: i) clinical surveillance, ii) abattoir/slaughter slab surveillance for lesions suggestive of CBPP, iii) isolation by cultural techniques and identification by Polymerase Chain Reaction (PCR), iv) serological techniques such as the Complement Fixation Test (CFT) and Competitive Enzyme Linked Immunosorbent Assay (c-ELISA).

The Group noted that the information provided on conducted surveillance activities were related mainly to some of the provinces belonging either to the infected or protection zones. Data from surveillance activities in the free zones were not presented in the dossier. The Group was of the opinion that the overall information related to the surveillance activities in the entire country, would give a more comprehensive picture of the current epidemiological situation.

#### vii. Diagnostic capability and procedure

The Group noted that the CVRI in Lusaka is the only laboratory responsible for CBPP diagnosis and confirmation in Zambia. Zambia informed the Group that serological (CFT and c-ELISA) and isolation and identification of *Mmm* by a PCR test are conducted.

Zambia informed the Group that the CVRI has implemented a quality management system according to ISO/IEC 17025:2017 standard and the CBPP tests (cELISA and CFT) are accredited by the Southern African Development Community Accreditation Services. In addition, the Group noted that the CVRI has satisfactorily participated in proficiency testing and/or inter-laboratory comparisons organised by the Botswana National Veterinary Laboratory (PCR and CFT) and CIRAD-France (cELISA).

## viii. Vaccination

The Group noted that Zambia's control programme employs a strategy of mass vaccination in designated areas (CBPP infected zone and CBPP protection zone with vaccination) using the attenuated strain T1/44. The mass vaccination campaigns are conducted once a year, preceded with public awareness activities carried out through sensitisation meetings, kraal visits, meetings with influential community leaders and public notices. Zambia informed that the Department vaccination coverage between 2017 and 2020 had been between 87-95% of the target population.

The Group appreciated that the DVS had increased allocation of resources to vaccination campaigns to ensure sustained delivery of adequate vaccines, vaccination equipment, and logistical support.

From the information provided in the dossier, it was not clear to the Group how the vaccinated animals were to be identified. In response to the Group's request, Zambia informed the Group that all animals in the vaccination areas were identified through the brand marks allocated to the specific area and recorded during vaccination under the particular CBPP vaccination form. These records are used in subsequent vaccinations to identify the particular animals. The Group expressed its concern about the absence of a system that provides evidence and traceability of each vaccination received by individual animals over the years. The Group encouraged Zambia to implement the electronic system for cattle individual identification and registration at national level where several information for each animal, including CBPP annual vaccinations received, are recorded into the system. In the

meantime, Zambia is encouraged to explore alternative methods as means to identify animals receiving CBPP annual vaccination avoiding further branding.

#### *ix.* Emergency preparedness and response plan

The Group took note that the emergency response plan in case of a CBPP outbreak was described in the dossier. Nevertheless, the Group was of the opinion that a more detailed contingency plan taking into consideration the CBPP epidemiology in each zone should be developed by Zambia. Upon the Group's request, Zambia provided its CBPP contingency plan that describes the actions taken in response to a CBPP outbreak according to each epidemiological zone. However, the Group was of the opinion that the contingency plan should be updated with all the fragmented information in the different documentation provided by Zambia.

The Group noted that a legal basis for a compensation policy was in place. From the dossier, the Group was informed that the DVS had negotiated with slaughterhouses to ensure that farmers are paid the market value (within 48 hours after slaughter) of the CBPP affected carcasses in the infected zones. The Group commended Zambia on establishing a public-private partnership in the slaughter of infected or exposed cattle to complete the cycle of the compensation system with regard to CBPP control.

#### *x.* Compliance with the questionnaire in Article 1.10.3.

The Group agreed that Zambia's dossier was compliant with the questionnaire in Article 1.10.3. of the *Terrestrial Code*.

#### Conclusion

Considering the information submitted in the dossier and the answers received from Zambia to the questions raised, the Group considered that the application was compliant with the requirements of Chapter 11.5. and with the questionnaire in Article 1.10.3. of the *Terrestrial Code*. The Group therefore recommended that Zambia's official control programme for CBPP be proposed for endorsement.

The Group recommended that evidence on the following information be submitted to the OIE when Zambia reconfirms its official control programme for CBPP (also detailed in the relevant sections above):

- Progress made in the implementation of the individual animal identification and registration system at the national level, alternative to branding marks that allow the veterinary services to record and retrieve information on any practice done (i.e., CBPP annual vaccination) at the animal level;
- An adjusted contingency plan so that it clearly describes the actions taken according to each epidemiological context, from detection of a clinical suspicion, immediate diagnosis by agent isolation and confirmation, to implementation of control measures, including compensation;
- Reinforcement of the coordination, collaboration and information-sharing activities with other countries and zones in the same region or ecosystem.
- Surveillance data from (i) surveillance zone without vaccination and (ii) the free zones should be included in the reports.

#### 5. Adoption of report

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

.../Appendices

Appendix I

# VIRTUAL MEETING OF THE OIE *AD HOC* GROUP ON THE EVALUATION OF CONTAGIOUS BOVINE PLEUROPNEUMONIA (CBPP) STATUS OF MEMBERS 5 – 7 October 2021

# **TERMS OF REFERENCE**

# Purpose

The purpose of the *ad hoc* Group (the Group) on contagious bovine pleuropneumonia (CBPP) status of Members is expected to evaluate applications for official recognitions of CBPP free status and for endorsement of their official control programme of CBPP.

# Background

In accordance with the OIE standard operating procedure (SOP) for official recognition of animal health status and for the endorsement of official control programmes, OIE Members can be officially recognised as country/zone free from CBPP or to have their official control programme endorsed by the OIE through the adoption of a resolution by the OIE World Assembly of Delegates at the General Session in May every year. A Member wishing to be recognised as free from CBPP or to have its official control programme for CBPP endorsed by the OIE should submit the required information to prove evidence that they comply with all the requirements specified in the *Terrestrial Animal Health Code (Terrestrial Code)* for CBPP. The assessment of the compliance with OIE standards of OIE Members' applications is conducted by the Scientific Commission for Animal Diseases (Scientific Commission) based on the recommendations formulated by a relevant *ad hoc* Group. The *ad hoc* Groups are convened under the authority of and report to the OIE Director General.

# Specific issues to be addressed

The Group will screen and evaluate in detail three applications from Members to assess compliance of the Members with the requirements specified for CBPP in the *Terrestrial Code*. Based on those evaluations, the Group will provide recommendations to the Scientific Commission that will meet in February next year.

# Prerequisites

Ad hoc Group members should:

- Sign the OIE Undertaking on Confidentiality of information (if not done before)
- Complete the Declaration of Interest Form;
- Understand that the membership of the Group may be retained between its meetings to ensure continuity of the work.

# Actions to deliver

# Before the meeting

Upon reception of an application from a Member, the Status Department (SD) conducts a preliminary screening to check the conformity of the dossier (structure of the dossier in accordance with the SOP and with the relevant questionnaire, main sections of the questionnaire, regular notification to the OIE, payment of the fee, PVS report, etc.). If an information gap is identified, the SD requests additional information to the Member.

As the OIE Performance of Veterinary Services (PVS) reports are bound by the OIE rules on confidentiality of information, the SD and experts will consider for the evaluation the available PVS reports if not obsolete (no more than 5 years) or confidential.

The SD will send the working documents to the *ad hoc* Group, including the dossiers received from applicants, at least one month before the virtual meeting (i.e., **5 September 2021**).

The experts can request support from the SD at any time.

The SD suggests the nomination of a Chair and Rapporteur for the Group's consideration.

The experts are expected to:

- Be familiar with Chapters <u>1.10</u> and <u>11.5</u> of the *Terrestrial Code* relative to CBPP;
- Evaluate and study in detail all dossiers provided by the OIE;
- Take into account any other information available in the public domain that is considered pertinent for the evaluation of the dossiers;
- Summarise the dossiers according to Chapter 1.10 requirements by completing the summary tables provided by the SD;
- Draft questions to the applicant Members whenever the evaluation of the dossiers identifies incomplete or unclear information;
- Submit to the SD the completed summary tables for each application together with possible questions at least 10 days before the virtual meeting (i.e., 24 September 2021);

The SD will compile the summary tables and the questions to be forwarded to the applicant Members before the virtual meeting. The SD will forward to experts all subsequent information and material provided by a Member prior to the virtual meeting.

#### During the meeting

- Agree on the appointment of the Chair and Rapporteur of the meeting (the Chair will lead the discussion and the Rapporteur will ensure that the report reflects the discussion and captures the detailed assessment of the dossiers);
- Mention any potential conflict of interest and, if relevant, withdraw him/herself from the discussion;
- Contribute to the discussions;
- Contribute to drafting the report.

If during the virtual meeting the Group decides that additional information should be requested to the applicant Members before an informed conclusion can be drawn, the SD forwards the additional information to the Group at a later date. The Chair is responsible for coordinating the finalisation of the assessment and for ensuring that the views of all Group members are taken into consideration.

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 virtual meeting if needed.

#### After the meeting

The SD will circulate the draft report after the virtual meeting is over. Experts are expected to contribute to the finalisation of the report within the following week.

The SD will circulate the final version of the report to the Group once endorsed by the Scientific Commission and is published online.

#### Deliverables

A detailed report to recommend to the Scientific Commission whether the Member should be (or should not be) recognised with an official CBPP free status or have its official control programme endorsed by the OIE. The report should indicate any information gaps or specific areas that should be addressed in the future by the Member regardless of the final recommendation to the Scientific Commission.

# Reporting / timeline

The OIE will circulate the draft report no more than seven days after the virtual meeting (no later than 15 October 2021) and the Group will finalise its report within the following week (deadline: 22 October 2021).

Appendix II

# VIRTUAL MEETING OF THE OIE *AD HOC* GROUP ON THE EVALUATION OF CONTAGIOUS BOVINE PLEUROPNEUMONIA (CBPP) STATUS OF MEMBERS 5 – 7 October 2021

-55-

# Agenda

- 1. Opening
- 2. Adoption of the agenda and appointment of chairperson and rapporteur
- 3. Evaluation of applications from Members for official recognition of contagious bovine pleuropneumonia (CBPP) free status
  - Ecuador
  - Mongolia
- 4. Evaluation of an application from a Member for the endorsement of official control programme for CBPP
  - Zambia
- 5. Adoption of the report

Appendix III

# OIE AD HOC GROUP ON THE EVALUATION OF CONTAGIOUS BOVINE PLEUROPNEUMONIA (CBPP) STATUS OF MEMBERS 5 – 7 October 2021

# List of participants

#### MEMBERS

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Annex 5

Original: English October 2021

# REPORT OF THE VIRTUAL MEETING OF THE OIE *AD HOC* GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE STATUS AND ENDORSEMENT OF OFFICIAL CONTROL PROGRAMMES OF MEMBERS 18-20, 22, 25 and 27 October 2021

A virtual meeting of the OIE *ad hoc* Group on the Evaluation of Foot and Mouth Disease (FMD) Status and endorsement of official control programmes of Members (hereafter the Group) was held from 18 - 27 October 2021.

#### 1. Opening

Dr Montserrat Arroyo, Deputy Director General for International Standards and Science of the OIE, welcomed and thanked the Group for its commitment and the extensive support towards the OIE mandates. She extended her appreciation to the institutions that kindly allowed the experts to participate in the meeting. She highlighted that the official recognition of animal health status was an important activity for the OIE and acknowledged the amount of work before, during and after the *ad hoc* Group meeting and the efforts required in reviewing the dossiers, particularly considering the high number of dossiers received each year with regard to FMD. She also thanked the Group for its availability and commitment throughout the year in responding to the request of the Scientific Commission for Animal Diseases on FMD-related matters.

Dr Arroyo reminded the Group of the confidentiality of the dossiers received for official recognition and thanked the experts for abiding by the undertaking of confidentiality. She underlined the OIE procedures for protecting the confidentiality of information and for declaring potential conflicts of interest.

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

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

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

# 3. Evaluation of a request for the official recognition of an FMD free zone where vaccination is not practised

The Group assessed a request from a Member for the recognition of an FMD free zone where vaccination is not practised. The dossier was referred back to the applicant Member.

# 4. Evaluation of requests for the official recognition of FMD free zones where vaccination is practised

#### a) Russia – Zone III Eastern Siberia

Russia was recognised as having a zone free from FMD where vaccination is not practised in May 2016 and two zones free from FMD where vaccination is practised in May 2021. In August 2021, Russia submitted an application for the recognition of a new zone free from FMD where vaccination is practised consisting of two Subjects (Republic of Tuva and Republic of Buryatia) and one administrative Raion of the Republic of Altai (Kosh-Agachsky Raion).

The Group requested additional information and received answers from Russia.

*i)* Animal disease reporting

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

*ii)* Veterinary Services

The Group acknowledged the provision of a comprehensive set of legislation related to FMD activities and the organisation of the Veterinary Service in Russia. The Group agreed that the Veterinary Authority had current knowledge of, and authority over, FMD susceptible animals in the proposed zone.

*iii)* Situation of FMD in the past two years

The Group noted that the last FMD outbreaks in the proposed free zone were reported in Zakamensky Raion of the Republic of Buryatia in 1965.

iv) Routine vaccination and vaccines

Russia explained that the viral strains in the vaccine were selected based on the circulating field viruses in Russia and its neighbouring countries. The Group agreed that the vaccine complies with the provisions of the *Manual of Diagnostic Test and Vaccines for Terrestrial Animals (Terrestrial Manual)*.

Russia described that the vaccines are purchased using federal budget and vaccinations are overseen by the *Veterinary Service* and provided to producers free of charge. Russia indicated that cattle, sheep, goats, buffaloes, yaks and camels are vaccinated, but not pigs.

The Group noted that according to the Russian vaccination programme, cattle are vaccinated from four months of age onwards, then every three months until they reach the age of 18 months, and after 18 months, vaccination is maintained twice a year. The Group acknowledged that Russia submitted tables with the number of animals per species and the number of FMD vaccine doses administered per region. However, it was not possible to estimate the vaccine coverage from the data provided.

The Group expressed concerns regarding the population immunity levels in cattle. Considering the vaccination regime and the time of collection of blood samples, the population immunity was lower than expected, particularly in young animals. The Group also noted that the small ruminant population was not included as part of the serological survey either for demonstration of absence of virus transmission or for demonstration of population immunity.

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

The Group acknowledged that the early detection system for FMD in the proposed zone uses passive surveillance. Russia described its passive surveillance based on investigations of FMD suspicions and clinical examinations during routine disease prevention activities that are carried out from three to five times a year. The Group noted that a common FMD surveillance strategy was applied in Russia regardless of the vaccination status in the different zones; regular serological surveillance was performed in the proposed free zone with structural protein and NSP tests and follow-up field investigations and testing in case of suspicious or inconclusive results. The results of the surveys conducted in 2020 and 2021 in the proposed free zone showed zero NSP reactors in the second paired sampling, leading to the rule out of the possibility of FMD virus transmission. The Group found the number of NSP reactors in the first test (screening) surprisingly low, considering the expected percentage of false positive reactors in surveys with large number of samples.

Russia indicated that NSP surveys are only conducted in cattle. Considering that the small ruminant population is almost six times higher than cattle in some Raions and that FMD clinical signs are not usually evident in sheep and goats, the Group recommended that serological surveillance be conducted not only in cattle but also in small ruminants.

Although the procedure of the survey included two stages of sampling (selecting the settlements and then the animals), a two-stage approach was not followed in the study design nor in the sample size calculation. In addition, the criteria used for the selection of epidemiological units was not clearly explained. A two-stage sampling design is recommended to account for clustering in the design of surveillance activities and in the statistical analysis of surveillance data (as described in Article 1.4.3., point 1.e. of the *Terrestrial Animal Health Code*).

The Group recommended Russia to review the design of the serological surveys to be able to rule out the presence of FMD virus transmission with a satisfactory level of confidence and sensitivity. Given the low number of NSP positive reactors in the serosurveys, the Group recommended assessing the protocol for the NSP test in the surveys to ensure a high sensitivity of the screening test. The Group suggested that the survey design, including the selection criteria for the epidemiological units and animals and sample size calculation, should be established for each zone with clear justification regarding the choice of survey design to ensure adequate power and to seek the best representativeness of the population in the samples.

The Group acknowledged the Russian laboratory's participation and satisfactory results in interlaboratory proficiency testing schemes in 2019, as well as its participation in 2020.

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

The Group noted that reporting of FMD suspect cases is enforced by law and FMD is included in the list of priority diseases for immediate notification to the Veterinary Authority. Information was also provided on awareness campaigns and training conducted for farmers and veterinarians to promote reporting of FMD suspicions.

Russia provided documented evidence on the regulatory measures for movement of animals and animal products between zones of different animal health status. Russia also provided the numbers of noncompliant movements detected and amounts of confiscated animal products. Additionally, following a request from the Group, Russia provided a clear description with regard to the control of animal movements including those of transhumance between Subjects. Russia described the specific activities in place to control and monitor transhumance using mobile and stationary control posts to prevent the movement of animals from infected zones into the rest of the country. Russia also provided a set of measures implemented to prevent the introduction of FMD virus across the borders with neighbouring countries with undetermined FMD status including indoor housing of FMD susceptible animals in the Subjects bordering infected countries.

The Group noted that legislation was in place for the treatment of swill, but it was unclear whether or not and how such a legislation was enforced and monitored. Therefore, the Group recommended that if this practice was to be continued, Russia should have a system to monitor the enforcement of the legislation and its compliance by relevant sectors.

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

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

The proposed free zone consists in two Subjects (Republic of Tuva and Republic of Buryatia) and one administrative Raion of the Republic of Altai (Kosh-Agachsky Raion). The Group agreed that the boundaries of the proposed zone were well defined and appropriately displayed with clear maps.

#### viii) Description of the system for preventing the entry of the virus (into the proposed FMD free zone)

The Group acknowledged the comprehensive legal framework provided by Russia on the identification and registration of animals, as well as for the traceability of animal movements using an electronic certification system. Each animal is assigned an individual number shown on its ear tag, brand or tattoo. The dossier stated that records of farms and animals are updated yearly at the end of the calendar year through a comprehensive census. Russia also explained that live animals imported into Russia or transported between the member states of the Euroasian Customs Union must also be identified either individually or as a group, by ear-tags, microchips, rings or tattoos.

The Group noted that live animals and animal products are subjected to inspections carried out at the border inspection posts (BIPs) prior to entry into the proposed zone and the country. Importation of live animals and animal products is permitted based on the results of a previous risk analysis conducted in accordance with the Customs Union Decisions and following the provisions of the *Terrestrial Animal Health Code (Terrestrial Code)*. Russia also explained that the control of movements of live animals and animal products between the different zones is ensured by the regional departments of the Veterinary Service.

The Group requested Russia to confirm whether fresh meat from slaughtered pigs originating from zones with undetermined FMD status can be released into a free zone without being subjected to a treatment that inactivates the FMD virus. Russia clarified that procedures equivalent to the ones described in Articles 8.8.23. and 8.8.31. applied to the meat products derived from pigs originating from an infected zone and slaughtered in the proposed free zone.

The Group considered the described measures adequate to prevent the entry of FMD virus into the proposed zone. Nevertheless, the Group emphasised the importance of continuous compliance with the provisions of the *Terrestrial Code* for importation of animals and their products from countries or zones with lesser animal health status, and for maintaining effective separation and control on movements of animals and their products between the zones of different animal health and vaccination status.

#### *ix)* Compliance with the questionnaire in Article 1.11.4.

The Group agreed that the format of the dossier was compliant with the questionnaire in Article 1.11.4.

# Conclusion

Considering the information submitted in the dossiers and to the questions raised, along with the long interval since the last FMD introduction into the zone and the accompanying low risk of FMD recurrence, the Group agreed that the application was compliant with the requirements of Chapter 8.8. and with the questionnaire in Article 1.11.4. of the *Terrestrial Code*. The Group, therefore, recommended that the proposed zone of Russia be recognised free from FMD where vaccination is practised.

#### b) other application

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

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

#### a) Botswana

Botswana has six FMD free zones where vaccination is not practised that are officially recognised by the OIE. In September 2021, Botswana submitted an application to the OIE for the endorsement of its official control programme for FMD which includes plans for improved control in Zones 1 and 2 in the north of the country that have no official FMD status recognised by the OIE. The Group requested additional information and received clarification from Botswana.

## *i)* Animal disease reporting

The Group noted that FMD is a notifiable disease as per legislation and considered that Botswana had a record of regular animal disease reporting to the OIE.

*ii)* Capacity of the Veterinary Services to control FMD

The Group was informed that Botswana had received a Performance of Veterinary Services (PVS) evaluation mission in 2010, followed by a Gap Analysis mission in 2011, PVS legislation mission in 2015 and PVS evaluation follow up mission in 2019. The Group agreed that Botswana's Veterinary Services had the capacity to control FMD based on achievement of several officially recognised FMD free zones without the use of vaccination in the country and successful maintenance of their FMD-free status.

*iii)* Applicability of the official control programme for FMD to the entire territory

The dossier provided information that the official control programme was applicable to the whole territory of Botswana while following a zoning approach for FMD control. The Group was informed that according to this approach, Botswana is currently at Stage 3 of the Progressive Control Pathway (PCP) and the programme was aimed at eliminating virus transmission to eventually have no endemic FMD in the national domestic livestock population.

