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REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Virtual meeting, 8–9, 11–12 February 2021

PART A – Texts to be proposed for adoption in May 2021

A virtual meeting of the OIE Biological Standards Commission was held from 8 to 9 and 11 to 12 February 2021. The list of participants can be found at Annex 1.

Considering the ongoing COVID-19 pandemic, the 88th Annual General Session will be held virtually from Monday 24 to Friday 28 May 2021. During this General Session new and revised chapters of the OIE International standards (the *Aquatic Animal Health Code*, the *Terrestrial Animal Health Code*, the *Manual of Diagnostic Tests for Aquatic Animals* and the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*) will be proposed for adoption.

To facilitate this process, the February 2021 meeting report of the Biological Standards Commission will be distributed in two parts: Part A (herewith) provides information about the new and revised texts for the *Terrestrial Manual* that will be proposed for adoption at the 88th General Session; and Part B (to be published in April 2021), will provide information about other topics discussed at the Commission's February 2021 meeting including the following items to be proposed for adoption: new applications for Reference Centre status and the OIE Register of diagnostic kits, as well as other topics for information.

In preparation for the 88th General Session, the OIE will organise a series of information webinars to ensure that Members are well aware of the background and key aspects of the standards being presented for adoption. Attendance to these webinars will be by invitation only. Please note that Delegates will soon receive detailed information about the virtual 88th General Session, and in particular the process for commenting and adoption of standards.

1. Welcome

Dr Matthew Stone, Deputy Director General (International Standards and Science) welcomed the Biological Standards Commission (the Commission), noting that this was the last meeting in the 3-year term, a term during which excellent productive output has been maintained despite significant challenges. Dr Stone recognised that the OIE has drawn heavily on the Specialist Commissions as it responded to the COVID-19 pandemic, and the response has always been in the spirit of goodwill, innovation and scientific excellence. Dr Stone thanked all members for their contributions during the term, including the forthcoming meeting, and extended this appreciation to the members' employing institutions and national governments. Dr Stone briefed the members on the ongoing design process for a full-virtual OIE General Session. He summarised the ongoing work on the OIE standards development and review system, including Standard Operating Procedures development and planning for digital tools. Finally, he provided an overview of the OIE's continuing support to the COVID-19 pandemic response, including *ad hoc* Groups, the development and implementation of the OIE Wildlife Health Management Framework and the compilation of services under the OIE Supporting Veterinary Services Resilience paper.

2. Adoption of Agenda

The proposed agenda was presented and adopted. The Agenda can be found at Annex 2.

3. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*

For this Agenda Item, the Commission was joined by Dr Steven Edwards, Consultant Editor of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (*Terrestrial Manual*).

3.3. Review of Member comments received on draft chapters and their endorsement for circulation for second-round comment and proposal for adoption in May 2021

Following Member comments that the terminology in Chapter 3.1.6 infection with *Echinococcus granulosus* and with *E. multilocularis* should be aligned with terms proposed by a WHO[1] expert group, and that the vaccine section should be expanded using the *Terrestrial Manual* vaccine section template, the Commission decided to put this chapter on hold and to request the OIE Reference Laboratory to address these comments with assistance from the WHO experts.

The Commission reviewed the comments that had been received on the 15 draft chapters that had been sent for first-round Member comment in October 2020. The Commission approved 14 for circulation, some subject to clarification of certain points by the experts, before presenting them for adoption by the Assembly in May 2021. At the 88th General Session in May 2021, these 14 chapters and the 24 chapters postponed in 2020, will all be proposed for adoption.

Comments had been received from: Australia, Canada, China (People's Rep. of), European Union, New Zealand, Switzerland.

The 14 chapters and a summary of the main amendments made in response to Member comments are provided below:

1.1.1. Management of veterinary diagnostic laboratories: added a sentence in Section A.1 *General considerations* on the support that veterinary laboratories can bring to national laboratory capacity during major human health events; amended text in Section A.2. *Accountability and oversight* to better reflect funding practices in national reference laboratories; in Section A.6.1 *Health and safety* added a specific recommendation to protect workers from chemicals, and a statement that training staff is key to avoiding accidents; expanded the title of Section A.6.2 *Biosecurity* to include biosafety and clarified the text on confidentiality requirements; deleted reference to ISO 9001 from Section B.3 Research; amended the title of Section B.4. *Disease surveillance* to *Information and data for disease surveillance* and updated the text accordingly; deleted sentences from Section C.3 Finance that were too prescriptive and focused on one specific way of running a laboratory.