Botswana indicated that the country is divided into several zones for disease control purposes. These being the:

- 'FMD free without vaccination zones' that constitute the southern two-thirds of Botswana and consist of zones 3b, 3c, 4a, 4b, 5, 6a, 6b, 7, 8, 9, 10, 11, 12 and 13;
- 'FMD vaccination zones' that comprise zones 1 and 2 (zone 2 is further divided into 2a, 2b, 2c, 2d, 2e and 2f) and zone 3d, of which zones, 2e and 3d act as protection zones; and
- 'Stock free zones' that comprise zones 16, and 17, which are reserved for wildlife. Botswana described that while zone 16 has a population of persistently infected African buffalo, there are no buffaloes in zone 17.

Considering the presence of persistently infected African buffalo in parts of the territory of Botswana, it should be acknowledged that final eradication of FMD will not be possible in the whole country.

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

Upon request, Botswana provided a timeline and detailed steps indicating its progressive plan to control FMD in the different zones covering the area with undetermined FMD status. Botswana stated its objective to attain FMD free status with vaccination for zones 2a, 2b, 2c and 2d by 2025; and to submit an application to the OIE by 2024 to achieve recognition of FMD free status without vaccination for zones 2e and 2f. Botswana also mentioned a plan to eventually declare zones 1 and 3d as free from FMD with vaccination. The strategy described in Botswana's complementary information using different 'disease control zones' to eventually expand the free zones without vaccination and also attain the official recognition of zones free from FMD with vaccination was considered adequate by the Group, also taking into account Botswana's experience in the achievement of several officially recognised FMD free zones and their maintenance.

#### v) Epidemiology of FMD in the country

In the dossier, Botswana described FMD outbreaks between 2002 and 2020 and the epidemiology of FMD in the country. Botswana has never recorded or detected any FMD virus serotypes other than the SATs.

Botswana reported that outbreaks of FMD in small ruminants have always been relatively rare in the country and mild compared to those in cattle, and therefore small ruminants normally were not vaccinated against FMD, even during outbreaks, due to their apparent insignificant role in the epidemiology of FMD in Botswana.

The Group was informed that incursion of African buffalo occasionally occurs in zones 1 (Chobe district) and 2, which are in close proximity to national parks, wildlife management areas, forest reserves and limited livestock farming areas. Therefore, vaccination against FMD has been historically conducted three times a year to mitigate the risk of FMD virus transmission. In zones further away from the areas with buffalo, cattle are vaccinated twice per year. Botswana described in the additional information the actions taken upon incursion of buffaloes into the vaccination zones. The Group considered that the actions taken including destruction of the buffaloes or driving them back were prompt and adequate.

#### *vi) FMD surveillance*

The Group noted that active and passive surveillance were in place and performed in general schemes as well as with a targeted approach in the different zones.

Botswana provided the Standard Operating Procedure (SOP) on the follow-up of NSP reactors. The Group noted in the SOP that resampling of serum and testing was required in the reactor animals only and additional animals will be sampled only if the reactor animals could not be found. The Group strongly recommended that the follow-up procedure in future cases of positive results should include clinical inspection, supplementary testing including collection of probangs of the animals found seropositive and serological testing of additional in-contact animals, and epidemiological investigation in accordance with Article 8.8.42. Point 1 of the *Terrestrial Code*.

Furthermore, based on the high proportions of goats with seropositive NSP results (particularly in zone 2), the Group strongly suggested that these be adequately followed up according to the aforesaid reference and studies on clustering be conducted to further investigate their potential role in the epidemiology of FMD in Botswana.

#### vii) Diagnostic capability and procedure

The dossier stated that laboratory diagnosis of FMD is conducted in two national laboratories, namely Botswana National Veterinary Laboratory (BNVL), a division of the Department of Veterinary Services, and Botswana Vaccine Institute (BVI), an OIE Reference Laboratory for FMD.

The Group noted from the dossier that the BNVL is an ISO/IEC 17025:2005 accredited laboratory and has 41 accredited tests with the South African National Accreditation System (SANAS) of which two are FMD serological tests (liquid phase blocking ELISA (LPBE) and non-structural protein (NSP) ELISA). The BVI laboratory is an ISO/IEC 9001:008 certified laboratory and has additional testing capabilities that include virus neutralisation test (VNT), antigen capture ELISA, PCR, vaccine matching and sequencing. The Group noted that BNVL had participated in proficiency testing schemes organised by the OIE Reference Laboratory for FMD in the United Kingdom (Pirbright Institute) for NSP while BVI had participated in the testing schemes for PCR, antigen ELISA and virus isolation tests. The Group strongly encouraged Botswana's continuous participation in such proficiency testing schemes. The Group also strongly encouraged BVI to apply for accreditaton of their FMD diagnostic tests with SANAS.

#### viii) Vaccination

The Group noted that Botswana adopted vaccination against the three SAT serotypes in cattle as part of the control strategy in high-risk areas of FMD, mainly those bordering wildlife management areas with buffalo. Vaccine is provided by the BVI, which also provides guidance on the strains to be included based on antigenic matching with field viruses from FMD outbreaks. Vaccination is done two to three times a year depending on the likelihood of potential contact between buffalo and cattle. Botswana mentioned that vaccination programmes are monitored and evaluated by post vaccination monitoring (PVM), but could not be conducted in recent years due to the COVID-19 situation. The Group encouraged that these surveys resume as soon as the sanitary situation would allow. Botswana described that different vaccination strategies such as ring vaccination, targeted vaccination or suppressive (dampening-down) vaccination are implemented in selected areas depending on the situation in order to decrease the rate of FMD virus transmission in the areas with undetermined FMD status.

#### ix) Emergency preparedness and response plan

The Group noted that Botswana has an early warning system in place to rapidly detect and investigate reports of suspicions. Botswana presented official documents substantiating its emergency preparedness and response. The Group acknowledged that Botswana had adequate measures in place for preparedness in case an incursion of African buffalo into Zones 1 or 2 or into the officially recognised FMD-free zones would occur. These measures included the tracing and follow-up investigations related to potential contact with susceptible domestic animals.

Considering the recent FMD outbreaks of serotype O in the region, the Group highlighted that serotype O could be a potential threat, particularly taking into consideration that this serotype is not included in the vaccine used in vaccination zones of Botswana. Thus, the Group strongly encouraged continued surveillance to detect possible incursions of serotypes not regularly found in Botswana and for the laboratories to have the appropriate diagnostic capabilities to detect these serotypes. Botswana should also ensure the supply of appropriate vaccines as part of its contingency plan.

#### *x) Compliance with the questionnaire in Article 1.11.5.*

The Group agreed that the format of the dossier was generally compliant with the questionnaire in Article 1.11.5. of the *Terrestrial Code*. However certain parts of the dossier lacked clarity and the organisation was not fully in line with the format of the questionnaire. The Group underlined that Botswana should follow strictly the format of the questionnaire for any future submission of dossiers.

# Conclusion

Considering the information submitted in the dossier and Botswana's answers to the questions raised, the Group considered that the application was compliant with the requirements of Chapter 8.8. and the questionnaire in Article 1.11.5. of the *Terrestrial Code*. The Group therefore recommended that Botswana's official control programme for FMD be proposed for endorsement.

The Group would draw Botswana's attention to the following recommendations and to provide documented evidence on the progress made on them as part of the submission of its annual reconfirmation for the endorsed official control programme for FMD in November 2022:

- the risk of undisclosed infection in small ruminants should not be overlooked and studies on clustering of positive serological results should be considered to further investigate the potential role of small ruminants in the epidemiology of FMD in Botswana;
- NSP reactors found in surveys should be followed-up in a timely manner including collecting sera and probangs from the reactor animals and testing of sera from other in-contact animals in accordance with Article 8.8.42. Point 1 of the *Terrestrial Code*;

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- Botswana to clearly describe the plan and progress made with regard to the protection zones;
- Considering the recent FMD outbreaks of serotype O in the region, the Group would appreciate receiving information on surveillance activities aimed at detecting possible incursions of serotype O and contingency planning for appropriate vaccines supply, as well as evidence of laboratory diagnostic capabilities for serotypes other than SATs.

## b) Other application

The Group assessed a request from a Member for the endorsement of an official control programme for FMD. The Group concluded that the application did not meet the requirements of the *Terrestrial Code*. The dossier was referred back to the applicant Member.

# 6. Evaluation of the maintenance of the official recognition of FMD free status

#### a) Turkey

## Background

At its February 2021 meeting, the Scientific Commission requested the submission of further documented evidence regarding the movements of live animals from the FMD-infected zone into the FMD-free zone during the religious ceremony (Kurban Festival), following the assessment of Turkey's 2020 annual reconfirmation of the FMD-free zone where vaccination is practised. This is to ensure that Turkey complies fully with the relevant provisions of the *Terrestrial Code* (Articles 8.8.8. or 8.8.12.) or provides a level of protection that is equivalent.

After two rounds of exchanges with Turkey and assessment of information by the Group and the Scientific Commission between March and July 2021, Turkey was requested to submit the following to be assessed by the Group at this meeting:

- 1. The risk assessment in relation to the movement of ruminants from the FMD infected zone (Anatolia) to the FMD-free zone where vaccination is practised (Turkish Thrace) considering the distribution, consumption, as well as disposal of animal products and by-products.
- 2. The action plan to implement the recommendations made by the Scientific Commission.

The Group requested additional information and received clarifications from Turkey.

*i) Risk assessment in relation to the movements of ruminants from the infected zone to the FMD-free zone of Turkey* 

The Group noted that the procedures implemented by Turkey are intended to align with Article 8.8.8. rather than 8.8.12. although not fully compliant with either.

The Group was of the opinion that Article 8.8.8. for direct transfer of FMD susceptible animals from an infected zone for slaughter in a free zone is more appropriate to follow in this scenario. The Group agreed that Turkey complies with all requirements in Article 8.8.8. of the *Terrestrial Code* at the farms of origin. However, although the Group considered that there is a low probability of risk of infection at the farms of origin, it did not agree that the risk was negligible.

Furthermore, the Group pointed out that clinical inspections in a vaccinated population is not sufficient to determine absence of FMD virus transmission. The Group agreed that additional guarantees are required to make the risk at this stage negligible. These additional measures to demonstrate the absence of FMD virus transmission can be provided through targeted non-structural protein (NSP) and post vaccination monitoring surveys to demonstrate absence of FMD virus transmission and appropriate immunity levels in those areas where the animals are originating from the infected zone of Turkey.

#### *ii)* Action plan to implement the recommendations made by the Scientific Commission:

The Scientific Commission made recommendations regarding the surveillance around the farms of origin in the FMD infected zone and the ante- and post-mortem inspections of the animals, as well as the treatment and processing of meat and animal products at the slaughterhouse.

Turkey described the use of both structural protein (SP) and NSP serosurveillance results pointing to high levels of population immunity and low levels of undisclosed infection in the ruminant population of the FMD infected zone (Anatolia). Furthermore, it was also specified that the results will be evaluated for the whole group of candidate animals, and that all animals belonging to the group will be rejected in case of the detection of a single reactor.

Turkey stated that undertaking RT-PCR testing before import of susceptible animals from the FMD infected zone was not feasible. Nevertheless, Turkey described its plans to encourage NSP ELISA testing in candidate animals from the FMD infected zone before the official registration of farms from which animals would be sent to the FMD free zone for the Kurban festival. Even though this measure would not be compulsory, the Group welcomed this initiative, as it would help to ensure the exclusion of candidate establishments with NSP reactor animals before the quarantine of the candidate animals.

Although Turkey had reiterated that clinical surveillance in and around the farms in the FMD infected zone (Anatolia) selected for export to the FMD free zone is conducted, it did not provide any indication that NSP serosurveillance will be used to provide assurance on absence of undisclosed infection within the ten-kilometre radius surrounding areas. In this regard, the Group recommended that Turkey undertake NSP serosurveillance to demonstrate that FMD virus is not circulating within the ten-kilometre radius of the farms from which animals are exported to the FMD free zone.

Turkey described its risk mitigation measures in compliance with Articles 8.8.8. and 8.8.22., including ante- and post-mortem inspections for FMD, implemented at the markets of the FMD-free zone where vaccination is practised (Thrace), and the removal of viscera, head and feet from carcasses. In this regard, the Group pointed out that provisions in Article 8.8.8. also request extra guarantees in the meat processing. The animals should have been subjected to ante- and post-mortem inspection within 24 hours before and after slaughter with no evidence of FMD, and the meat derived from them treated in accordance with Article 8.8.22. (point 2) or Article 8.8.23. In addition, other products obtained from the animals and any products coming into contact with them should be treated in accordance with Articles 8.8.31. to 8.8.38. in order to destroy any FMD virus potentially present, particularly by removing the major lymphatic nodes and deboning and maturation.

The Group agreed that Turkey does not comply fully with the treatment of the meat as required in the *Terrestrial Code* under these circumstances. However Article 8.8.8. presupposes that the meat can be freely released in the country from the abattoir, which is not the case under the special circumstances of the Kurban festival. The meat is only provided to the customers to be cooked and the leftovers are responsibly disposed of.

#### Conclusion and next steps

As agreed in previous exchanges between Turkey and the OIE, the Group was informed that a two-step approach would be taken to seek further clarification on the measures reported by Turkey and to assess their proper implementation. This two-step includes a virtual interview between OIE experts and Turkish Veterinary Services before the end of 2021, followed by a deployment of an OIE mission prior to the next Kurban festival in 2022.

The Group formulated questions for Turkey to provide additional information before the virtual interview on the biosecurity measures implemented at the farms of origin in the FMD infected zone during quarantine prior to exporting animals to the FMD free zone. Additional information on the NSP serosurveillance to be

# Annex 5 (contd)

carried out in the ten-kilometre radius of the farms in the FMD infected zone from which the animals are exported to the FMD free zone, including NSP sampling design, survey procedure and timing of the survey in relation to the annual religious ceremony has also been asked.

# 7. Adoption of the report

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

.../Appendices

Appendix I

# VIRTUAL MEETING OF THE OIE *AD HOC* GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE STATUS AND ENDORSEMENT OF OFFICIAL CONTROL PROGRAMMES OF MEMBERS 18-20, 22, 25 and 27 October 2021

# **Terms of Reference**

# Purpose

The purpose of the *ad hoc* Group on the evaluation of foot and mouth disease (FMD) of Members (the Group) is to evaluate applications for official recognition of FMD free status and for endorsement of the FMD official control programme of Members.

# Background

In accordance with the <u>OIE procedure for official recognition of animal health status</u>, OIE Members can be officially recognised by the OIE as having a FMD status or an official FMD control programme endorsed by the OIE through the adoption of a resolution by the World Assembly of Delegates of the OIE (the Assembly) in May every year. A Member wishing to apply for the official recognition of its FMD free status or an official FMD control programme endorsed by the OIE should complete and submit the relevant questionnaire laid out in <u>Chapter 1.11</u>. of the OIE *Terrestrial Animal Health Code (Terrestrial Code*) and comply with all requirements specified in the *Terrestrial Code*. The OIE Scientific Commission for Animal Diseases (<u>Scientific Commission</u>) is responsible for undertaking, on behalf of the Assembly, the assessment of OIE Members' applications for their compliance with OIE standards. The assessment carried out by the Scientific Commission is based on the recommendations formulated by a relevant *ad hoc* Group. *Ad hoc* groups are convened under the authority of and report to the OIE Director General.

# Specific issues to be addressed

The Group will evaluate Members' applications in detail on their compliance with the requirements specified in the *Terrestrial Code* for infection with foot and mouth disease virus. Based on the evaluations, the Group will provide its conclusions and recommendations to the Scientific Commission.

# Prerequisites

The Group members should:

- Sign the OIE Undertaking on Confidentiality of information (if not done already);
- Complete the Declaration of Interest Form;
- Understand that the membership of the Group may be retained between its meetings to ensure continuity of the work.

# Actions to deliver

# Before the meeting

Upon reception of an application from a Member, the Status Department (SD) conducts a preliminary screening to check the conformity of the dossier (structure of the dossier in accordance with the SOP and with the questionnaire under Chapter <u>1.11</u>. of the *Terrestrial Code*, main sections of the questionnaire, regular notification to the OIE, payment of the fee, OIE Performance of Veterinary Services (PVS) report, etc.). If an information gap is identified, the SD requests additional information from the Member.

As the PVS reports are bound by the OIE rules on confidentiality of information, the SD and experts will consider for the evaluation the available PVS report(s) if not obsolete (PVS reports from more than five years ago) or confidential.

The SD will send the working documents to the Group, including the dossiers received from applicant Members, at least one month before the Group meeting (i.e., **17 September 2021**).

The experts can request support from the SD at any time.

The SD suggests the nomination of a Chair and Rapporteur for the Group's consideration.

# Annex 5 (contd)

The SD can suggest a preparatory meeting with the Chair, the Rapporteur or all experts to address specific points in advance, if needed

The experts are expected to:

- Be familiar with Chapters <u>1.11.</u> and <u>8.8.</u> of the *Terrestrial Code*;
- Evaluate and study in detail all dossiers provided by the OIE;
- Take into account any other information available in the public domain that is considered pertinent for the evaluation of the dossiers;
- Summarise the dossiers according to the *Terrestrial Code* requirements by completing the summary tables provided by the SD (the summary tables will be provided at a later stage along with the working documents for the meeting). Experts are expected to capture and summarise in each corresponding section of the summary table the main gaps as well as strengths identified during the assessment of the dossiers, using extracted texts or reference to pages/annexes from the application;
- Draft questions to the applicant Members whenever the analysis of the dossiers identifies incomplete or unclear information;
- Submit to the SD the completed summary tables for each application together with possible questions for the applicant Members at least 10 days before the teleconference and preferably by **8 October 2021**;

The SD will compile the summary tables and the questions to be forwarded to the applicant Members before the teleconference. All subsequent information and material provided by a Member will be forwarded to the Group.

#### During the meeting

- Agree on the appointment of the Chair and Rapporteur of the meeting (the Chair will lead the discussion and the Rapporteur will ensure that the report reflects the discussion and captures the detailed assessment of the dossiers);
- Mention any potential conflict of interest and, if relevant, withdraw him/herself from the discussion;
- Contribute to the discussions;
- Provide a detailed report in order to recommend, to the Scientific Commission, the Member(s) and zone(s) to be recognised (or not) as free from FMD and the official control programme of Member(s) to be endorsed by the OIE and to indicate any information gaps or specific areas that should be addressed in the future by the applicant Members.

If during the teleconference the Group decides that additional information should be requested from an applicant Member before an informed conclusion can be drawn, the SD can request it and forward the additional information to the Group at a later date. The Chair is responsible for coordinating the finalisation of the assessment and for ensuring that the views of all members of the Group are taken into consideration.

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 if needed.

#### After the meeting

The SD will circulate the draft report after the teleconference is over. Experts are expected to contribute to the finalisation of the report within approximately one week.

The SD will circulate the final version of the report to the Group once endorsed by the Scientific Commission and is published online.

#### Deliverables

A detailed report to recommend to the Scientific Commission whether an applicant Member(s) should be (or not) recognised with an official FMD free status or an official FMD control programme endorsed by the OIE. The report should indicate any information gaps or specific areas that should be addressed in the future by the Members.

#### Reporting / timeline

The OIE will circulate the draft report no more than seven days after the teleconference (no later than 4 November 2021) and the Group will finalise its report within ten days (indicative deadline: 15 November 2021).

## Appendix II

# VIRTUAL MEETING OF THE OIE *AD HOC* GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE STATUS AND ENDORSEMENT OF OFFICIAL CONTROL PROGRAMMES OF MEMBERS 18-20, 22, 25 and 27 October 2021

# Agenda

- 1. Opening
- 2. Adoption of the agenda and appointment of chairperson and rapporteur
- 3. Evaluation of a request for the official recognition of an FMD free zone where vaccination is not practised
- 4. Evaluation of requests for the official recognition of FMD free zones where vaccination is practised
  - a. Russia Zone III
  - b. Other application
- 5. Evaluation of requests for the endorsement of official control programme for FMD
  - a. Botswana
  - b. Other application
- 6. Evaluation of the maintenance of the official recognition of FMD free status
  - a. Turkey
- 7. Adoption of report

Appendix III

# OIE AD HOC GROUP ON THE EVALUATION OF FOOT AND MOUTH DISEASE STATUS AND ENDORSEMENT OF OFFICIAL CONTROL PROGRAMMES OF MEMBERS

# 18-20, 22, 25 and 27 October 2021

# List of participants

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Annex 6

Original: English October 2021

# REPORT OF THE VIRTUAL MEETING OF THE OIE *AD HOC* GROUP ON THE EVALUATION OF CLASSICAL SWINE FEVER STATUS OF MEMBERS 26 and 28 October 2021

A virtual meeting of the OIE *ad hoc* Group on the Evaluation of Classical swine fever (CSF) Status of Members (hereafter the Group) was held from on 26 and 28 October 2021.

# 1. Opening

Dr Montserrat Arroyo, Deputy Director General for International Standards and Sciences of the OIE, welcomed the Group. She thanked the experts for their availability and contribution to the work of the OIE and extended her appreciation to their international organisations, institutes and national governments for allowing their participation in this meeting. Dr Arroyo acknowledged the amount of work before, during and that would be done after the *ad hoc* Group meeting in reviewing the dossiers and writing the report. Dr Arroyo thanked the Group for its commitment and support to the OIE in fulfilling the mandates given by Members.

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

Dr Arroyo highlighted the sensitivity and confidentiality of the dossiers received for official recognition and thanked the experts for having signed the updated forms for undertaking of confidentiality. She also mentioned that if any members of the Group had any conflict of interest in the evaluation of a dossier, the expert(s) should withdraw from the discussions and decision making of the particular application.

The experts and the OIE welcomed Drs Katsuhiko Fukai, Žilvinas Ilevičius and Weerapong Thanapongtharm as new members of the Group.

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

The Group was chaired by Dr Mario Eduardo Peña Gonzalez. Dr Mary-Louise Penrith acted as rapporteur, with the support of the OIE Secretariat. The Group endorsed the proposed agenda.

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

# 3. Evaluation of applications from Members for official recognition of a CSF free country status

The Group assessed a request from a Member for the official recognition of a CSF free country status. The Group concluded that the application did not meet the requirements of the *Terrestrial Code*. The dossier was referred back to the applicant Member.

## 4. Other matters

The Group noted that there is a lack of scientific evidence currently available to indicate that peccaries are playing a significant role in the epidemiology of CSF. Therefore, the Group recommended the OIE to review and amend the Technical Disease Card on CSF accordingly; the Group proposed text and provided the scientific references.

# 5. Adoption of report

The *ad hoc* Group reviewed and amended the draft report. The Group agreed that the report would be subject to a short period of circulation to the Group for comments and adoption. Upon circulation, the Group agreed that the report captured the discussions.

.../Appendices

Appendix I

# VIRTUAL MEETING OF THE *AD HOC* GROUP ON THE EVALUATION OF CLASSICAL SWINE FEVER STATUS OF MEMBERS 26 and 28 October 2021

### **TERMS OF REFERENCE**

### Purpose

The purpose of the *ad hoc* Group on the evaluation of classical swine fever (CSF) status of Members (the Group) is to evaluate applications for official recognition of CSF status of Members.

### Background

In accordance with the <u>OIE procedure for official recognition of animal health status</u>, OIE Members can be officially recognised by the OIE as having a CSF free status through the adoption of a resolution by the World Assembly of Delegates of the OIE (the Assembly) in May every year. A Member wishing to apply for the official recognition of its CSF free status should complete and submit the <u>questionnaire</u> laid out in Chapter 1.9. of the OIE *Terrestrial Animal Health Code (Terrestrial Code)* and comply with all requirements specified in the *Terrestrial Code*. The OIE Scientific Commission for Animal Diseases (<u>Scientific Commission</u>) is responsible for undertaking, on behalf of the Assembly, the assessment of OIE Members' applications for their compliance with OIE standards. The assessment carried out by the Scientific Commission is based on the recommendations formulated by a relevant *ad hoc* Group. *Ad hoc* groups are convened under the authority of and report to the OIE Director General.

### Specific issues to be addressed

The Group will evaluate Members' applications in detail on their compliance with the requirements specified in the *Terrestrial Code* for CSF. Based on the evaluations, the Group will provide its conclusions and recommendations to the Scientific Commission.

### Prerequisites

The Group members should:

- Sign the OIE Undertaking on Confidentiality of information (if not done already);
- Complete the Declaration of Interest Form;
- Understand that the membership of the Group may be retained between its meetings to ensure continuity of the work.

### Actions to deliver

#### Before the meeting

Upon reception of an application from a Member, the Status Department (SD) conducts a preliminary screening to check the conformity of the dossier (structure of the dossier in accordance with the SOP and with the questionnaire under Chapter 1.9. of the *Terrestrial Code*, main sections of the questionnaire, regular notification to the OIE, payment of the fee, OIE Performance of Veterinary Services (PVS) report, etc.). If an information gap is identified, the SD requests additional information from the Member.

As the PVS reports are bound by the OIE rules on confidentiality of information, the SD and experts will consider for the evaluation the available PVS report(s) if not obsolete (PVS reports from more than five years ago) or confidential.

The SD will send the working documents to the Group, including the dossiers received from applicant Members, at least one month before the Group meeting (i.e., **24 September 2021**).

The experts can request support from the SD at any time.

#### Annex 6 (contd)

The SD suggests the nomination of a Chair and Rapporteur for the Group's consideration.

The SD can suggest a preparatory meeting with the Chair, the Rapporteur or all experts to address specific points in advance, if needed.

The experts are expected to:

- Be familiar with Chapters <u>1.9.</u> and <u>15.2.</u> of the *Terrestrial Code*;
- Evaluate and study in detail all dossiers provided by the OIE;
- Take into account any other information available in the public domain that is considered pertinent for the evaluation of the dossiers;
- Summarise the dossiers according to the *Terrestrial Code* requirements by completing the summary tables provided by the SD (the summary tables will be provided at a later stage along with the working documents for the meeting). Experts are expected to capture and summarise in each corresponding section of the summary table the main gaps as well as strengths identified during the assessment of the dossiers, using extracted texts or reference to pages/annexes from the application;
- Draft questions to the applicant Member whenever the analysis of the dossiers identifies incomplete or unclear information;
- Submit to the SD the completed summary tables for each application together with possible questions for the applicant Members at least 10 days before the teleconference and preferably by **15 October 2021**;

The SD will compile the summary tables and the questions to be forwarded to the applicant Members before the teleconference. All subsequent information and material provided by a Member will be forwarded to the Group.

#### During the meeting

- Agree on the appointment of the Chair and Rapporteur of the meeting (the Chair will lead the discussion and the Rapporteur will ensure that the report reflects the discussion and captures the detailed assessment of the dossiers);
- Mention any potential conflict of interest and, if relevant, withdraw him/herself from the discussion;
- Contribute to the discussions;
- Provide a detailed report in order to recommend, to the Scientific Commission, the Member(s) and/or zone(s) to be recognised (or not) as free from CSF and to indicate any information gaps or specific areas that should be addressed in the future by the applicant Members.

If during the teleconference the Group decides that additional information should be requested from an applicant Member before an informed conclusion can be drawn, the SD can request it and forward the additional information to the Group at a later date. The Chair is responsible for coordinating the finalisation of the assessment and for ensuring that the views of all members of the Group are taken into consideration.

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 if needed.

#### After the meeting

The SD will circulate the draft report after the teleconference is over. Experts are expected to contribute to the finalisation of the report within approximately one week.

The SD will circulate the final version of the report to the Group once endorsed by the Scientific Commission and is published online.

### Deliverables

A detailed report to recommend to the Scientific Commission whether an applicant Member(s) should be (or not) recognised with an official CSF free status. The report should indicate any information gaps or specific areas that should be addressed in the future by the Members.

### **Reporting / timeline**

The OIE will circulate the draft report no more than seven days after the teleconference (no later than 4 November 2021) and the Group will finalise its report within ten days (indicative deadline: 15 November 2021).

Appendix II

# VIRTUAL MEETING OF THE *AD HOC* GROUP ON THE EVALUATION OF CLASSICAL SWINE FEVER STATUS OF MEMBERS 26 and 28 October 2021

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#### Agenda

- 1. Opening
- 2. Adoption of the agenda and appointment of Chairperson and Rapporteur
- 3. Evaluation of applications from Members for official recognition of CSF free country status
- 4. Other matters
- 5. Adoption of the report

## AD HOC GROUP ON THE EVALUATION **OF CLASSICAL SWINE FEVER STATUS OF MEMBERS** 26 and 28 October 2021

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Annex 7

Original: English November 2021

# REPORT OF THE VIRTUAL MEETING OF THE OIE *AD HOC* GROUP ON THE EVALUATION OF BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS OF MEMBERS

#### 16 to 19 November 2021

A virtual meeting of the OIE *ad hoc* Group on the evaluation of bovine spongiform encephalopathy (BSE) risk status of Members (hereafter the Group) was held from 16 to 19 November 2021.

#### 1. Opening

Dr Montserrat Arroyo, Deputy Director General for International Standards and Science of the OIE, welcomed the Group. She thanked the experts for their availability and contribution to the work of the OIE and extended her appreciation to their institutes and national governments for allowing their participation in this meeting. Dr Arroyo acknowledged the amount of work achieved before, during and after the meeting in reviewing the dossiers and writing the report. Dr Arroyo thanked the Group for its commitment and support to the OIE in fulfilling the mandates given by Members.

Dr Arroyo highlighted the importance of the quality of the report to be scrutinised by Members before adopting the proposed list of countries/zones with a risk status for BSE. She also encouraged the Group to continue providing detailed feedback to Members with a negative outcome to support them in identifying the main gaps and points for improvement to achieve their desired BSE risk status, as well as providing informative recommendations to those Members with positive outcomes for further improvement in maintenance of their BSE risk status.

The Group and the OIE welcomed Dr Fabien Schneegans as a new member of the Group.

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

Dr Alicia Cloete was appointed Chair and Dr Mark Stevenson acted as rapporteur with the support of the OIE Secretariat. The Group endorsed the proposed agenda.

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

# 3. Evaluation of an application from a Member for the official recognition of its negligible BSE risk status

#### 3.1 France

In accordance with the established procedures, the participating expert working for the European Commission expressed a possible conflict of interest and withdrew from all discussions of the Group on France's dossier.

France was recognised as having a controlled BSE risk status in May 2008 and was later recognised as having a negligible BSE risk status in May 2015. After an indigenous case of classical BSE in a five-year-old bovine was reported to the OIE in March 2016, a controlled BSE risk status was reinstated.

In September 2021, France submitted a dossier seeking its recognition as a country presenting a negligible BSE risk status.

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

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

• Risk assessment for entry of the BSE agent

Regarding importations of live cattle, the Group noted that in the past eight years all cattle were imported from countries with a controlled or negligible BSE risk status under the European Union (EU) standards (EC 999/2001) that comply with Articles 11.4.7. and 11.4.8. of the OIE *Terrestrial Animal Health Code (Terrestrial Code)*.

The Group noted that meat-and-bone meal (MBM) in France are categorised under three categories: C1 which includes the carcasses of ruminants and specified risk materials (SRMs), C2 which includes animal by-products not in C1 or C3, and C3 which includes slaughterhouse products which are fit but not intended for human consumption.

Regarding importations of MBM, greaves and feed containing either, the Group acknowledged that C1 or C2 materials intended for use in feed for terrestrial farmed animals have not been imported since 2000, except for negligible amounts of C2 for the fertilizer sector, and that C3 materials have been imported for use limited to pet food and fertilizers.

Overall, the Group concluded that the risk that the BSE agent could have entered France during the interval covered by the assessment was considered to be negligible.

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

The Group noted that France has had a legislation banning the use of animal meals in cattle feed since 1990 which was extended to cover all ruminants in 1994 and all terrestrial farmed animals in 2000.

The Group took note that the definition, collection and disposal of SRMs followed the EU standards (EC 999/2001) and are compliant with the provisions of the *Terrestrial Code*. The Group noted that C1 materials are disposed of by incineration or co-incineration or used to produced materials that do not enter the food chain. Similar methods are applied for C2 animal by products with the difference that these materials can be recovered for technical use or to produce fertilizers. C3 materials can be processed into animal food applying restrictive conditions when cattle feed is involved.

The Group regretted that France did not provide a clear description of the rendering industry although the Group acknowledged the information provided on the relevant legislation that governs rendering and the management of animal by-products. Considering the methods described above to disposed C1 materials, the Group considered that any potential BSE infectivity is destroyed and cannot enter the animal feed chain. The Group took note that the inspection frequency of rendering plants is based on risk analysis that assigns a risk to each plant. This ensures that each plant is inspected at least once every four years. The Group took note that no infractions were reported during the interval covered.

Regarding the feed industry, the Group took note that most feed mills are for mixed species. The Group could not determine whether there are separated lines for feed mills producing feed for ruminants or non-ruminants; however, the Group took note that processing plants that manufacture petfood are exclusively dedicated to this scope. The Group took note that the methods used in France to reduce the BSE infectivity in MBM are in accordance with Article 11.4.19 of the *Terrestrial Code*. The Group took note that facilities that produce feed for farmed animals, including aquaculture animals, are regularly supervised by official inspectors primarily

to check for the absence of MBM and greaves in ruminant feed and more broadly the use of animal proteins in feeding for farm animals. The Group noted that the frequency of inspection of feed mills follows the same approach as for rendering plants and that no infractions were reported during the interval covered.

Also, the Group took note that France inspects the livestock farms regarding implementation of EU rules to prevent TSE risk in cattle and this inspection includes the sampling of raw materials or feed.

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

#### b. Surveillance according to Articles 11.4.20. - 11.4.22.

The Group noted that the surveillance undertaken over a seven-year period from 2014 to 2020 exceeded the minimum requirements of type B surveillance in accordance with Article 11.4.22. on BSE surveillance of the *Terrestrial Code*. Based on the information provided in the dossier, 965,521 surveillance points were collected from 2014 to 2020, exceeding the minimum requirement of 150,000 for an adult cattle population (i.e., over two years of age) of over 1,000,000 animals.

The Group acknowledged that the age of cattle was determined based on birth records and that in the case of absence of birth records, the body size of the animal and dentition were used. The Group considered that France's definitions of surveillance subpopulations were in accordance with Article 11.4.21 of the *Terrestrial Code*.

The Group took note that France's surveillance programme for BSE targeted all four surveillance subpopulations every year.

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

Awareness programme

The Group noted that an awareness program on BSE present since 1990 has been continuously applied. While France reported that the awareness program covered all the country, the Group was unsure whether this was the case as no supportive information was available.

The Group took note that the veterinarians and relevant officials, cattle farmers, slaughterhouse operators, and personnel in the animal by-product sector were covered by their awareness program although it mainly targeted official veterinarians. The Group was of the opinion that, considering the BSE situation in Europe, France should maintain awareness at all levels.

The Group acknowledged that France has measures in place for the management of BSE cases should they arise in the country.

Compulsory notification and investigation

The Group noted that notification for BSE has been mandatory since 1990 under the relevant Regulation. Upon requesting and receiving additional information, the Group was informed that measures to stimulate notification, penalties for failure to notify BSE suspect cases, and a compensation policy for farmers are in place. The Group concluded that the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

Laboratory examination

The Group noted that BSE diagnosis is conducted in France. The French National Reference Laboratory for BSE in France is the French Agency for Food, Environmental and Occupational

Health & Safety (ANSES) laboratory in Lyon. The Group took note that France has a number of licensed laboratories with French Accreditation Committee accreditation for the diagnosis of TSEs which use mainly ELISA tests. In the case of positive or inconclusive results, the confirmatory testing is performed in the ANSES laboratory by western blot. The Group was also informed that the European Union Reference Laboratory might be consulted for its opinion or further testing when needed.

The Group concluded that the laboratory diagnosis for BSE conducted in France was compliant with Chapter 3.4.5 of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*).

#### d. BSE history in the country

The Group noted that the first BSE case was detected in France in 1991 with the last case occurring in 2016 in an animal born in 2011. Up to the evaluation of this report, there has been 1,042 cases reported (994 of classical BSE, 20 cases of atypical L-type BSE, and 28 cases of atypical H-type BSE).

At the time of writing this report, the youngest indigenous case of classical BSE was born on 8 April 2011, meaning that all indigenous cases of classical BSE would have been born more than 11 years before the World Assembly in May 2022.

#### e. Compliance with the questionnaire in Chapter 1.8.

The Group agreed that the dossier submitted was compliant with the format of the questionnaire of Chapter 1.8. of the *Terrestrial Code*.

#### f. Conclusion

Recommended status

Considering the information submitted in the dossier and France's answers to follow-up questions raised, the Group concluded that the application was compliant with both the requirements of Article 11.4.3. and the BSE questionnaire in Chapter 1.8. of the *Terrestrial Code*. The Group therefore recommended that France be recognised as 'negligible BSE risk' country.

# 4. Evaluation of an application from a Member for the official recognition of its controlled BSE risk status

#### 4.1 Russia

In September 2021, Russia submitted a dossier seeking its recognition as a country presenting a controlled BSE risk status. The Group requested additional information and received clarifications from Russia. Points specifically discussed by the Group are summarised below:

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

Risk assessment for entry of the BSE agent

Regarding importation of MBM, greaves or feed ingredients containing either, the Group noted that Russia imported MBM derived from cattle between 2013 and 2017. Based on the information provided in the dossier, the Group took note that a significant proportion (over 90%) of the overall volume of importations between 2013 and 2017 originated from countries with an undetermined BSE risk status. Nevertheless, the Group acknowledged that, since 2019, Russia has officially banned the imports of MBM and greaves from countries with an undetermined BSE risk status.

The Group noted that the majority (96%) of the imports of live cattle into Russia within the past seven years were from countries with a negligible or controlled BSE risk status, while 4% of

the cattle imported during that period originated from countries with an undetermined BSE risk status. From the dossier, the Group was informed that live cattle imported in 2018 and 2019 from countries with an undetermined BSE risk status were immediately slaughtered and their SRM were removed and disposed of. The Group acknowledged that, since 2020, no live cattle from controlled or undetermined risk countries have been imported.

Regarding products of ruminant origin imported within the past seven years, the Group noted that bovine offal including heart, liver, kidneys, tongues, rumens and tendons; and meat including deboned chilled, frozen and bone-in meat were imported. Based on the data available in the dossier, the Group estimated that about 5% of bovine offal and about 30% of bovine meat was imported from countries with and undetermined BSE risk status.

The Group acknowledged the information provided on the veterinary import requirements for cattle and cattle products; nevertheless, the Group regretted that the detailed requirements providing evidence of compliance with the relevant articles of the *Terrestrial Code* were not available nor provided with the additional information requested (i.e. the requirements of the *Terrestrial Code* were broadly referred to in the import model certificates of Russia, but these were not specified in detail as part of the import requirements).

Overall, regarding the entry assessment, the Group concluded that the risk that the BSE risk agent could have entered Russia could be considered negligible since 2019.

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

The Group acknowledged that the definition of SRM was consistent with Article 11.4.14 of the Terrestrial Code. The Group asked and received additional information regarding the fate and disposal of fallen stock and SRM. The Group could not determine the scope of the relevant regulations provided. Nevertheless, the Group was of the opinion that Russia has prohibited since 2019, by way of the relevant regulation, the rendering of ruminant carcasses from fallen ruminants and acknowledged that these carcasses were incinerated or buried. In addition, the Group took note, from the information provided by the Russian authorities that SRMs have been categorised as "highly dangerous hazards" and these are incinerated; despite this only happening since 2020 when the relevant regulation was issued and put in place in Russia, it was not explicitly clear in the relevant legislation. The Group agreed, based on the information in the dossier and the additional information, that SRMs from healthy animals sent to slaughter have been excluded from further processing into MBM intended for feed since 2019 and probably earlier than 2019 for imported animals. The Group was uncertain about the situation for rendering ruminant material from fallen stock and the potential for SRM to enter the rendering stream prior to 2019. Although the Group acknowledged that Russia interpreted SRM as "highly hazardous materials" and handled them as such; the Group recommended that SRM should be explicitly listed in paragraph 4 of the Ministry of Agriculture Order No. 626 of 26 October 2020.

The Group requested and received additional information regarding the rendering industry in Russia. The Group took note that while the parameters for rendering materials in the countries of the Eurasian Economic Union are 133 degrees Celsius for at least 20 minutes at a pressure of 3 bar, how these measures were monitored, verified and enforced by the competent authorities were not provided. The Group noted that the additional information provided was consistent with Point 1 of Article 11.4.19 of the *Terrestrial Code* on reduction of particle size of raw materials for the reduction of BSE infectivity in MBM; however, the Group regretted that Russia did not provide supportive evidence of the official monitoring and enforcement of the rendering parameters. The Group also noted that a number of rendering facilities process ruminant raw material to produce ruminant MBM, and non-ruminant raw material to produce non-ruminant MBM intended for feed purposes. However, the Group failed to receive detailed information on

the specific measures implemented in these 'mixed' rendering plants to prevent cross contamination between the ruminant and non-ruminant material or MBM.

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Regarding the inspections in rendering plants and feed mills, the Group acknowledged the improvements made since 2019 regarding the number of inspections. Despite the questions raised by the Group on the methodology for inspection of rendering plants and feed mills, the Group did not receive information about how these are conducted. While the Group acknowledged that Russia's methodological guidance for *BSE risk control anti-epidemic measures and surveillance* provides a general overview, the Group highlighted the fact that a document clearly articulating the detail of inspections of rendering plants or feed mills, to ensure that BSE-related risk points are sufficiently assessed was not provided.

The Group acknowledged that the ruminant-to-ruminant feed ban has been in place since 1990. However, the Group was unclear about the nature of the feed ban regarding the use of MBM from various species in non-ruminant feed. In the additional information provided, Russia informed that dedicated feed mills may use ruminant MBM for pet food, pig and poultry feed. These ruminant MBM are sent directly to these establishments under the control of the State Veterinary Service through the issuance of Veterinary Accompanying Documents (VADs). After feed production, the risk of cross contamination of finished feed products is deemed to be insignificant, as their traffic flows do not overlap with ruminant feed during production, transportation and storage. Russia clarified that large livestock establishments are dedicated to a specific animal species and therefore the risk of cross-contamination in the establishments is unlikely. The Group acknowledged the legislations provided by Russia. However, the Group did not receive sufficient evidence demonstrating how the various BSE risk mitigation measures are implemented, enforced and monitored at rendering plants, feed mills and at the establishment level.

Overall, regarding the exposure assessment, the Group concluded that the risk of recycling and amplification of the BSE agent, if it was present in Russia's cattle population, can be considered to have been negligible from 2019 onwards provided that the legislated ordered control measures have been and continue to be correctly and consistently implemented.

#### b. Surveillance according to Articles 11.4.20. - 11.4.22.

The Group concluded that the level of surveillance over the seven-year period from 2014 to 2020 exceeded the minimum requirements of Type A surveillance in accordance with Article 11.4.22. of the *Terrestrial Code* on BSE surveillance. Based on the information provided in the dossier, 369,269.25 surveillance points were accumulated, compared to a minimal requirement of 300,000 for an adult cattle population over two years of age of over 1 million.

The Group noted that Russia's surveillance programme for BSE targeted all surveillance subpopulations every year and that samples were sufficiently representative of the distribution of the total cattle population in the country. The Group acknowledged that Russia stated that all cattle are individually identified (either by tags, brands, and/or tattoos) and that the age of animals is determined based on the individual number. The Group noted the information on the determination of age by dentition for imported slaughter animals in the Manual for SRM removal. Regarding aging of Russian cattle where they fail to be individually identified by their tags, brands or tattoos, Russia clarified that there is a process to replace lost tags and also to use dentition.

The Group took note that all clinical suspects had been tested and BSE was ruled out. The Group noted that up until 2017, only "nervous pathology" was listed as clinical signs for clinical suspects investigated; however, since 2018 the clinical signs listed for clinical suspects have been more specific (i.e., fearfulness, not recognizing barriers, hypersensitivity, and mobility issues) which is more in line with Article 11.4.21. of the *Terrestrial Code* and subsequent increase in the surveillance of suspected cases. The Group commended Russia for the improvements made in this regard.

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

Awareness programme

The Group acknowledged that an awareness programme for BSE had been present since 1999 targeting mainly official veterinarians. Since 2000, seminars and advanced training courses on BSE had been continued. In addition, online training on BSE epidemiology, diagnosis, surveillance, and prevention have been organised annually since 2018. The Group took note that 22 courses have been conducted since 2014 on a variety of topics related to BSE. Nevertheless, the Group was unsure whether the courses were distributed uniformly across the country. In addition, the Group noted that private veterinarians could also participate on the trainings on paid basis, but regretted that no figures were provided on their participation. The Group was of the opinion that private veterinarians play an important role in the control of BSE, and should have free access to the training courses.

The Group took note that Russia has a contingency plan for the control and eradication of BSE at the Federal level approved in May 2021. At the Regional level, the Group was informed that every Veterinary Department of Russia had developed a BSE contingency plan and an example was provided. Nevertheless, the Group noted that the contingency plan provided appears to have been in place since June 2019. It was unclear to the Group whether Russia had a contingency plan approved by the relevant Veterinary Authority prior to 2019.

Compulsory notification and investigation

The Group noted that BSE had been declared a notifiable disease since 1999. The relevant ordinance stipulates that the veterinary specialists working in the regions of Russia shall report animals with BSE clinical signs. The Group was informed that methodological guidelines for the identification of BSE clinical signs are available. The Group took note that penalties for failure to notify BSE suspect cases and a compensation policy are in place. Nevertheless, the Group regretted that Russia did not provide more detailed information on the level of the compensation and penalties imposed for not reporting suspect cases.

Overall, the Group concluded that, on face value, the system for compulsory notification and investigation met the requirements of the *Terrestrial Code*.

Laboratory examination

Regarding BSE diagnosis, the Group noted that BSE diagnosis is carried out in the Russian Reference Laboratory for Rabies and BSE of the Federal Centre for Animal Health (FGBI "ARRIAH"). The Group was informed that this laboratory has been ISO accredited (GOST ISO/IEC 17025-2009) since 2017 and participated in an international inter-laboratory comparison test in the same year. There was no information on participation in inter-laboratory comparison tests for BSE after 2017.

The Group was informed that screening has been conducted using an ELISA rapid test and that positive tests are sent to the OIE Reference Laboratory for BSE in Italy (Istituto Zooprofilattico Sperimentale del Piemonte Liguria e Valle d'Aosta). The Group noted that the TeSeE test-kits (an ELISA test, Bio-Rad) has been used before 2014, and that since 2014 the HerdCheck BSE-Scrapie Ag Test (an ELISA test, IDEXX Laboratories Inc) has been used for surveillance.

The Group concluded that the laboratory examination for BSE carried out in Russia was compliant with Chapter 3.4.5 of the *Terrestrial Manual*.

The Group also recommended that the FGBI "ARRIAH" participate in international interlaboratory comparison tests on a regular basis.

#### d. BSE history in the country

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

#### e. Compliance with the questionnaire in Chapter 1.8.

The Group agreed that the dossier submitted was compliant with the format of the questionnaire of Chapter 1.8. of the *Terrestrial Code*. The Group acknowledged and commended Russia for their effort made to demonstrate improvements in several critical areas since 2019 and encouraged Russia to continue working on them. Nevertheless, the Group noted that they had difficulties evaluating the application due to a lack of clear, detailed information in the dossier and the additional information provided. In addition, the Group pointed out that the submitted dossier and the additional information provided by Russia relied extensively on references to legislative acts and regulations without clear descriptions of the actions carried out to implement them. This led to significant challenges to evaluate this application despite multiple rounds of questions.

#### f. Conclusion

After multiple rounds of questions and lengthy discussions, a consensus was reached by the Group that Russia had addressed the questions raised, highlighting that evidence of enforcement and monitoring of activities was generally lacking, which made it difficult to conclude how legislation, decrees, and orders are implemented. Therefore, and in order to ensure the appropriate implementation of these activities, the Group recommended that future submissions for annual reconfirmation of Russia's controlled BSE risk status should be comprehensively reviewed by the Scientific Commission for Animal Diseases (Scientific Commission); see section 'Recommended status'.

Recommended status

Considering the information submitted in the dossier and the additional information provided by Russia to the questions raised, the Group concluded that the application was compliant with the requirements of Chapter 11.4. of the *Terrestrial Code* and therefore recommended that Russia be recognised as having fulfilled the requirements for a 'controlled BSE risk country'.

However, the Group advised that Russia should (also detailed in the relevant sections above):

- Provide supportive evidence of the monitoring of the effective implementation of the BSE-specific technical parameters at rendering plants.
- Provide supportive information with regard to the appropriate level of control, audit and inspections conducted by official veterinarians at rendering plants and feedmills. Provide official standard operating procedures (SOP)/manual/guideline in which the procedures for inspection in both rendering plants and feedmills are clearly detailed and highlight those procedures that are applicable to BSE control.
- Provide supportive evidence of the implementation and monitoring mitigation measures for preventing cross-contamination in rendering plants that process material from ruminant and non-ruminant species.
- Participate in international inter-laboratory comparison tests on a regular basis.

# 5. Proposal of criteria in determining the starting date when the risk of the BSE agents being recycled within the cattle population has been demonstrated to be negligible

The Group noted that the Point 4c. in Article 1.8.5 of the draft Chapter 1.8. of the *Terrestrial Code* clearly asks Members to indicate the date from which it can be considered that the risk of BSE agents recycling within the cattle population can be considered negligible (the 'starting date'). Therefore, the Group was of the opinion that for Members or zones recognised under the new standards (once adopted), this starting date would be indicated in the relevant OIE reports and used by Members during bi-lateral negotiations. On the other hand, the Group acknowledged that the starting date would not be necessary captured in the relevant OIE reports for Members already recognised as presenting a BSE risk status.

#### AHG on BSE risk status evaluation of Members/November 2021

The Group acknowledged the recommendation of the Scientific Commission to the OIE to publish the date of official recognition of BSE risk status on the OIE website (refer to the September 2021 meeting report of the Scientific Commission for more information). The Group concurred that the starting date for i) Members or zones with a negligible BSE risk status would be at least eight years prior to the date of recognition. For Members or zones that had been recognised as presenting a negligible BSE risk that had their negligible BSE risk status suspended, reinstated as presenting a controlled BSE risk, and eventually recognised as presenting a negligible BSE risk, the Group recommended that the starting date would be eight years prior to the date when the Member or zone was first recognised as presenting a negligible BSE risk, subject to confirmation in and acceptance of an epidemiological report submitted to the OIE.

The Group acknowledged that some Members or zones already recognised either as presenting a negligible or a controlled BSE risk could demonstrate that the starting date could be different to what was proposed above. Nevertheless, the Group was not in favour to develop a simplified criteria to determine the starting date because it considered that a detailed objective evaluation was needed. Therefore, the Group recommended the OIE to invite these Members to submit the necessary evidence to the OIE and to be evaluated by experts, should they wish to pursue evaluation by the OIE. The outcome of these evaluations including the starting date for these Members would be captured in the relevant reports. While the Group acknowledged that the draft Chapter 1.8. of the *Terrestrial Code* contains the necessary guidance for these Members to provide the evidence to determine the starting date, the Group was of the opinion that submission of a complete dossier was unnecessary due to the amount of information to be collected by Members. The Group acknowledged that the starting date could be derived based on the information of the exposure assessment alone; nevertheless, some members of the Group considered that few elements of the entry assessment and consequence assessment could also provide key information to complement the evaluation. In light of this, the Group recommended that the OIE should ask Members to refer to Article 1.8.5 of the draft Chapter 1.8. of the *Terrestrial Code* (once adopted) to use it as a baseline to include the relevant information that applies to their own situation.

#### 6. Adoption of report

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

.../Appendices

Appendix I

# VIRTUAL MEETING OF THE OIE *AD HOC* GROUP ON THE EVALUATION OF BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS OF MEMBERS 16 to 19 November 2021

#### Terms of Reference

#### Purpose

The purpose of the *ad hoc* Group on the evaluation of bovine spongiform encephalopathy (BSE) risk status of Members (the Group) is to evaluate applications for official recognition of BSE risk status of Members, and to propose the criteria to be used by Members having an official BSE risk status by the OIE for determining the starting date when the risk of the BSE agents being recycled within the cattle population has been demonstrated to be negligible.

#### Background

In accordance with the <u>OIE procedure for official recognition of animal health status</u>, OIE Members can be officially recognised by the OIE as having a negligible or controlled BSE risk status by the OIE through the adoption of a resolution by the World Assembly of Delegates of the OIE (the Assembly) in May every year. A Member wishing to apply for the official recognition of its BSE risk status by the OIE should complete and submit the relevant questionnaire laid out in <u>Chapter 1.8</u> of the OIE *Terrestrial Animal Health Code (Terrestrial Code*) and comply with all requirements specified in the *Terrestrial Code*. The OIE Scientific Commission for Animal Diseases (<u>Scientific Commission</u>) is responsible for undertaking, on behalf of the Assembly, the assessment of OIE Members' applications for their compliance with OIE standards. The assessment carried out by the Scientific Commission is based on the recommendations formulated by a relevant *ad hoc* Group. *Ad hoc* groups are convened under the authority of and report to the OIE Director General.

In February 2018, the Terrestrial Animal Health Standards Commission (Code Commission) and the Scientific Commission agreed on an in-depth review of Chapter 11.4. Bovine Spongiform Encephalopathy (BSE). Since then, five *ad hoc* Groups have been convened to complete the revision of BSE standards and the impact that the revised provisions might have on currently officially recognised Members. The revised provisions recommend Members to trade certain commodities based on the risk of BSE agents being recycled in the cattle population. That is, the risk of certain commodities are different if they originate from animals born before the date when the risk of the BSE agents being recycled in the cattle population has been demonstrated to be negligible compared to those originating from animals born after that date.

The BSE *ad hoc* Group, convened in June 2021, proposed an approach to determine this starting date for Members having a negligible BSE risk status; however, they could not agree on a proposal for Members having a controlled BSE risk status. The Scientific Commission, at its September 2021 meeting, agreed that it would be up to the Member to demonstrate this starting date, if beyond the years covered by the revised BSE standard, in trade negotiations between Members. In order to support the Members in their bilateral discussions, the Scientific Commission recommended that the BSE *ad hoc* Group develop criteria to guide Members in determining the starting date.

#### Specific issues to be addressed

- 1. The Group will evaluate Members' applications in detail on their compliance with the requirements specified in the *Terrestrial Code* for BSE.
- 2. The Group will propose criteria for determining the date when the risk of the BSE agents being recycled within the cattle population has been demonstrated to be negligible (the 'starting date').

#### Annex 7 (contd)

Based on the evaluations of the Members' applications and the criteria for Members to determine the starting date, the Group will provide its conclusions and recommendations to the Scientific Commission.

#### Prerequisites

The Group members should:

- Sign the OIE Undertaking on Confidentiality of information;
- Complete the Declaration of Interest Form;
- Understand that the membership of the Group may be retained between its meetings to ensure continuity of the work.

#### Actions to deliver

#### Before the meeting

Upon reception of an application from a Member, the Status Department (SD) conducts a preliminary screening to check the conformity of the dossier (structure of the dossier in accordance with the SOP and with the questionnaire under Chapter 1.8 of the *Terrestrial Code*, main sections of the questionnaire, regular notification to the OIE, payment of the fee, OIE Performance of Veterinary Services (PVS) report, etc.). If an information gap is identified, the SD requests additional information from the Member.

As the PVS reports are bound by the OIE rules on confidentiality of information, the SD and experts will consider for the evaluation the available PVS report(s) if not obsolete (PVS reports from more than five years ago) or confidential.

The SD highlights and extracts relevant areas from Chapters 1.8. and 11.4. of the *Terrestrial Code* for the discussion of the Group on the assessment of the criteria to determine the 'starting date'.

The SD will send the working documents to the Group, including the dossiers received from applicant Members, at least one month before the Group meeting (i.e., **18 October 2021**).

The experts can request support from the SD at any time.

The SD suggests the nomination of a Chair and Rapporteur for the Group's consideration.

The SD can suggest a preparatory meeting with the Chair, the Rapporteur or all experts to address specific points in advance, if needed.

The experts are expected to:

- Be familiar with the current and revised Chapters <u>1.8</u> and <u>11.4</u> of the *Terrestrial Code*;
- Evaluate and study in detail all dossiers provided by the OIE;
- Take into account any other information available in the public domain that is considered pertinent for the evaluation of the dossiers;
- Summarise the dossiers according to the *Terrestrial Code* requirements by completing the summary tables provided by the SD (the summary tables will be provided at a later stage along with the working documents for the meeting). Experts are expected to capture and summarise in each corresponding section of the summary table the main gaps as well as strengths identified during the assessment of the dossiers, using extracted texts or reference to pages/annexes from the application;
- Draft questions to the applicant Members whenever the analysis of the dossiers identifies incomplete or unclear information;
- Submit to the SD the completed summary tables for each application together with possible questions for the applicant Members at least 10 days before the teleconference and preferably by 5 November 2021;

The SD will compile the summary tables and the questions to be forwarded to the applicant Members before the teleconference. All subsequent information and material provided by a Member will be forwarded to the Group.

#### During the meeting

- Agree on the appointment of the Chair and Rapporteur of the meeting (the Chair will lead the discussion and the Rapporteur will ensure that the report reflects the discussion and captures the detailed assessment of the dossiers);
- Mention any potential conflict of interest and, if relevant, withdraw him/herself from the discussion;
- Contribute to the discussions;
- Provide a detailed report in order to recommend, to the Scientific Commission, the Members and/or zone(s) to be recognised (or not) as having a controlled or negligible BSE risk status, indicate any information gaps or specific areas that should be addressed in the future by the applicant Members, and a criteria for Members already having a controlled or negligible BSE risk status to determine the starting date.

If during the teleconference the Group decides that additional information should be requested from an applicant Member before an informed conclusion can be drawn, the SD can request it and forward the additional information to the Group at a later date. The Chair is responsible for coordinating the finalisation of the assessment and for ensuring that the views of all members of the Group are taken into consideration.

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 if needed.

#### After the meeting

The SD will circulate the draft report after the teleconference is over. Experts are expected to contribute to the finalisation of the report within approximately one week.

The SD will circulate the final version of the report to the Group once endorsed by the Scientific Commission and is published online.

#### Deliverables

A detailed report to recommend to the Scientific Commission whether an applicant Member(s) should be (or not) recognised with an official BSE risk status, and the criteria to determine the starting date for Members already having a BSE risk status. The report should indicate any information gaps or specific areas that should be addressed in the future by the Members.

#### Reporting / timeline

The OIE will circulate the draft report no more than seven days after the teleconference (no later than 26 November 2021) and the Group will finalise its report within ten days (indicative deadline: 6 December 2021).

AHG on BSE risk status evaluation of Members/November 2021

Annex 7 (contd)

<u>Appendix II</u>

# VIRTUAL MEETING OF THE OIE *AD HOC* GROUP ON THE EVALUATION OF BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS OF MEMBERS 16 to 19 November 2021

### Agenda

- 1. Opening
- 2. Adoption of the agenda and appointment of Chair and Rapporteur
- 3. Evaluation of an application from a Member for official recognition of negligible BSE risk status

3.1 France

4. Evaluation of an application from a Member for official recognition of controlled BSE risk status

4.1 Russia

- 5. Proposal of criteria in determining the starting date when the risk of the BSE agents being recycled within the cattle population has been demonstrated to be negligible
- 6. Adoption of the report

Appendix III

# OIE AD HOC GROUP ON THE EVALUATION OF BOVINE SPONGIFORM ENCEPHALOPATHY RISK STATUS OF MEMBERS 16 to 19 November 2021

#### List of participants

#### **MEMBERS**

#### **Dr Alicia Cloete**

State Veterinarian Sub-Directorate: Disease Control Department of Animal Health Department of Agriculture, Land Reform and Rural Development Pretoria SOUTH AFRICA

#### **Dr Noel Murray**

Senior Advisor on Risk Analysis Canadian Food Inspection Agency Ottawa CANADA

#### **Dr Andrea Marcos**

Coordinadora General Coordinación de Epidemiología Dirección de Planificación y Estrategia de Sanidad Animal Dirección Nacional de Sanidad Animal Servicio Nacional de Sanidad y Calidad Agroalimentaria Buenos Aires ARGENTINA

#### Dr Mark Stevenson

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# REPORT OF THE ANNUAL RECONFIRMATION ASSESSMENTS FOR MAINTENANCE OF OFFICIAL DISEASE STATUS AND OF THE ENDORSEMENT OF OFFICIAL CONTROL PROGRAMMES

The Scientific Commission for Animal Diseases (the Commission) dedicated time during its February 2022 meeting to comprehensively review all annual reconfirmations provided by Members having an OIE endorsed official control programme on the progress made, as well as a selection (approximately 10%) of the annual reconfirmations for officially recognised status. The Commission pre-selected these annual reconfirmations at its September 2021 meeting based on the list of technical and administrative considerations according to the Standard Operating Procedures (SOP) on reconfirmations: <u>en-sop-application.pdf (oie.int)</u>

A letter of reminder was sent in October 2021 by the OIE Director General to the Delegates of Members having at least one officially recognised disease status or an endorsed official control programme. The pre-selected Members were also informed of their official status selected for a comprehensive review.

In accordance with the Standard Operating Procedures governing the official recognition of disease status, all annual reconfirmations were screened by the OIE Status Department, and when necessary, additional information was requested in accordance with the relevant provisions of the *Terrestrial Animal Health Code*. The annual reconfirmations that had not been selected for this comprehensive review by the Commission were further assessed by the OIE Status Department and a report was prepared and provided for the Commission's consideration and endorsement as presented below.

#### 1. Maintenance of the AHS free status

#### 1.1. Annual reconfirmations comprehensively reviewed by the Commission:

The annual reconfirmations for AHS free status of **Brazil**, **China** (People's Rep. of), Estonia, India, Kazakhstan, Oman and Philippines were selected for comprehensive review by the Commission. Specific comments made by the Commission were:

**Brazil:** The Commission acknowledged the information provided by Brazil regarding the AHS surveillance strategy in place. The Commission noted that currently there is no targeted surveillance at the borders with countries having an undetermined AHS status but noted that Brazil conducts regular inspections at these borders to ensure compliance with national legislation, which considering the AHS situation in South America would be sufficient for early detection of a potential suspect case.

China (People's Rep. of)<sup>1</sup>: The Commission acknowledged the information submitted by China on the sanitary requirements applied to imports of horses from countries not officially recognised by the OIE as AHS free. Nevertheless, the Commission noted that the laboratory testing protocol for AHS (day of sampling after introduction in isolation, method of analysis used) followed in those cases during the quarantine period was not compliant with Article 12.1.7. of the *Terrestrial Code*. The Commission also stressed the importance of implementing protective measures against *Culicoides* attacks at all times during transportation of horses. The Commission requested China to reconsider the import requirements in accordance with Article 12.1.7. of the *Terrestrial Code*. The Commission noted that such non-compliance could lead to suspension of the official status, and requested China to provide updated evidence of full compliance with Article 12.1.7. when submitting the 2022 annual reconfirmation. The Commission also highlighted the importance of vector surveillance particularly at the borders with infected Members.

<sup>&</sup>lt;sup>1</sup> Including Hong Kong and Macau.

**Estonia:** The Commission appreciated the development and dissemination of awareness material on AHS to relevant stakeholders as part of enhancing the sensitivity of the early detection system in place for AHS.

**India**: The Commission acknowledged the information provided by India regarding the AHS laboratory tests performed in the country and its participation in proficiency testing schemes organised by an OIE Reference Laboratory for AHS. The Commission encouraged India to continue participating in the ring trials conducted by the OIE Reference Laboratory on AHS.

**Kazakhstan:** The Commission noted that the importation of horses from countries with undetermined AHS status was not fully compliant with Article 12.1.7. of the *Terrestrial Code* and firmly reiterated the importance of full compliance with the provisions of the *Terrestrial Code*. The Commission noted that such non-compliance could lead to suspension of the official status. In this regard, the Commission requested Kazakhstan to fully comply with Article 12.1.7. and submit documented evidence clearly stating the conditions for importation of these commodities from AHS infected countries when submitting the annual reconfirmation in November 2022.

**Oman:** The Commission acknowledged the information provided in support of Oman's annual reconfirmation for its AHS free status. The Commission noted that the import requirements for horses from a country with an undetermined AHS status did not precisely describe isolation in vector-protected establishments (prior to shipment and during transport) and testing for AHS. In this regard, the Commission requested that the requirements stated in the certificates be refined for full compliance with Article 12.1.7. of the *Terrestrial Code*. The Commission mentioned that such non-compliance could lead to suspension of the official status, and requested Oman to provide documented evidence of full compliance with Article 12.1.7. when reconfirming in November 2022.

**Philippines**: The Commission noted the progress made and the evidence provided by the Philippines on the establishment of national diagnostic capacity for AHS. The Commission encouraged the Philippines to continue maintaining and improving laboratory diagnostic capacity by participating in interlaboratory proficiency testing schemes for AHS organised by OIE Reference Laboratories on AHS.

*Conclusion*: The Commission recommended the maintenance of the officially recognised AHS free status of the above-listed Members.

#### 1.2. Annual reconfirmations screened by the OIE Status Department

The OIE Status Department reviewed the rest of the annual reconfirmations for AHS free status and reported the outcome of its analysis to the Commission as follows:

The annual reconfirmations for the following Members were reviewed:

Algeria	Cyprus	Latvia	Qatar
Andorra	Czech Rep.	Liechtenstein	Romania
Argentina	Denmark	Lithuania	Singapore
Australia	Ecuador	Luxembourg	Slovakia
Austria	Finland <sup>2</sup>	Malta	Slovenia
Azerbaijan	France <sup>3</sup>	Mexico	Spain <sup>4</sup>
Belgium	Germany	Morocco	Sweden
Bolivia	Greece	New Caledonia	Switzerland
Bosnia and Herzegovina	Hungary	New Zealand	The Netherlands
Bulgaria	Iceland	North Macedonia (Rep. of)	Tunisia
Canada	Ireland	Norway	Turkey
Chile	Italy	Paraguay	United Arab Emirates
Chinese Taipei	Japan	Peru	United Kingdom <sup>5</sup>

2 Including Åland Islands

<sup>3</sup> Including French Guiana, Guadeloupe, Martinique, Mayotte, Réunion, Saint Barthélémy, Saint Martin, Saint Pierre and Miquelon.

<sup>4</sup> Including Balearic Islands and Canary Islands.

<sup>5</sup> Including Cayman Islands, Guernsey (incl. Alderney and Sark), Isle of Man, Jersey, Saint Helena and Falkland Islands

Colombia	Korea (Rep. of)	Poland	United States of America <sup>6</sup>
Croatia	Kuwait	Portugal <sup>7</sup>	Uruguay

The Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 12.1. of the *Terrestrial Code* for the maintenance of the officially recognised AHS free status.

#### 2. Maintenance of BSE risk status

13 of the 61 annual reconfirmations have been identified by the Status Department as not fully compliant with Point 4 of Article 11.4.22. of the *Terrestrial Code*: Members should sample at least three of the four subpopulations (routine slaughter, fallen stock, casualty slaughter, and clinical suspects). Five annual reconfirmations did not reach the BSE surveillance target points. Considering that the OIE standards on BSE are under revision, including the surveillance provisions applicable for maintenance of controlled and negligible BSE risk status, the Commission concluded to maintain the BSE risk status of these Members.

#### 2.1. Annual reconfirmation comprehensively reviewed by the Commission:

The Commission comprehensively reviewed the annual reconfirmations and additional information submitted by eight Members in response to the questions raised by the BSE *ad hoc* Group on the revision of BSE standards and its impact on the official status recognition (June 2021), and endorsed by the Commission (see Item 6.4.2. of the main report).

The annual reconfirmation of the **United Kingdom** (one zone consisting of England and Wales as designated by the Delegate of the United Kingdom in documents addressed to the Director General in September and October 2016) was comprehensively reviewed by the Commission. The Commission commended the United Kingdom on its epidemiological investigation of the classical BSE case in England and for its transparency in making the report publicly available. The Commission acknowledged that a number of potential source risk factors and pathways have been identified, investigated and their level of risk estimated, and the appropriate mitigating measures implemented. The Commission appreciated the extension of the assessment of the pre-1996 on farm feed receptacles (silos) and would appreciate to receive an update when the United Kingdom reconfirms its controlled BSE risk status in November 2022. The Commission encouraged the United Kingdom to continue conducting awareness activities regarding BSE.

#### 2.2. Annual reconfirmations screened by the OIE Status Department

#### 2.2.1. Maintenance of a controlled BSE risk status

The OIE Status Department reviewed all annual reconfirmations for controlled BSE risk status including those in section 2.1. and reported the outcome of its analysis to the Commission.

Chinese Taipei France United Kingdom<sup>8</sup> Ecuador Greece

<sup>(</sup>Malvinas). (A dispute exists between the Government of Argentina and the Government of the United Kingdom of Great Britain and Northern Ireland concerning sovereignty over the Falkland Islands (Malvinas) (see resolution 2065 (XX) of the General Assembly of the United Nations).

<sup>6</sup> Including American Samoa, Guam, Northern Mariana Islands, Puerto Rico and US Virgin Islands.

<sup>7</sup> Including Azores and Madeira.

<sup>&</sup>lt;sup>8</sup> One zone consisting of Scotland as designated by the Delegate of the United Kingdom in documents addressed to the Director General in September and October 2016 and in December 2018.

The Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 11.4. of the *Terrestrial Code* for the maintenance of the officially recognised controlled BSE risk status.

#### 2.2.2. Maintenance of a negligible BSE risk status

The OIE Status Department reviewed all annual reconfirmations for negligible BSE risk status including those in section 2.1. and reported the outcome of its analysis to the Commission.

Argentina	Germany	Norway
Australia	Hungary	Panama
Austria	Iceland	Paraguay
Belgium	India	Peru
Bolivia	Ireland	Poland
Brazil	Israel*	Portugal <sup>9</sup>
Bulgaria	Italy	Romania
Canada	Japan	Serbia <sup>10</sup>
Chile	Korea (Rep. of)	Singapore
China (People's Rep. of) <sup>11</sup>	Latvia	Slovakia
Colombia	Liechtenstein	Slovenia
Costa Rica	Lithuania	Spain <sup>12</sup>
Croatia	Luxembourg	Sweden
Cyprus	Malta	Switzerland
Czech Republic	Mexico	The Netherlands
Denmark	Namibia	United Kingdom <sup>13</sup>
Estonia	New Zealand	United States of America
Finland <sup>14</sup>	Nicaragua	Uruguay

The OIE Status Department raised the attention of the Commission to the Member marked with an asterisk (\*). The corresponding annual reconfirmation was discussed during the Commission's meeting as follows:

**Israel**: The Commission commended Israel for the transparency demonstrated in providing detailed information on an inconclusive BSE result detected following the laboratory testing of a cow not exhibiting clinical signs suggestive of BSE but sampled at an incineration center under casualty slaughter. The Commission noted that Israel took corrective actions with regard to its shortcomings in sample processing (e.g., not enough tissue collected for further testing, delay in sending the sample to national and OIE Reference Laboratory) that may have prevented from reaching a prompt and conclusive diagnosis and that Israel had started working to address these weaknesses by revising its sampling and laboratory procedures. The Commission acknowledged that, even in the absence of a conclusive result, Israel conducted an epidemiological investigation. The Commission requested Israel to provide documented evidence of the corrective actions taken with regard to sampling and laboratory procedures and their effectiveness, as well as an update on the follow-up of the two cohort animals identified during the epidemiological investigation, when reconfirming its BSE risk status in November 2022.

<sup>9</sup> Including Azores and Madeira.

<sup>10</sup> Excluding Kosovo administered by the United Nations.

<sup>11</sup> A zone designated by the Delegate of China in a document addressed to the Director General in November 2013, consisting of the People's Republic of China with the exclusion of Hong Kong and Macau.

<sup>12</sup> Including Balearic Islands and Canary Islands.

<sup>13</sup> One zone consisting of Northern Ireland as designated by the Delegate of the United Kingdom in a document addressed to the Director General in September 2016 and one zone consisting of Jersey as designated by the Delegate of the United Kingdom in a document addressed to the Director General in August 2019.

<sup>14</sup> Including Åland Islands.

*Conclusion:* The Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 11.4. of the *Terrestrial Code* for the maintenance of the officially recognised negligible BSE risk status.

#### 3. Maintenance of the CBPP free status

#### 3.1. Annual reconfirmations comprehensively reviewed by the Commission:

The annual reconfirmations for CBPP free status of **Italy and Paraguay** were comprehensively reviewed by the Commission. Specific comments made by the Commission were as follows:

**Italy**: The Commission appreciated the information provided by Italy on the actions taken with regard to the recommendations of the *ad hoc* Group. The Commission encouraged Italy to continue its progress and activities to ensure successful maintenance of the official CBPP free status and submit an update on the system on definition of CBPP lesions while submitting the CBPP annual reconfirmation in November 2022.

**Paraguay**: The Commission appreciated the information on the actions taken by Paraguay with regard to the recommendations of the *ad hoc* Group. The Commission encouraged Paraguay to continue its progress and activities to ensure successful maintenance of the official CBPP free status and requested an update when reconfirming in November 2022 regarding the participation and outcome of Paraguay's laboratories in the interlaboratory proficiency testing scheme, as well as on the specific training conducted for all laboratories on the protocol to be followed in case of detection of CBPP suspicions.

*Conclusion:* The Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 11.5. of the *Terrestrial Code* for the maintenance of the officially recognised CBPP free status.

#### 3.2. Annual reconfirmations screened by the OIE Status Department

The OIE Status Department reviewed the rest of the annual reconfirmations for CBPP free status and reported the outcome of its analysis to the Commission as follows:

The annual reconfirmations for the following Members were reviewed:

Argentina	Eswatini	Portugal <sup>15</sup>
Australia	France <sup>16</sup>	Russia
Bolivia	India	Singapore
Botswana	Mexico	South Africa
Brazil	Namibia <sup>17</sup>	Switzerland
Canada	New Caledonia	United States of America
China (People's Republic of)*	Peru	Uruguay

The OIE Status Department raised the attention of the Commission to the Member marked with an asterisk (\*). The corresponding annual reconfirmation was discussed during the Commission's meeting as follows:

**China (People's Rep. of):** The Commission acknowledged the information provided by China on the provisions applied to imports of cattle from countries not officially recognised as CBPP free by the OIE. The Commission noted with concern that some of these imports were intended for breeding, which is not compliant with Article 11.5.8. of the *Terrestrial Code*. The Commission noted that such non-compliance could lead to suspension of the official status. In this regard, the Commission requested China to fully comply with Article 11.5.8. of the *Terrestrial Code* and provide documented evidence of compliance when reconfirming in November 2022.

<sup>&</sup>lt;sup>15</sup> Including Azores and Madeira.

<sup>16</sup> Including French Guiana, Guadeloupe, Martinique, Mayotte and Réunion.

<sup>17</sup> One zone located south to the Veterinary Cordon Fence, designated by the Delegate of Namibia in a document addressed to the Director General in October 2015.

*Conclusion*: The Commission recommended the maintenance of the officially recognised CBPP free status of the above-listed Members.

#### 4. Maintenance of the endorsement of the official control programme for CBPP

The Commission reviewed the information provided by **Namibia** in support of the reconfirmation of its endorsed official control programme for CBPP.

The Commission commended Namibia for improving the CBPP vaccination coverage in the high-risk areas and developing a new CBPP contingency plan. Considering the delay in the construction of the infrastructure related to CBPP control due to the national policy and procedural requirements, the Commission recommended Namibia to strengthen other CBPP preventive measures including livestock movement control and biosecurity, surveillance particularly in the high-risk areas. The Commission recommended Namibia to review and update the timeline and key performance indicators for the next three to five years to enable assessment of the efficacy of the control measures of the official control programme, and to share the revised contingency response plan.

The Commission also encouraged Namibia to participate in inter-laboratory proficiency tests and invited Namibia to provide information on its participation and results including on the abovementioned when submitting its annual reconfirmation in November 2022.

The Commission reiterated its recommendations and strongly encouraged Namibia to provide a clear and concise update focusing on the main achievements and progress made, specifically on CBPP activities for the reporting period (and provide each disease information separately), to facilitate the review of the information provided.

#### 5. Maintenance of the CSF free status

#### 5.1. Annual reconfirmations comprehensively reviewed by the Commission:

The annual reconfirmations for CSF free status of **Brazil (zone)**, **Colombia (zone)**, **Kazakhstan** and **Slovakia** were comprehensively reviewed by the Commission. Specific comments made by the Commission were as follows:

**Brazil (one zone** consisting of the State of Paraná as designated by the Delegate of Brazil in a document addressed to the Director General in October 2020): The Commission acknowledged the information provided by Brazil regarding the recommendations of the CSF *ad hoc* Group. The Commission noted that Brazil will implement a new surveillance system targeting swine diseases and that the results of such implementation will be presented during the next reconfirmation campaign.

**Colombia (the central-eastern zone** as designated by the Delegate of Colombia in a document addressed to the Director General in October 2020): The Commission appreciated the detailed information provided by Colombia with regard to the recommendations made by the *ad hoc* Group and commended Colombia by the efforts demonstrated in the monitoring and control of CSF. The Commission noted that a traceability system linked to the current identification system is being developed by the ICA and PorkColombia for implementation by the second semester of 2022. The Commission encouraged Colombia to present the progress in the next reconfirmation campaign.

**Kazakhstan:** The Commission noted with strong concerns that vaccinated pigs were imported into Kazakhstan for slaughter and breeding from a country with undetermined CSF status. Whilst noting the requirement of quarantine and testing as well as that the pigs should be originating from CSF-free areas, the information provided by Kazakhstan lacked clarity in terms of the precise timeline of quarantine and testing and type of test used, and was considered not compliant with Article 15.2.10. of the *Terrestrial Code*. The Commission noted that such non-compliance could lead to suspension of the official status. In this regard, the Commission requested Kazakhstan to fully comply with Article 15.2.10. of the *Terrestrial Code* and submit documented evidence of compliance to the OIE before the OIE General Session in May 2022.

The Commission was also concerned by the lack of suspicions for CSF, in particular given the ASF situation in the region and similar clinical presentation of the two diseases. The Commission noted that

Kazakhstan had not yet started participating in interlaboratory proficiency testing schemes for CSF but had planned to do so in 2022. The Commission strongly encouraged Kazakhstan's laboratories to participate in ring trials with respect to CSF diagnostic tests and provide the results when reconfirming in November 2022. The Commission also encouraged Kazakhstan to continue conducting CSF awareness raising activities to maintain the early warning system for CSF in the country.

**Slovakia:** The Commission acknowledged the information provided by Slovakia regarding the awareness activities conducted to enhance the notification of CSF/ASF suspect cases. The Commission encouraged Slovakia to continue its efforts in CSF prevention and awareness campaigns.

*Conclusion*: With the exception of Kazakhstan that was requested additional information, the Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 15.2. of the *Terrestrial Code* for the maintenance of the officially recognised CSF free status.

The annual reconfirmation of the Kazakhstan would be finalised after receipt of the additional information and electronic consultation by the Commission prior to the forthcoming OIE General Session in May 2022.

#### 5.2. Annual reconfirmations screened by the OIE Status Department

The OIE Status Department reviewed the rest of the annual reconfirmations for CSF free status and reported the outcome of its analysis to the Commission as follows:

The annual reconfirmations for the following Members were reviewed:

Argentina Australia Austria Belgium Brazil <sup>21</sup> Bulgaria Canada Chile Colombia <sup>26</sup>	Croatia Czech Republic Denmark Ecuador <sup>20</sup> Finland <sup>22</sup> France <sup>23</sup> Germany Hungary Ireland	Latvia Liechtenstein Luxembourg Malta Mexico New Caledonia New Zealand Norway Paraguay	Portugal <sup>18</sup> Slovenia Spain <sup>19</sup> Sweden Switzerland The Netherlands United Kingdom <sup>24</sup> United States of America <sup>25</sup>
Chile Colombia <sup>26</sup> Costa Rica	Hungary Ireland Italy	Norway Paraguay Poland	United States of America <sup>23</sup> Uruguay

<sup>18</sup> Including Azores and Madeira.

<sup>19</sup> Including Balearic Islands and Canary Islands.

<sup>20</sup> One zone consisting of the insular territory of the Galápagos, as designated by the Delegate of Ecuador in a document addressed to the Director General in October 2018.

<sup>21</sup> One zone composed of the States of Rio Grande do Sul and Santa Catarina as designated by the Delegate of Brazil in a document addressed to the Director General in September 2014 and one zone covering the States of Acre, Bahia, Espírito Santo, Goias, Mato Grosso, Mato Grosso do Sul, Minas Gerais, Rio de Janeiro, Rondônia, São Paulo, Sergipe and Tocantins, Distrito Federal, and the municipalities of Guajará, Boca do Acre, South of the municipality of Canutama and Southwest of the municipality of Lábrea in the State of Amazonas as designated by the Delegate of Brazil in a document addressed to the Director General in September 2020.

<sup>22</sup> Including Åland Islands.

<sup>23</sup> Including French Guiana, Guadeloupe, Martinique, Mayotte and Réunion.

<sup>24</sup> Including Guernsey (incl. Alderney and Sark), Isle of Man and Jersey.

<sup>25</sup> Including Guam, Puerto Rico and US Virgin Islands.

<sup>26</sup> One zone designated by the Delegate of Colombia in a document addressed to the Director General in September 2015.

The Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 15.2. of the *Terrestrial Code* for the maintenance of the officially recognised CSF free status.

#### 6. Maintenance of the endorsement of the official control programme for dog-mediated rabies

The annual reconfirmations of **Namibia** and **Philippines** were comprehensively reviewed by the Commission. Specific comments made by the Commission were as follows:

**Namibia:** The Commission acknowledged the information provided by Namibia in support of the reconfirmation of its endorsed official control programme for dog-mediated rabies. The Commission commended the progress made on stakeholder involvement and awareness raising activities. The Commission reiterated that Namibia should continue with these efforts in the future to confirm the role of stray dogs in rabies transmission in the Northern Communal Areas (NCA) and utilise methods for population estimation and vaccination monitoring described in Articles 7.7.5. and 4.18.9. of the *Terrestrial Code*. The Commission noted the additional actions planned to improve the vaccination coverage in the NCA and that the results of these efforts would be presented in the next reconfirmation. The Commission requested Namibia to provide i) the results of the knowledge, attitude and practice (KAP) study, ii) detailed information about the surveys to estimate the stray dog population and understanding its role in rabies transmission, and iii) progress of implementation of the dog population management strategy in accordance with Chapter 7.7. of the *Terrestrial Code* when reconfirming the endorsement of its official control programme in November 2022.

**Philippines:** The Commission acknowledged the information provided by the Philippines in support of the reconfirmation of its endorsed official control programme for dog-mediated rabies. The Commission noted the work done in classification of dog population and testing of rabies suspected cases. The Commission noted that the objectives and indicators of achievement, which were presented in the application of the endorsed programme, could not be met due to the COVID-19 restrictions and the priority to control the African swine fever outbreaks. The Commission recognised the difficulties and the shortage of financial resources redirected associated with these factors. The Commission acknowledged that the Philippines is reviewing the outputs of 2021 which will be used to adjust the targets for the next years; this information, the corrective measures taken in face of the above-noted difficulties, and an updated workplan was to be shared with the OIE in April 2022. The Commission strongly encouraged the Philippines to continue its efforts in making progress on its workplan, particularly in collecting comprehensive data and characterising the dog population in accordance with Chapter 7.7. of the *Terrestrial Code*.

#### 7. Maintenance of the FMD free status

#### 7.1. Annual reconfirmations comprehensively reviewed by the Commission

The annual reconfirmations for FMD free status of Albania, one zone of Colombia, Guatemala, Guyana, Indonesia, Kazakhstan, one zone of Malaysia, two zones of Russia, Ukraine and one zone of Turkey were selected for comprehensive review by the Commission. Specific comments made by the Commission were as below:

**Albania**: The Commission considered the supportive information provided by Albania. Whilst noting that there were no imports from countries not officially recognised free from FMD by the OIE in the reporting period, the Commission requested Albania to provide a clear description of the import conditions for countries not officially recognised free from FMD supported by legislation when submitting the annual reconfirmation in 2022.

**Colombia (one zone** consisting of two merged zones designated by the Delegate of Colombia in documents addressed to the Director General in September 2019 and in August 2020, which includes Zone II (Eastern border) and the former high surveillance zone covering the Departments of Arauca and Vichada and the municipality of Cubará of the Department of Boyacá): The Commission appreciated the concise information provided by Colombia with regard to the recommendations of the *ad hoc* Group and commended the efforts demonstrated by Colombia on the progress made on individual animal identification of cattle and buffaloes in the departments bordering a Member with undetermined FMD status. Nevertheless, the Commission recommended Colombia's continuous vigilance for FMD and to continue reporting its progress and maintenance of measures when annually reconfirming its official FMD-free status to the OIE.

**Guatemala:** The Commission acknowledged the information provided on passive surveillance activities for vesicular diseases including data on suspected cases. However, the Commission expressed strong concerns on the delays for shipping the samples to the laboratory for confirmation (or ruling out) of FMD suspicions and requested corrective actions be made and reported in the annual reconfirmation of 2022. In addition, the Commission reiterated its recommendations made after the assessment of Guatemala's 2020 annual reconfirmation in reference to the revision of the protocol for the investigation of suspected cases of vesicular disease. The Commission emphasised that Guatemala should not rely only on epidemiological investigations and clinical inspections to rule out FMD in clinical suspicions but should also implement relevant follow-up procedures involving virological and serological laboratory testing of suspicious cases (when epithelial sampling is not possible), and in-contact animals in demonstrating continuous absence of infection with FMDV, in accordance with Articles 8.8.40. to 8.8.42. of the *Terrestrial Code*.

**Guyana:** The Commission noted the information provided by Guyana on surveillance activities and awareness campaigns conducted in the reporting period, as well as on the changes implemented for preventing the entry of FMDV into the country. The Commission acknowledged the regular surveillance activities conducted in the farms of Regions 1 and 7 bordering a Member with undetermined FMD status and that the results of the serological sampling will become available in April-May 2022. The Commission requested Guyana to provide the results as soon as they become available.

The Commission reiterated its concerns about the excessive delay in submitting the annual reconfirmation and providing the additional information to support an informed assessment by the Commission, despite the recommendations from previous years. In accordance with the Standard Operating Procedure on the reconfirmation of officially recognised animal health status, the Commission stressed that this could result in the suspension of an official status.

**Indonesia:** The Commission appreciated Indonesia's activities with regard to the FMD surveillance in place and the measures implemented for the control of the potential pathways of introduction of FMD in the country. The Commission noted that, as part of these measures, random controls of carry-on baggage at international airports and seaports had been carried out and all animal products detected were subjected to laboratory testing for FMD using RT-PCR. The Commission took note that an evaluation of the effectiveness and efficacy of this approach was underway with the support of a FMD expert committee and requested Indonesia to provide an update on the results of this study in the annual reconfirmation of 2022. Based on the identified potential pathways of introduction, the Commission encouraged Indonesia to strengthen the controls at land borders, airports and seaports and intensify awareness on the risks and subsequent costs of disease introduction.

The Commission further noted that the protocol recommended by Indonesia for the inactivation of FMDV in swill was not fully in line with Article 8.8.31. The Commission strongly recommended Indonesia to revise the treatment procedure according to Article 8.8.31. The Commission also recommended that, once the treatment protocol is revised, an enforcement framework should be established to monitor compliance with the revised protocol. The Commission also re-emphasised the importance of using a smaller unit (e.g., village) in the serological survey design with reference to the OIE Glossary terminology of epidemiological unit.

The Commission maintains its recommendation of a field mission to be conducted (when health situation related to COVID-19 pandemic improves) to assess compliance with the relevant requirements of Chapter 8.8. of the *Terrestrial Code* for the maintenance of FMD free status.

Kazakhstan (five zones with vaccination and four zones without vaccination)<sup>27</sup>: The Commission raised strong concerns regarding the early warning system of Kazakhstan, as well as the procedures to immediately investigate and test for FMD and notify the OIE. Whilst noting the common procedure in place for the control of animal movements between zones, the Commission requested Kazakhstan to provide the results of the epidemiological investigations conducted on animals originating from the suspended Zone 5 that were moved to other zones of Kazakhstan, as soon as possible. This should include, but not be limited to, documented evidence on the actions taken to monitor and manage those transported animals demonstrating that there was no spread of FMDV into other zones.

**Malaysia (one zone without vaccination** consisting of the provinces of Sabah and Sarawak as designated by the Delegate of Malaysia in a document addressed to the Director General in December 2003): The Commission appreciated that Malaysia harmonised the serological sampling strategy in the two provinces of Sabah and Sarawak, and encouraged Malaysia to conduct a risk assessment to select the premises based on risk rather than selecting them randomly. The Commission maintains its recommendation of a field mission to be conducted (when health situation related to COVID-19 pandemic improves) to assess compliance with the relevant requirements of Chapter 8.8. of the *Terrestrial Code* for the maintenance of FMD free status.

**Russia** (two zones with vaccination as designated by the Delegate of Russia in documents addressed to the Director General in August 2020): The Commission acknowledged the detailed supportive information provided by Russia. The Commission noted that Russia had planned investigations to identify and address the causes of the low immunity levels below 75% in concerned areas and that the results of these investigations will serve to amend the FMD Vaccination Plan for 2022. In this regard, the Commission requested submission of the final report describing the results of the investigation and corrective actions taken based on the results, as well as any adjustments made on the survey design be provided when reconfirming in November 2022.

Ukraine: The Commission appreciated the actions taken by Ukraine to revise the case definition in line with point 3. of Article 8.8.1. of the *Terrestrial Code*.

**Turkey (one zone** free with vaccination designated by the Delegate of Turkey in a document addressed to the Director General in November 2009): The Commission appreciated the comprehensive information provided by Turkey in addressing the recommendations of the FMD *ad hoc* Group and the Commission through submission of documents and discussion during the virtual interviews. The Commission also appreciated the advice and efforts of the experts that participated in the virtual interviews. Based on the conclusions of the virtual interviews report, the Commission recommended that the field mission should assess the implementation of biosecurity measures at supply farms, during transportation of animals from the infected zone (Anatolia) into the free zone (Thrace), and at temporary animal markets in Thrace. During the field mission, the protocol and criteria applied for the selection of provinces/villages to supply animals for the 2022 Kurban festival should be assessed, as well as the procedures implemented when a NSP positive reactor is detected in the 10-km radius of the candidate farms. The Commission strongly encouraged that Turkey produce and submit prior to the field mission a formal risk assessment to demonstrate how the measures implemented by Turkey have an equivalent result to the provisions of the *Terrestrial Code*.

*Conclusion:* With the exception of Kazakhstan that was requested additional information, the Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 8.8. of the *Terrestrial Code* for the maintenance of the officially recognised FMD free status.

<sup>27</sup> Four zones without vaccination as designated by the Delegate of Kazakhstan in a document addressed to the Director General in August 2018 consisting of as follows: Zone 1 consisting of West Kazakhstan, Atyrau, Mangystau and south-western part of Aktobe region; Zone 2 including north-eastern part of Aktobe region, southern part of Kostanay region and western part of Karaganda region; Zone 3 including northern and central parts of Kostanay region, western parts of North Kazakhstan and Akmola regions; Zone 4 including central and eastern parts of North Kazakhstan region and northern parts of Akmola and Pavlodar regions; Five zones with vaccination as designated by the Delegate of Kazakhstan in documents addressed to the Director General in August 2016 as follows: one zone consisting of Almaty region; one zone including part of Kyzylorda region, northern part of South Kazakhstan region; one zone including southern part of Kyzylorda region and south-western part of South Kazakhstan region; one zone including southern part of Kyzylorda region and south-western part of South Kazakhstan region; one zone including southern part of Kyzylorda region and south-western part of South Kazakhstan region; one zone including southern part of South Kazakhstan region.

The annual reconfirmation of the Kazakhstan would be finalised after receipt of the additional information and electronic consultation by the Commission prior to the forthcoming OIE General Session in May 2022.

#### 7.2. Annual reconfirmations screened by the OIE Status Department

The OIE Status Department reviewed the rest of the annual reconfirmations for FMD free status and reported the outcome of its analysis to the Commission as follows:

The annual reconfirmations for the following Members were reviewed:

Australia	El Salvador	Luxembourg	San Marino
Austria	Estonia	Madagascar	Serbia <sup>28</sup>
Belarus	Eswatini	Malta	Singapore
Belgium	Finland <sup>29</sup>	Mexico	Slovakia
Belize	France <sup>30</sup>	Montenegro	Slovenia
Bosnia and Herzegovina	Germany	New Caledonia	Spain <sup>31</sup>
Brunei	Greece	New Zealand	Suriname
Bulgaria	Haiti	Nicaragua	Sweden
Canada	Honduras	North Macedonia (Rep. of)	Switzerland
Chile	Hungary	Norway	The Netherlands
Costa Rica	Iceland	Panama	United Kingdom <sup>32</sup>
Croatia	Ireland	Paraguay	United States of America <sup>33</sup>
Cuba	Italy	Peru	Uruguay
Cyprus	Japan	Philippines	Vanuatu
Czech Rep.	Latvia	Poland	
Denmark <sup>34</sup>	Lesotho*	Portugal <sup>35</sup>	
Dominican Republic	Lithuania	Romania	

#### Argentina: Three zones without vaccination

- one zone designated by the Delegate of Argentina in a document addressed to the Director General in January 2007;
- the summer pasture zone in the Province of San Juan as designated by the Delegate of Argentina in a document addressed to the Director General in April 2011;
- Patagonia Norte A as designated by the Delegate of Argentina in a document addressed to the Director General in October 2013;

**Two zones with vaccination** designated by the Delegate of Argentina in documents addressed to the Director General in March 2007 and October 2013, and in August 2010 and February 2014;

#### **Bolivia:** Two zones without vaccination consisting of:

- one zone in the Macro-region of the Altiplano designated by the Delegate of Bolivia in documents addressed to the Director General in November 2011;

<sup>28</sup> Excluding Kosovo administered by the United Nations

<sup>&</sup>lt;sup>29</sup> Including Åland Islands.

<sup>&</sup>lt;sup>30</sup> Including French Guiana, Guadeloupe, Martinique, Réunion, Saint Pierre and Miquelon.

<sup>&</sup>lt;sup>31</sup> Including Balearic Islands and Canary Islands.

<sup>&</sup>lt;sup>32</sup> Including Guernsey (incl. Alderney and Sark), Isle of Man, Jersey and Falkland Islands (Malvinas). (A dispute exists between the Government of Argentina and the Government of the United Kingdom of Great Britain and Northern Ireland concerning sovereignty over the Falkland Islands (Malvinas) (see resolution 2065 (XX) of the General Assembly of the United Nations).

<sup>&</sup>lt;sup>33</sup> Including American Samoa, Guam, Northern Mariana Islands, Puerto Rico and US Virgin Islands.

<sup>&</sup>lt;sup>34</sup> Including Faroe Islands and Greenland.

<sup>&</sup>lt;sup>35</sup> Including Azores and Madeira.

 one zone consisting of the Department of Pando as designated by the Delegate of Bolivia in a document addressed to the Director General in August 2018;

**One zone with vaccination** covering the regions of Chaco, Valles and parts of Amazonas and Altiplano as designated by the Delegate of Bolivia in documents addressed to the Director General in October 2013, February 2014 and August 2018;

- **Botswana**: Four zones without vaccination designated by the Delegate of Botswana in documents addressed to the Director General in August and November 2014 as follows:
  - one zone consisting of Zones 3c (Dukwi), 4b, 5, 6a, 8, 9, 10, 11, 12 and 13;
  - one zone consisting of Zone 3c (Maitengwe);
  - one zone covering Zone 4a;
  - one zone covering Zone 6b;

**One zone without vaccination** covering Zone 3b designated by the Delegate of Botswana in a document addressed to the Director General in August 2016;

**One zone without vaccination** covering Zone 7 designated by the Delegate of Botswana in a document addressed to the Director General in August 2018;

**Brazil**: **One zone without vaccination** – State of Santa Catarina designated by the Delegate of Brazil in a document addressed to the Director General in February 2007;

**Three zones without vaccination** as designated by the Delegate of Brazil in a document addressed to the Director General in August 2020 as follows:

- State of Paraná;
- State of Rio Grande do Sul;
- one zone (Block 1) including the States of Acre and Rondônia and 14 municipalities in the State of Amazonas and five municipalities in the State of Mato Grosso;

**One with vaccination** designated by the Delegate of Brazil in documents addressed to the Director General as follows:

- one zone consisting of two merged zones designated by the Delegate of Brazil in documents addressed to the Director General in August 2010, September 2017 and September 2019, covering the States of Alagoas, Amapá, Amazonas, Bahia, Ceará, Espíritu Santo, Goiás, Mato Grosso, Mato Grosso do Sul, Maranhão, Minas Gerais, Pará, Paraíba, Pernambuco, Piauí, Rio de Janeiro, Rio Grande do Norte, Roraima, São Paulo, Sergipe, Tocantins and Distrito Federal, with the exclusion of the municipalities of the States of Amazonas and Mato Grosso that are part of the zone of Block 1 (free from FMD where vaccination is not practised) as addressed to the Director General in August 2020;
- <u>Chinese Taipei</u>: One zone without vaccination covering Taiwan, Penghu and Matsu areas, as designated by the Delegate of Chinese Taipei in a document addressed to the Director General in August 2019;

**One zone with vaccination:** one zone consisting of Kinmen County as designated by the Delegate of Chinese Taipei in a document addressed to the OIE Director General in September 2017;

#### **<u>Colombia</u>**: Two zones without vaccination:

- one zone designated by the Delegate of Colombia in documents addressed to the Director General in November 1995 and in April 1996 (Area I - Northwest region of Chocó Department);
- one zone designated by the Delegate of Colombia in documents addressed to the Director General in January 2008 (Archipelago de San Andrés and Providencia).

**Three zones with vaccination** designated by the Delegate of Colombia in documents addressed to the Director General in September 2019 as follows:

- Zone I (Northern border) consisting of Departments of La Guajira, Cesar and part of the Department of Norte de Santander;
- Zone III (Trade) consisting of the Departments of Atlántico, Córdoba, Magdalena, Sucre and part of Antioquia, Bolívar and Chocó Departments;
- Zone IV (Rest of the country), consisting of the Departments of Amazonas, Caldas, Caquetá, Cauca, Casanare, Cundinamarca, Guainía, Guaviare, Huila, Meta, Nariño, Quindío, Putumayo, Risaralda, Santander, Tolima, Valle del Cauca, Vaupés and part of Antioquia, Bolívar, Boyacá, and Chocó Departments.
- **Ecuador:** One zone without vaccination consisting of the insular territory of the Galapagos, as designated by the Delegate of Ecuador in a document addressed to the Director General in August 2014;

**One zone with vaccination** consisting of the continental Ecuador, as designated by the Delegate of Ecuador in a document addressed to the Director General in August 2014;

- <u>Moldova</u>: One zone without vaccination designated by the Delegate of Moldova in a document addressed to the Director General in July 2008;
- <u>Namibia</u>: One zone without vaccination designated by the Delegate of Namibia in a document addressed to the Director General in February 1997;
- **<u>Russia</u>**: **One zone without vaccination** designated by the Delegate of Russia in documents addressed to the Director General in August 2015 and March 2016;

The OIE Status Department informed the Commission that the annual reconfirmations that were received and assessed were compliant with the relevant provisions of Chapter 8.8. of the *Terrestrial Code*. However, the OIE Status Department raised the attention of the Commission to the Member marked with an asterisk (\*). This annual reconfirmation was discussed during the Commission's meeting as follows:

Lesotho: The Commission acknowledged the surveillance programme for FMD implemented by Lesotho including the Central Veterinary Laboratory (CVL) testing capacity. Although the CVL results were negative for FMD, the Commission noted with concern the delays in receiving results of the representative samples sent to the Reference Laboratories. The Commission requested Lesotho to participate in proficiency testing schemes for FMD and to review its surveillance strategy to ensure that results are received timely for the annual reconfirmation of the officially recognised FMD-free status in November substantiating compliance with the surveillance provisions of the *Terrestrial Code*. The Commission suggested Lesotho to consider a risk-based sampling/surveillance approach to optimise the use of resources on FMD surveillance, based on a risk assessment taking into account the current FMD situation in South Africa and in southern Africa.

The Commission concluded that, in general, the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 8.8. of the *Terrestrial Code* for the maintenance of the officially recognised FMD free status.

#### 8. Maintenance of the endorsement of the official control programme for FMD

The annual reconfirmations of China (People's Rep. of), India, Kyrgyzstan, Mongolia, Morocco, Namibia and Thailand were comprehensively reviewed by the Commission. Specific comments made by the Commission were as follows:

**China (People's Rep. of)**: The Commission acknowledged the information submitted by China regarding its progress made in implementing the official FMD control programme. The Commission appreciated that an electronic animal health certification system had been established to strengthen animal movement control, as per last year's recommendation. However, the Commission noted that the rest of the recommendations had not been addressed. The Commission noted that FMDV positive animals detected through pathogenic surveillance were still not classified as FMD cases or outbreaks and reiterated the importance of aligning the FMD case definition with Article 8.8.1. point 3 of the *Terrestrial Code*. The Commission further noted a discrepancy between the number of FMD outbreaks reported by China in 2021 in its annual reconfirmation and through WAHIS and urged China to report to the OIE all FMD cases.

The Commission took note of the high vaccination coverage and herd immunity level; however, the Commission reiterated the epidemiological importance of analysing PVM data stratified by age. The Commission also recommended China to investigate the vaccination status and the herd immunity level of the farms where clinically positive animals had been detected.

The Commission requested China to provide a progress report on the implementation of recommendations in its annual reconfirmation in November 2022. Lastly, the Commission took note that China was in progress of revising the prevention and control targets and performance indicators of its FMD official control plan, in the light of SEACFMD Roadmap 2021-2025 and requested its submission as soon as it becomes available.

**India:** The Commission appreciated the detailed information submitted by India addressing the recommendations from the 2020 reconfirmation campaign. The Commission noted that a new serological sampling design following two-stage sampling strategy was developed jointly by ICAR-NIVEDI and ICAR-DFMD and strongly encouraged sampling coverage of more States to better understand the FMD epidemiology based on animal movement patterns into and within the country. The Commission took note of India's efforts made on the development of a procedure for systematic follow-up investigations on positive reactors to NSP tests and emphasised that the follow-up should not only include probang samples but also clinical inspection, supplementary testing of the animals found seropositive and the in-contact animals, and epidemiological investigation in accordance with Article 8.8.42. Point 1 of the *Terrestrial Code*, especially for those areas aimed at demonstrating freedom from FMD. The Commission requested India to submit as part of its 2022 reconfirmation the following: i) progress made to improve serological sampling coverage over all States, as well as to improve vaccination coverage and population immunity levels; and ii) the follow-up investigations performed on positive reactors to NSP tests.

The Commission requested India to submit information of the reporting year including indicators demonstrating progress made on the OIE endorsed official control programme for FMD.

**Kyrgyzstan:** The Commission acknowledged the continuing efforts of Kyrgyzstan on serosurveillance and vaccination activities, as well as on the progress made on the traceability of animals and the control of movements of animals and animal products. The Commission also noted the information on the purity of the vaccine used in Kyrgyzstan and recommended to carry out further investigations regarding the NSP reactors, including clinical inspection and supplementary testing of the seropositive cattle, but also on the in-contact animals, both cattle and other FMD susceptible species if any present. Furthermore, the Commission encouraged Kyrgyzstan to conduct epidemiological investigations in accordance with Article 8.8.42. point 1 of the *Terrestrial Code*, and studies on clustering as described in Article 1.4.3., point 1.e. of the *Terrestrial Code*.

#### Annex 8 (contd)

The Commission reiterated the importance of fully implementing the recommendations made by the FMD *ad hoc* Group of November 2019 and endorsed by the Commission, before applying for official recognition of an FMD-free status by the OIE. The Commission requested Kyrgyzstan to provide an update on the implemented activities and progress made against the work plan and performance indicators when submitting its reconfirmation in November 2022.

**Mongolia:** The Commission appreciated the information submitted by Mongolia on the outbreaks detected in the regions intended to be proposed as free without vaccination and took note that in response to the outbreaks, emergency vaccination has been introduced as a control measure. The Commission further noted that a Mongolian saiga had been tested positive to NSP ELISA and that investigation was ongoing to determine the cause of mortality in Mongolian saigas. The Commission also noted, from information publicly available, that additional FMD outbreaks had been detected in Mongolia but not reported to the OIE and urged Mongolia to report to the OIE all FMD cases, including those in wildlife as soon as the investigation was finalised.

The Commission noted the vaccine purity study results provided by Mongolia, according to which FMD vaccines used in the country did not provoke the development of antibodies to non-structural proteins even after multiple vaccinations.

In addition, the Commission noted that, due to financial constraints, the NSP positive reactors were not followed up properly. The Commission reiterated the importance of follow-up on NSP positive reactors by further investigations including clinical inspection, supplementary testing of animals found seropositive and the incontact animals, and epidemiological investigation to better understand the source of NSP positive antibodies in accordance with Article 8.8.42. point 1 of the *Terrestrial Code*, and by studies on clustering as described in Article 1.4.3., point 1.e. of the *Terrestrial Code*.

The Commission noted that Mongolia was working to revise its FMD control programme to reflect and address the changes in the epidemiological situation and requested Mongolia to provide the updated programme to the OIE as soon as the revisions are completed.

**Morocco**: The Commission acknowledged the results of the serological survey conducted in 2021. Whilst noting the significant decrease in the NSP reactors both at herd and individual level, the Commission strongly encouraged Morocco to continue the serological surveys for monitoring FMD virus transmission, maintain the vaccination strategy for cattle and small ruminants, participate in interlaboratory proficiency testing and inform on progress of these activities when reconfirming in November 2022.

Namibia: The Commission acknowledged the information provided by Namibia in support of the reconfirmation of its endorsed official control programme for FMD.

The Commission commended Namibia for conducting follow up investigations on the outbreaks of SAT 2 that identified the concurrent infection, emergence and first occurrence of FMD Serotype O in the infected area. The Commission recommended Namibia to review and provide an updated FMD control strategy taking into consideration the recent epidemiological developments, noting the delay in construction of disease control infrastructure at the international border and the related key performance indicators of the official control programme. The Commission encouraged Namibia to continue strengthening livestock movement control in the area and use FMD vaccines covering all circulating serotypes reported in Namibia. The Commission recommended Namibia to also continue investigations on FMD post-vaccination monitoring including response to serotype O, and to submit the outcomes of the investigations, including any corrective actions when submitting its annual reconfirmation in November 2022.

The Commission reiterated its recommendation and strongly encouraged Namibia to provide a clear and concise update focusing on the main achievements and progress made, specifically on FMD activities for the reporting period (and provide each disease information separately), to facilitate the review of the information provided.

**Thailand**: The Commission noted that Thailand's FMD vaccination strategy had shifted from risk-based vaccination into mass vaccination and that the vaccination coverage target had been set at 80% of all FMD susceptible animals. The Commission recommended that, in line with the Global FMD Control Strategy, the

vaccination coverage should aim at 100 % of the eligible susceptible animal population, which should be clearly defined. In addition, the Commission noted that the results of the post-vaccination monitoring (PVM) conducted in 2021 revealed low herd immunity levels and that Thailand was planning to investigate the reasons for such levels in coordination with other national agencies and relevant stakeholders. The Commission appreciated that this investigation would include among others a review of the vaccination management and guidelines as well as of the vaccine efficacy and the risk factors associated with protective herd immunity and recommended to Thailand to implement quality controls of the vaccines not only after their production but also few months later to verify their stability. The Commission requested Thailand to provide in its annual reconfirmation of 2022 an update on the results of this investigation and the corrective actions taken to ensure an adequate level of vaccine efficacy and effectiveness, as well as on PVM results after the next vaccination campaign.

*Conclusion:* The Commission considered that the annual reconfirmations of the above-listed Members were compliant with the relevant provisions of Chapter 8.8. of the *Terrestrial Code* for an endorsed official control programme for FMD. However, the Commission noted a lack of progress of countries having an OIE endorsed official control programmes for FMD.

#### 9. Maintenance of the PPR free status

#### 9.1. Annual reconfirmations comprehensively reviewed by the Commission:

The annual reconfirmations for PPR free status of, Lesotho, Madagascar, Mauritius, Namibia (zone), North Macedonia (Rep. of) and Russia were comprehensively reviewed by the Commission. Specific comments made by the Commission were as follows:

**Lesotho:** The Commission commended Lesotho on its efforts to implement the recommendations of the Commission. The Commission acknowledged PPR testing results and the planned activities to strengthen the national laboratory capacity on molecular testing for PPR, and recommended Lesotho to participate in proficiency testing schemes and continue the training of laboratory personnel. This will maintain competencies and ensure quality of the results taking into consideration the delays in obtaining the tests results of surveillance samples from laboratories that Lesotho has agreements with. Whilst taking note of the passing of the Livestock Policy in 2021 by government, the Commission reiterated its recommendation that Lesotho should implement legislation that makes PPR a notifiable disease and that provides the legal basis for the prohibition for PPR vaccination. The Commission requested Lesotho to provide an update on progress made when reconfirming its PPR status in November 2022.

**Madagascar:** The Commission noted the progress reported on the implementation of its recommendations regarding the development of the legal framework on prohibition of PPR vaccination, identification and traceability, and on the acquisition of PPR molecular diagnosis equipment. The Commission recommended Madagascar to consider participation in proficiency testing schemes for PPR in the absence of testing by RT-PCR samples from PPR suspect cases. This will ensure maintenance of competencies in PPR molecular diagnostics. The Commission reiterated its recommendation to Madagascar to continue its progress and activities to ensure the adoption of legal framework on prohibition of vaccination against PPR, identification and traceability. In addition, the Commission recommended Madagascar to include farmers and other key stakeholders in the upcoming training and awareness education on PPR. The Commission requested an update on the progress made when reconfirming in November 2022.

**Mauritius:** Whilst taking note of the advancements made on issuance of drafting instructions of the Animal Health Bill, the Commission reiterated its recommendation that Mauritius should implement legislation enforcing PPR notifiability and general PPR control including import conditions of live animals and products of animal origin in accordance with the *Terrestrial Code*. The Commission also noted the serious delay in the acquiring of PPR test kits and recommended corrective actions be taken for prompt testing of samples. The Commission requested Mauritius to provide an update on the enactment of the Bill and improvement of prompt PPR diagnostics when reconfirming its PPR status in November 2022.

**Namibia** (one zone located south to the Veterinary Cordon Fence, designated by the Delegate of Namibia in a document addressed to the Director General in November 2014): The Commission appreciated the supportive information provided by Namibia on its PPR free zonal status. The Commission took note that the serological survey that was initially planned for 2021 was not performed and would be conducted in February 2022 when the control of Trans-boundary Animal Diseases (TADs) project is implemented. The Commission noted that through this project, trainings specific to PPR will also be conducted in addition to awareness programmes to ensure proper response in case of a suspected PPR outbreak including early

detection, chain of command for reporting, sampling, laboratory diagnosis and implementation of relevant control measures. The Commission encouraged Namibia to participate in proficiency testing schemes to maintain laboratory competencies on PPR and provide the outcomes when submitting the reconfirmation in November 2022, together with the results of the serological survey which will be conducted in the first quarter of 2022.

The Commission reiterated its recommendation and strongly encouraged Namibia to provide a clear and concise update focusing on the main achievements and progress made and specifically on PPR activities for the reporting period (and provide each disease information separately) to facilitate the review of the information provided.

**North Macedonia (Rep. of):** The Commission noted the information regarding the serological survey for PPR under the sampling framework of brucellosis. The Commission took note of the three seropositive results which were followed-up with clinical examination of those animals, and that the proportion of seropositive results fell within the expected range of the diagnostic test specificity. The Commission requested North Macedonia to provide an update regarding i) the protocol for follow-up of PPR seropositive reactors, ii) the simulation exercise planned for the first half of 2022 and iii) further progress made on improving control and reducing non-compliant internal movement of animals, when reconfirming in November 2022.

**Russia:** The Commission commended Russia for the comprehensive information and documented evidence provided on the actions taken with regard to the recommendations for the imports of small ruminants conducted from PPR infected countries in compliance with Article 14.7.10. of the *Terrestrial Code* and requested Russia to continue provide information on importation of PPR susceptible animals and their products including documented evidence demonstrating compliance with Chapter 14.7. in future annual reconfirmations. The Commission took note of the follow up investigations of PPR suspect cases in wildlife following mass mortality events in roe deer and noted that all samples from these events tested negative for PPR by qRT-PCR performed in the National Reference Laboratory accredited for performing diagnosis of highly dangerous animal diseases. Considering that the diagnostic tools for PPRV detection and assessment have not yet been standardised and properly validated according 'fit for purpose' principle in wildlife, the Commission recommended to Russia that any samples taken in wildlife are sent for further laboratory testing to an OIE Reference Laboratory for PPR for its confirmation.

*Conclusion:* The Commission concluded that the annual reconfirmations of the above-listed Members were compliant with the relevant requirements of Chapter 14.7. of the *Terrestrial Code* for the maintenance of the officially recognised PPR free status.

#### 9.2. Annual reconfirmations screened by the OIE Status Department

The OIE Status Department reviewed the rest of the annual reconfirmations for PPR free status and reported the outcome of its analysis to the Commission as follows:

The annual reconfirmations for the following Members were reviewed:

#### Annex 8 (contd)

A	C 1 D 11	T. A.	D .
Argentina	Czech Republic	Latvia	Romania
Australia	Denmark	Liechtenstein	Singapore
Austria	Ecuador	Lithuania	Slovakia
Belgium	Estonia	Luxembourg	Slovenia
Bolivia	Eswatini	Malta	South Africa
Bosnia and Herzegovina*	Finland <sup>36</sup>	Mexico	Spain <sup>37</sup>
Botswana	France <sup>38</sup>	New Caledonia	Sweden
Brazil	Germany*	New Zealand	Switzerland
Canada	Greece*	Norway	The Netherlands
Chile	Hungary	Paraguay	United Kingdom <sup>39</sup>
Chinese Taipei	Iceland	Peru	United States of America <sup>40</sup>
Colombia	Ireland	Philippines	Uruguay
Croatia	Italy*	Poland	
Cyprus	Korea (Rep. of)	Portugal <sup>41</sup>	

Report of the annual reconfirmation assessments

The OIE Status Department raised the attention of the Commission to the Members marked with an asterisk (\*). The corresponding annual reconfirmations were discussed during the Commission's meeting as follows:

**Bosnia and Herzegovina:** The Commission acknowledged the comprehensive information provided by Bosnia and Herzegovina. The Commission noted with concern that small ruminants had been imported into Bosnia and Herzegovina from a country not officially recognised as PPR free by the OIE, and without having been subjected to quarantine (for slaughter purpose) or laboratory testing for PPRV neither prior shipment nor during quarantine, as stipulated in Article 14.7.10. of the *Terrestrial Code*. The Commission highlighted that the importation of these commodities should fully comply with Article 14.7.10 of the *Terrestrial Code* and that such non-compliance could lead to risk of suspension of the official status. In this regard, the Commission requested Bosnia and Herzegovina to fully comply with Article 14.7.10. and provide documented evidence of compliance when reconfirming in November 2022.

**Germany:** The Commission acknowledged the information provided by Germany on the imports of PPR susceptible animals. However, the Commission noted with concern that small ruminants had been imported into Germany from a country with undetermined PPR status, without having been subjected to quarantine and laboratory testing for PPRV prior to shipment, as per Article 14.7.10. of the *Terrestrial Code*. In addition, the veterinary certificate that accompanied this import did not specify any requirement for attestation that the animals had not been vaccinated against PPR. The Commission mentioned that such non-compliance could lead to suspension of the official status, and requested Germany to reconsider the requirements stated in the veterinary certificate and provide documented evidence of full compliance with Article 14.7.10. when reconfirming in November 2022.

**Greece**: The Commission appreciated the comprehensive information on surveillance and awareness activities in place with regard to PPR as well as the imports of PPR susceptible animals provided by Greece. However, the Commission noted with concern that two small ruminants had been imported into Greece from a country with undetermined PPR status, without having been subjected to quarantine and laboratory testing for PPRV prior to shipment, as per Article 14.7.10. of the *Terrestrial Code*. In addition, the veterinary certificate that accompanied this import did not specify any requirement for attestation that the animals had not been vaccinated against PPR. The Commission noted that such non-compliance could lead to suspension of the official status. The Commission requested Greece to fully comply with Article 14.7.10. of the *Terrestrial Code* and provide documented evidence of compliance when reconfirming in November 2022.

<sup>&</sup>lt;sup>36</sup> Including Åland Islands.

<sup>&</sup>lt;sup>37</sup> Including Balearic Islands and Canary Islands.

<sup>&</sup>lt;sup>38</sup> Including French Guiana, Guadeloupe, Martinique, Réunion, Saint Barthélémy, Saint Martin, Saint Pierre and Miquelon.

<sup>&</sup>lt;sup>39</sup> Including Cayman Islands, Guernsey (incl. Alderney and Sark), Isle of Man, Jersey, Saint Helena and Falkland Islands (Malvinas). (A dispute exists between the Government of Argentina and the Government of the United Kingdom of Great Britain and Northern Ireland concerning sovereignty over the Falkland Islands (Malvinas) (see resolution 2065 (XX) of the General Assembly of the United Nations).

<sup>&</sup>lt;sup>40</sup> Including American Samoa, Guam, Northern Mariana Islands, Puerto Rico and US Virgin Islands.

<sup>&</sup>lt;sup>41</sup> Including Azores and Madeira.

**Italy**: The Commission acknowledged the import regulations regarding PPR implemented by Italy. However, the Commission noted that the veterinary certificate that accompanied the import of sheep skins from a country with undetermined PPR status did not fully comply with the Chapter 14.7. of the *Terrestrial Code*. The Commission noted that such non-compliance could lead to suspension of the official status. The Commission requested Italy to reconsider the requirements stated in the veterinary certificate in accordance with Article 14.7.24 of the *Terrestrial Code* and provide documented evidence of compliance when reconfirming in November 2022.

*Conclusion*: The Commission recommended the maintenance of the officially recognised PPR free status of the above-listed Members.

Original: English January 2022

#### SUMMARY OF THE EXPERT ASSESSMENT OF PARATUBERCULOSIS AGAINST THE LISTING CRITERIA OF TERRESTRIAL CODE CHAPTER 1.2.

#### **JANUARY 2022**

Three experts participated in this consultation:

- Dr Bernardo ALONSO (OIE Reference Laboratory for Paratuberculosis SENASA, Argentina)
- Dr Virginie POISSON (OIE Reference Laboratory for Paratuberculosis, ANSES, France)
- Prof. Richard WHITTINGTON (The University of Sydney, Australia).

#### 1. Summary

Criterion	1	2	3
<b>Criterion 1:</b> International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven.	YES	YES	YES
<b>Criterion 2:</b> At least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the provisions of Chapter 1.4.	NO	YES	YES
<b>Criterion 3:</b> Reliable means of detection and diagnosis exist, and a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections or infestations.	YES	YES	YES
Criterion 4a: Natural transmission to humans has been proven, and human infection is associated with severe consequences.	NO	NO	inconclusive
<b>Criterion 4b:</b> The disease has been shown to have a significant impact on the health of domestic animals at the level of a country or a zone taking into account the occurrence and severity of the clinical signs, including direct production losses and mortality.	YES	YES	YES

#### Summary of the Expert Assessment of Paratuberculosis

<b>Criterion 4c:</b> The disease has been shown to, or scientific evidence indicates that it would, have a significant impact on the health of wildlife taking into account the occurrence and severity of the clinical signs, including direct economic losses and mortality, and any threat to the viability of a wildlife population.	NO	inconclusive	YES
CONCLUSION: Does paratuberculosis match the listing criteria that are described in the Terrestrial Animal Health Code Chapter 1.2?	NO	YES	YES

#### 2. Scientific rationale

### 2.1. Criterion 1: International spread of the pathogenic agent (via live animals or their products, vectors or fomites) has been proven

The causative agent *Mycobacterium avium* subsp. *paratuberculosis* (MAP) is an obligate parasite of animals. The most common means of spread is through movement of live animals, most of which are subclinically infected. MAP can survive for months in soil, water, pasture but transboundary spread in these matrices is probably uncommon. Transboundary spread of MAP has led to outbreaks of disease that have required long term responses to bring under control. Examples of international spread of MAP through movement of infected live animals include:

- Germany to Iceland (1933) [1]
- New Zealand to Australia (1970s) [2]
- Australia to Japan (2016)<sup>1</sup>
- Various to Sweden (historically) [3,4]

## 2.2. Criterion 2: At least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the provisions of Chapter 1.4

The experts noted publications that provide evidence that Sweden is free from paratuberculosis in cattle [5–7]. However, acknowledging a European Food Safety Authority report [8] that disagrees with this assessment, one expert selected 'NO' for this criterion. In contrast, the other experts selected 'YES', and one made the following remarks:

With reference to EU countries, EFSA stated that 'There are not sufficient data to prove disease freedom or near-zero prevalence in any member state. Some countries such as Sweden may have a low prevalence in cattle, but claims to support disease freedom (Frossling et al., 2013) are not based on sampling and testing schemes designed and carried out to prove disease freedom.' [8]. This statement is not correct and requires elaboration because:

i) Sweden based its 2020 claim of freedom on historical stamping out and control measures, detection only in imported cattle, low numbers of imported cattle, clinical surveillance, post mortem sampling, voluntary surveillance, bulk milk testing and abattoir testing, i.e. activities designed, coordinated and carried out with a clear intention. Bulk milk testing alone would provide 99% probability of freedom by 2021.

ii) contemporary epidemiologically based surveillance programs use holistic approaches that combine information from different sources

iii) OIE mandates surveillance that encompasses a range of data sources beyond structured surveys [9], including the types of surveillance activity used by Sweden.

## 2.3. Criterion 3: Reliable means of detection and diagnosis exist, and a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections or infestations

The experts all responded 'YES' to this question. All referred to Chapter 3.1.15. 'Paratuberculosis (Johne's disease)' of the OIE *Terrestrial Manual* [10].

One expert emphasised that paratuberculosis presents as a range of sub-clinical and clinical forms during its long incubation period, and that this chronicity of pathogenesis contributes to difficulties with disease diagnosis at each stage of progression. However, case definition terminologies and application of case definitions for paratuberculosis have been proposed [11] and the characteristics of diagnostic tests in the

<sup>&</sup>lt;sup>1</sup> https://www.awe.gov.au/sites/default/files/sitecollectiondocuments/biosecurity/export/live-animals/advice-notices/2016/2016-17.pdf

#### Summary of the Expert Assessment of Paratuberculosis

context of each stage of the disease are well known. This expert recommended updating the *Terrestrial Manual* chapter to accommodate recent advances in diagnostic tests for paratuberculosis.

### 2.4. Criterion 4a: Natural transmission to humans has been proven, and human infection is associated with severe consequences

The experts expressed uncertainty with respect to this criterion. Each mentioned the possible association of MAP with the inflammatory bowel disease Crohn's disease, but noted that causation is not yet confirmed [12–14].

### 2.5. Criterion 4b: The disease has been shown to have a significant impact on the health of domestic animals at the level of a country or a zone taking into account the occurrence and severity of the clinical signs, including direct production losses and mortality

The experts agreed that paratuberculosis is a wasting disease with substantial economic, health and welfare impacts. Many references were provided to support this position (available on request); the findings of many of these are summarised in a recent review article [4].

# 2.6. Criterion 4c: The disease has been shown to, or scientific evidence indicates that it would, have a significant impact on the health of wildlife taking into account the occurrence and severity of the clinical signs, including direct economic losses and mortality, and any threat to the viability of a wildlife population

Although the experts agreed that paratuberculosis is described in wild animals ('practically all mammals'; 'more than 100 vertebrate species'), they differed in their assessment of the significance (for example, deaths, or loss of biodiversity) of this finding. However, one expert provided information about apparent spillover or endemnicity described in wildlife in some countries, with economic consequences for farmed wildlife, and unknown consequences for conservation of free-ranging wildlife, endangered species or those in captive breeding programs [15,16].

#### 2.7. Conclusion

Despite the uncertainty in the assessment of paratuberculosis against criterion 2, the experts were unanimously firm in their opinion that paratuberculosis should be maintained as an OIE-listed terrestrial animal disease. They noted that paratuberculosis is responsible for important economic losses, and that, if uncontrolled, it will continue to spread internationally.

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Annex 10

Original: English October 2021

#### REPORT OF THE DEVELOPMENT OF THE CASE DEFINITION FOR INFECTION WITH COXIELLA BURNETII (Q FEVER)

#### 18 May to 1 October 2021

The objective of this report is to provide the rationale and scientific justification for elements of the case definition for infection with *Coxiella burnetii* (Q fever) which was developed via videoconference and email exchange between 11 May and 1 October 2021.

The purpose of the case definition is to support notification to the OIE as described in the OIE *Terrestrial Animal Health Code* (*Terrestrial Code*) Chapter 1.1.

Details of the experts and OIE staff who contributed to the drafting process are provided in Appendix 1.

#### 1. Process

*The Official 2021-1* provides a synopsis of this initiative: 'Developing case definitions for OIE-listed diseases for terrestrial animals'<sup>1</sup>.

This report including the draft case definition will be presented for consideration first to the Biological Standards Commission (BSC) and then to the Specialist Commission for Animal Diseases (SCAD) at their next meetings. After endorsement by SCAD, and provided there is no conflict with the OIE Terrestrial Code, the finalised case definition will be published on the OIE website and, following the standard-setting process, eventually will be included in the *Terrestrial Code*.

#### 2. Background

#### 2.1. Listing, OIE Terrestrial Code and Terrestrial Manual

'Q fever' is listed in the *Terrestrial Code* Chapter 1.3. 'Diseases, infections and infestations listed by the OIE' in Article 1.3.1. in the category of multiple species diseases, infections and infestations. There is no corresponding disease-specific chapter in the *Terrestrial Code*, but the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2021* (the *Terrestrial Manual*) contains Chapter 3.1.16. 'Q fever', the most recent updates to which were adopted in 2018.

#### 2.2. OIE-WAHIS information

OIE-WAHIS was consulted on 20 December 2021 for summary information<sup>2</sup> on 'Q fever' developed from data contained in official reports (six-monthly reports, and immediate notification and follow-up reports). Figure 1 summarises the total numbers of new outbreaks reported to the OIE between January 2005 and June 2021.

<sup>&</sup>lt;sup>1</sup> <u>https://oiebulletin.fr/?officiel=10-3-2-2021-1 case-definitions</u> 2 https://uubic.cic.int/#/deable.acde/cat.int.html

<sup>&</sup>lt;sup>2</sup> <u>https://wahis.oie.int/#/dashboards/qd-dashboard</u>

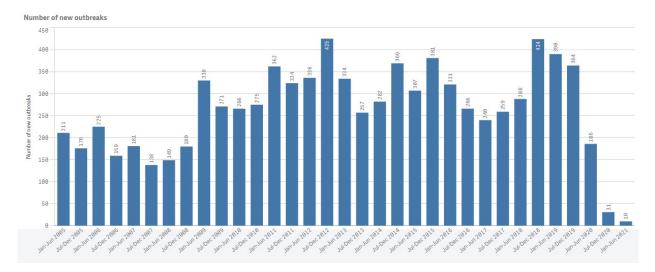


Figure 1 New outbreaks of 'Q fever' notified to OIE-WAHIS by Members between January 2005 and June 2021.

#### 3. Discussion

#### 3.1. Disease name

The experts discussed the use of differing terms for infection of *Coxiella burnetii* in humans ('Q fever') and in animals ('coxiellosis') [1] and noted that 'Q fever' is commonly used among public health and animal health professionals and is widely understood to refer to infection with *C. burnetii* regardless of host species.

The experts suggested that the OIE listing for this condition be updated to follow the pattern of 'infection with [pathogenic agent]'.

#### 3.2. Pathogenic agent

The pathogenic agent for 'Q fever' is the Gram-negative, intracellular bacterium C. burnetii [2].

#### 3.3. Host

The experts agreed that humans and a wide range of domestic and wild animal species are susceptible to infection with *C. burnetii* [3] but considered that wild animal species play minor roles in the epidemiology of the disease. For the purpose of *notifications* to the OIE, they recommended that the animal hosts be defined as domestic and captive wild ruminants (noting that reliable diagnostic tests are available for some domestic species) and included dogs and cats because of the potential risks to public health [4–6].

#### 3.4. Epidemiologic and diagnostic criteria

The experts noted that an important characteristic of *C. burnetii*, shared with some Gram-positive bacteria, is the development of a spore-like form which plays a major role in host persistence as well as environmental resistance and spread.

The experts emphasised that Q fever (or coxiellosis) is a very complex disease and that diagnosis, particularly on an individual level, remains difficult. Issues include: cross reaction of PCR tests with *Coxiella*-like bacteria [7], individual variations in the course of the infection (i.e. heterogeneity of the sites for detection of *C. burnetii*, diversity of routes and intermittence of bacterial excretion), reliability of the sensitivity and specificity of available serological tests [8], and in the kinetics of antibodies (in precocity, rate, or duration). The experts discussed sampling and diagnostic protocols and procedures (e.g. timing of sampling for vaginal swabs, regularly repeated tank milk tests, serological screening, and environmental testing [9,10]). They recommended that Chapter 3.1.16 of the *Terrestrial Manual* be

updated to provide details of recent advances, additional guidance on the relevant samples to collect, and diagnostic protocols at individual or group levels.

The experts did not incorporate use of bacterial staining on samples (microscopy) in the case definition, because this technique lacks sensitivity and (especially) specificity, and requires experienced personnel. Further, a positive result must be then confirmed by molecular testing as described in the *Terrestrial Manual*.

The experts identified three options (any one of which is sufficient) to confirm a case of infection with *C. burnetii* for the purposes of notification to the OIE (Appendix 1).

They included as the first option the isolation and characterisation of *C. burnetii*, noting that the second option (detection of nucleic acid specific to *C. burnetii*) may be the most practical, as obtaining isolates is more laborious. The interpretation of small quantities should be conducted with caution. The detection of DNA from the bacteria in small quantities on vaginal swabs or in faeces samples could be due to environmental contamination (especially if the environment is highly contaminated [11–13]). Moreover, the experts acknowledged that cross reactions between *C. burnetii* and other *Coxiella*-like bacteria have been observed when molecular testing is used to detect genetic material in samples from ticks [7]. However, they considered that the likelihood of this occurring in samples from animals is negligible, so did not recommend any additional requirements to rule out infection with *Coxiella*-like bacteria.

The experts were not aware of the commercial availability of any multi-species competitive sandwich ELISA for the detection of *C. burnetii* antigens. Although some laboratories might develop their own inhouse methods, the experts agreed that the detection of *C. burnetii* antigen is not relevant for defining a case of infection with *C. burnetii* [14].

The experts extensively discussed the role of serological testing in confirming a case of infection with *C. burnetii*. They mentioned the limitations of serological testing, particularly at the individual level, and emphasised the importance of conducting testing at the group level, noting again that practical guidance should be made available in the *Terrestrial Manual*.

They noted that serological evidence of active infection by detection of seroconversion alone would not be sufficient to confirm a case of infection with *C. burnetii*, due to the possibility of serological cross reactions with other bacteria [15-18] so this option was excluded from the case definition.

The experts discussed the clinical signs that may be observed with infection of an animal host with *C. burnetii*, and decided that these are not sufficiently disease-specific to confirm a case of infection with *C. burnetii*, even in the presence of an antibody response (again, noting the possibility of serological cross reactions with other bacteria), so this combination (presence of antibodies and clinical signs) was not included in the case definition.

However, the experts agreed that the presence of antibodies in an animal host that is epidemiologically linked to a suspected or confirmed case infection with *C. burnetii* would constitute a confirmed case (option 3). The experts considered that, as it is currently not possible to differentiate antibodies due to natural infection from those resulting from vaccination, a requirement to do so should not form part of the case definition.

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 $\ldots$ /Appendices

Case definition: Infection with Coxiella burnetii (Q fever)

Appendix 1

#### REPORT OF THE DEVELOPMENT OF THE CASE DEFINITION FOR INFECTION WITH COXIELLA BURNETII (Q FEVER)

#### 18 May to 1 October 2021

#### List of contributors

#### **EXTERNAL EXPERTS**

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Original: English January, 2022

#### REPORT OF THE DEVELOPMENT OF THE CASE DEFINITION FOR INFECTION WITH CAMELPOX VIRUS (CAMELPOX)

#### 21 September 2021 to 8 January 2022

The objective of this report is to provide the rationale and scientific justification for elements of the case definition for infection with camelpox virus (camelpox), developed via videoconference and email exchange between 21 September 2021 and 8 January 2022.

The purpose of the case definition is to support notifications to the OIE as described in the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) Chapter 1.1.

Details of the experts and OIE staff who contributed to the drafting process are provided in Appendix I.

#### 1. Process

*The Official 2021-1* provides a synopsis of this initiative: 'Developing case definitions for OIE-listed diseases for terrestrial animals'<sup>1</sup>.

This report including the draft case definition will be presented for consideration first to the Biological Standards Commission (BSC) and then to the Specialist Commission for Animal Diseases (SCAD) at their next meetings. After endorsement by SCAD, and provided there is no conflict with the OIE *Terrestrial Code*, the finalised case definition will be published on the OIE website and, following the standard-setting process, eventually will be included in the *Terrestrial Code*.

#### 2. Background

Camelpox is listed in the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) Chapter 1.3. 'Diseases, infectious and infestations listed by the OIE' in Article 1.3.9. in the category of 'other diseases and *infections*'. There is no corresponding disease-specific chapter in the *Terrestrial Code*, but the current (2021) OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (the *Terrestrial Manual*) contains Chapter 3.5.1. 'Camelpox', the most recent update to which was adopted in May 2021.

OIE-WAHIS was consulted on 17 December 2021 for summary information<sup>2</sup> on 'camelpox' developed from data contained in official reports (six-monthly reports, and immediate notification and follow-up reports). Figure 1 summarises the total numbers of new outbreaks reported to the OIE between January 2006 and June 2021.

<sup>&</sup>lt;sup>1</sup> <u>https://oiebulletin.fr/?officiel=10-3-2-2021-1</u> case-definitions

<sup>&</sup>lt;sup>2</sup> <u>https://wahis.oie.int/#/dashboards/qd-dashboard</u>

#### Annex 11 (contd)

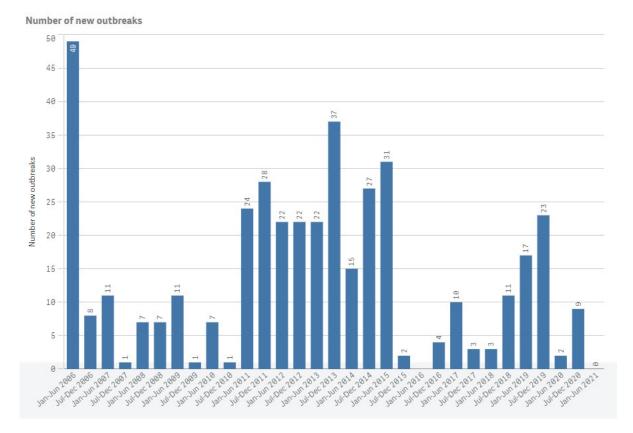


Figure 1 New outbreaks of 'camelpox' notified to OIE-WAHIS by Members between January 2006 and June 2021

#### 3. Discussion

#### 3.1. Disease name

The experts noted that as disease-specific chapters in the *Terrestrial Code* are created or updated, the convention is to refer to the disease or infection as 'infection with [pathogenic agent]' and to reflect<sup>3</sup> this in both the title of the disease-specific chapter, and in the corresponding listed entry in Chapter 1.3. In consequence, the experts recommended that the entry for camelpox in Chapter 1.3 be updated to 'infection with camelpox virus'.

#### **3.2.** Pathogenic agent

The experts agreed that the pathogenic agent for this condition is the camelpox virus, a member of the *Orthopoxvirus* genus in the *Poxviridae* family[1,2].

#### 3.3. Host animals

Although most publications documenting natural infection with camelpox virus describe this as occurring in dromedary camels (the single-humped species *Camelus dromedarius*), the two-humped Bactrian camel (*Camelus bactrianus*) is also susceptible [3,4]. The experts considered that for the purposes of notification to the OIE, the host animal is the camel and includes both dromedary and Bactrian species.

<sup>&</sup>lt;sup>3</sup> Since 2012.

#### 3.4. Diagnostic and epidemiologic criteria

The experts identified **four options** (any one of which is sufficient) for confirming a case of infection with camelpox virus for the purposes of notification to the OIE (<u>Appendix 1</u>).

#### 3.4.1. Option 1

The distinctive size and shape of camelpox orthopox virions when viewed by transmission electron microscopy allows differentiation of camelpox virus from both camel contagious ecthyma (camel orf) and papillomatosis [5]. However, the experts recommended that to confirm a case of infection with camelpox virus, this finding should be accompanied by either the presence of clinical signs consistent with camelpox or that an epidemiological link to a confirmed case of camelpox should be present.

#### 3.4.2. Option 2

The experts agreed that isolating and characterising camelpox virus from samples from a camel would be sufficient to confirm a case of infection with camelpox virus. They elected to omit 'excluding vaccine strains' from this option as this was not considered relevant. Although both inactivated and live attenuated vaccines against camelpox are commercially available [3], reversion to virulence has not been demonstrated and the experts further noted that vaccine virus would not be isolated from the skin samples typically collected for diagnostic purposes.

#### 3.4.3. Option 3

The experts discussed the detection of antigens or genetic material specific to camelpox virus in samples from a camel. The role of arthropod vectors in the transmission of camelpox has been suggested [6] but not yet confirmed; nevertheless, genetic material from the camelpox virus has been isolated from *Hyalomma dromedarii*, the predominant tick species infesting camels [7]. Recognising the possibility that a tick infected with camelpox virus might transmit viral genetic material (but not necessarily infective viral particles) to a camel, the experts emphasised the need to include the additional supporting requirements (either the camel is showing clinical signs consistent with infection with camelpox virus) for confirming a case when genetic material specific to camelpox virus has been identified.

#### 3.4.4. Option 4

The experts noted that antibody testing would not be used to confirm a case of infection with camelpox for the purposes of notification in many countries, as vaccination against the disease is widespread and antibodies are persistent after infection. In addition, it is currently not possible to differentiate infected from vaccinated animals. However, noting that there is at least one country (Australia) with significant populations of dromedary camels where camelpox is not present and vaccination against camelpox is not practised [8], the experts recommended the inclusion of this option.

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.../Appendices

#### Appendix I

#### REPORT OF THE DEVELOPMENT OF THE CASE DEFINITION FOR INFECTION WITH CAMELPOX VIRUS (CAMELPOX)

#### Virtual, 21 September 2021 to 8 January 2022

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#### WORK PROGRAMME OF THE OIE SCIENTIFIC COMMISSION FOR ANIMAL DISEASES

#### February 2022

	Issue and priority order (1-3; 1 being highest priority)	February 2022
Upd	ate of OIE standards	
	Glossary	Not on agenda
1	Ch. 1.2. 'Criteria for the inclusion of diseases, infections or infestations in the OIE list'	Not on agenda
1	Ch. 1.3. 'Diseases, infections and infestations listed by the OIE'	Not on agenda
	Ch.8.8. Infection with foot and mouth disease virus	Considered comments from Members, proposed amendments, and forwarded to TAHSC.
	Ch. 8.14. 'Infection with rabies virus'	Not on agenda
	Chapter 8.15. Infection with Rift Valley fever virus	Not on agenda
	Chapter 8.16. Infection with rinderpest virus	SCAD was informed that the draft revised Chapter will be proposed for adoption in May 2022. SCAD was informed and agreed on the timeline that the risk assessment questionnaire, as well as the questionnaire template for recovery of rinderpest-free status and SOP describing the guidelines for this process will be presented for its review in September 2022 and subsequently made available on the OIE website.
1	Chapter 8.X. Infection with Trypansoma evansi (surra)	Not on agenda
	Ch. 11.4. Bovine spongiform encephalopathy	SCAD considered specific questions forwarded by the Code Commission in its February 2022 meeting in relation to the official recognition and maintenance of BSE risk status of Members. SCAD specifically addressed Members comments regarding i) determination and publishing of a precise 'starting date' when the risk of BSE agents being recycled within the cattle population could be considered negligible, ii) development of guidelines on BSE surveillance to help Members to revise their surveillance programmes in accordance with the new BSE standards. SCAD opinion forwarded to TAHSC and addressed at its February 2022 meeting.

	Issue and priority order	February 2022
(1-3; 1 being highest priority)		
Upd	ate of OIE standards	
1	Ch. 12.1. Infection with African horse sickness virus	Not on agenda
3	Ch. 12.2. Contagious equine metritis	Not on agenda
1	Chapter 12.3. 'Dourine'	Not on agenda
3	Ch. 12.7. Equine piroplasmosis	Not on agenda
Offi	cial animal health status recognition	
1	Evaluation of Member dossiers	SCAD considered five reports of <i>ad hoc</i> Groups on the evaluation of Members' status and endorsement of official control programmes (AHS, BSE, CBPP, CSF and FMD). No applications were received for PPR and dog-mediated rabies. Eight applications were recommended for recognition of official status/endorsement and six applications were rejected.
2	Expert missions to Members	<ul> <li>Same as September 2021: The sanitary situation precluded in-person missions; until this becomes possible, animal health situations will be monitored through the annual reconfirmation campaign and (as needed) with virtual interviews.</li> <li>SCAD recommended one field mission for the maintenance of FMD status in June 2022, provided that the sanitary situation allows.</li> </ul>
2	Follow up of Members 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; ongoing process.February 2022:Kazakhstan, suspension of FMD free zone status where vaccination is not practised (Zone 5).Myanmar (AHS) and Thailand (PPR), withdrawal of suspended status.
1	Review of annual reconfirmations	<ul> <li>[Each February meeting] SCAD evaluates the annual reconfirmations of selected Members' animal health status and OIE-endorsed official control programmes.</li> <li>[Each September meeting] SCAD selects 10% of Members' animal health status for comprehensive review at its February meeting.</li> <li>February 2022: SCAD comprehensively reviewed the preselected 48 annual reconfirmations, as well as eight additional ones raised by the Status Department. SCAD considered a discussion paper regarding the documented evidence needed for CSF and PPR annual reconfirmations upon adoption of these Chapters including harmonised requirements in May 2021.</li> </ul>

	Issue and priority order (1-3; 1 being highest priority)	February 2022
Offi	cial animal health status recognition	
1	Harmonisation of the requirements in the <i>Terrestrial Code</i> Chapters for recognition and maintenance of official disease-free status	Not on agenda
1	Impact of revisions of BSE standards on Members' BSE risk status	SCAD comprehensively reviewed the annual reconfirmations and additional information submitted by eight Members based on the recommendations of the <i>ad hoc</i> Group on the revision of BSE standards and its impact on the official status recognition (June 2021). After assessing the implications and different options for better transition and management of the official BSE risk status recognition and maintenance procedure, SCAD agreed that the new standards will be implemented for official status purposes after May 2023.
Dise	ase control issues	
2	Advise on global strategies and initiatives (FMD, PPR, rabies, ASF)	Updated on the progress made.
1	Consider non-disease-Status and non- standard-setting <i>ad hoc</i> Groups reports falling into the SCAD remit	Not on agenda
2	Assess recent developments in control and eradication of infectious diseases	All covered under specific subject areas.
1	Evaluation of emerging diseases	The Bureaus did not agree with the proposal that the <i>Terrestrial</i> <i>Code</i> (Glossary or Chapter 1.1) should be revised, because the SOP describes, standardises, and makes transparent the current emerging diseases notification process. However, they agreed on 1) the need to review the SOP to ensure it is seen as a guidance process for notification, and ensuring the involvement of Delegates in the process; and 2) to improve communications to promote the understanding of Delegates on the identification and notification of emerging diseases (e.g. further disseminate the SOP and the guidance document, both of which are currently available through the OIE website) and on the progress of the work for considering potential emerging diseases.
1	Evaluation of pathogenic agents against the listing criteria of Chapter 1.2.	SCAD discussed the listing criteria of Chapter 1.2, and emphasised that the criteria need to be interpreted in the context of OIE's mandates to facilitate safe trade, and to improve animal welfare and improve disease control (or eradication) measures. SCAD noted the potential to improve the clarity of the existing criteria and expressed the need to prioritise the revision of Terrestrial Code Chapter 1.2. This was noted at the meeting of the SCAD and TAHSC bureaus. Paratuberculosis: SCAD noted that if the criteria were strictly applied as (currently) written, paratuberculosis would not remain on the OIE list of terrestrial animal diseases. However, SCAD does not recommend delisting paratuberculosis at this time and instead recommends that it be reassessed after the criteria of Chapter 1.2 of the Terrestrial Code have been reviewed and revised.

Issue and priority order (1-3; 1 being highest priority)		February 2022
Disease control issues		
1	Development of case definitions	SCAD considered the progress made to date, and the feedback from Code Commission received at the meeting of the two bureaus on progress, process, and outputs. SCAD noted TAHSC input on prioritisation. SCAD revised the case definition for bovine viral diarrhoea (host range), and decided that isolation of a named pathogen implies that its identity is confirmed, so removed the expression 'and characterised' from this option in this and the other case definitions discussed at this meeting. Reviewed and revised the case definitions proposed in the
		expert reports (which they endorsed) for Q fever, and camelpox.
3	Insects	Covered under: 'Updates provided for SCAD information'
Liai	son with other Specialist Commissions	
1	Terrestrial Animal Health Commission	SCAD and TAHSC discussed the following topics separately and then together in a meeting of the two bureaus: listing/delisting assessments of pathogenic agents; bovine spongiform encephalopathy-related issues associated with proposed changes to Chapters 11.4 and 1.8. which are scheduled for adoption in May 2022; revisions proposed to Chapter 8.16. ('Infection with rinderpest virus'); case definitions, including the current implementation of the process; OIE's standard operation procedure for determining if a disease meets the Terrestrial Code definition of 'emerging disease', including discussion of concerns raised by a Member at the May 2021 General Session; the revised proposed case definition for infection with foot and mouth disease virus in Chapter 8.8. See the separate topics for more information.
1	Biological Standards Commission	Both BSC and SCAD were consulted about the DIVA PCR methods used to distinguish vaccine strains from field strains of lumpy skin disease virus (LSDV), and the challenges encountered in recent years with correctly identifying new recombinant field strains that have emerged in certain parts of the world. SCAD emphasized the need for infected countries to engage with OIE Reference Laboratories to facilitate the process of whole genome sequencing and the need for improving DIVA PCR methods.
Wo	rking Groups	
2	Antimicrobial resistance Working Group	Not on agenda
2	Wildlife Working Group	Not on agenda

Issue and priority order (1-3; 1 being highest priority)		February 2022
	er activities that could impact SCAD k programme	
1	Evaluation of applications for OIE Collaborating Centre status	Not on agenda
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 September 2021, including for African swine fever and lumpy skin disease.
3	Updates provided for SCAD information	<ul> <li>SCAD was informed about:</li> <li>OFFLU</li> <li>SIRCAH STAR-IDAZ International Research Consortium</li> <li>OIE antimicrobial resistance activities</li> <li>Global Burden of Animal Diseases programme (GBADS)</li> <li>OIE staff contribution to upcoming <i>Sci. Tech. Rev.</i> issue on 'Safety, regulatory, and environmental issues related to breeding and international trade of insects'.</li> </ul>
	Any other business	None at this meeting.