3.1.3. Bluetongue (infection with bluetongue virus): in the summary, replaced "various other Artiodactyla" with "camelids" to clarify the species affected by bluetongue; deleted a sentence from the summary and introduction on the economic impact of the disease and trade restrictions as this text is beyond the scope of the *Terrestrial Manual*; deleted mention in the summary that the agar gel immunodiffusion test is one of the most frequently used serological tests; deleted the words "in Europe" from text referring to a higher incidence of clinical disease in cattle infected by serotype 8 as similar behaviour has been demonstrated with serotype 8 in North Africa and the Middle East; rejected a proposal to include a statement in Section A.1 *Description of the disease* on which serotypes are listed for intervention in one region as it is too area specific and disease notification is not covered in the *Terrestrial Manual*; in Table 1. *Test methods available and their purpose,* amended the ranking of the virus neutralisation test

1 WHO: World Health Organization

for the purpose "Individual animal freedom from infection prior to movement" because antibodies to all 27 serotypes would need to be tested to qualify an animal free from infection prior to movement, which is not practical; in Section B.1.3.1 Real-time RT-PCR[2] deleted the proposed amendments to the protocol so that the original method remains unchanged; in Section 2.4 *Agar gel immunodiffusion* explained what is meant by "problem samples".

3.1.12. Leptospirosis: regarding *Leptospira* taxonomy, added a reference and a hyperlink in the introduction to the latest information on strains, serovars, serogroups and species; in Table 1. *Test methods available and their purpose*, purpose "Contribute to eradication policies", amended the rating of isolation and identification [of leptospires] as it is difficult and time consuming, and for the purpose "Immune status in individual animals or populations post-vaccination" amended the rating of the MAT[3] as it is not suitable post-vaccination because it is not specific to a serovar, cannot differentiate between vaccinates and infected individuals, lacks sensitivity for vaccination induced antibodies and is transient, and removed the footnote that stated that isolation and typing should be carried out only on those animals that have positive serology because strains have been isolated from serologically negative animals; in Section A.1.1 *Isolation of* Leptospira added text that the diagnostic sensitivity of isolation is low but that having the strain provides important epidemiological information; rejected a request to reinstate a number of references: the Commission reminded Members that the *Terrestrial Manual* is not intended to provide comprehensive reviews of the literature, but rather to provide key, up-to-date references as an entry point to the literature for those who wish to study further – the Commission aims to limit the number of references in each chapter to a maximum of 30; rejected a proposal to change the temperature range for cultivation of cultures because no reference was provided; in the description of the MAT, the Commission rejected a request to identify counting leptospires in a counting chamber as the gold standard because it is only part of the procedure and the term "gold standard" is not used the *Terrestrial Manual*.

3.1.23. Vesicular stomatitis: harmonised the nomenclature and abbreviations used for the viruses causing vesicular stomatitis, and deleted mention of serotype throughout the chapter; removed mention of WAHIS from the summary and introduction because, as the disease is no longer listed, WAHIS is not a reliable source of current data; added Senecavirus A to Section B.1.1 *Direct visualisation* for differential consideration as outbreaks have been reported in regions that also experience VS outbreaks; made technical amendments to the test protocol in Section B.1.2 *Virus isolation in cell culture*; in Section B.1.6 *Real-time RT-PCR detection and typing*, amended the name and some of the sequences given in *Table 2. Oligonucleotides target for real-time RT-PCR of VSV;* made technical amendments to the test protocol in Section B.2.3 *Virus neutralisation*.

3.2.7. Varroosis of honey disease (infestation of honey bees with *Varroa* spp.): replaced the word "phoretic" with "dispersal phase" throughout the chapter as the latter is the correct term; added an arrow to Figure 2b to point out the location of the *Varroa* mite on a bee specimen; added a sentence in the introduction clarifying that for the purpose of the *Terrestrial Manual*, varroosis is linked to the detection of *Varroa* spp., regardless of the occurrence of clinical signs; did not agree to a request for clarification of a statement that deformed wing virus is well adapted to the life cycle of the *Varroa* mite because the statement is followed by a literature reference that would provide the information sought; replaced one of the photographs in Section B. *Diagnostic techniques* as it better illustrates the dorsal aspect of a female *V. destructor*.

2 RT-PCR: reverse-transcription polymerase chain reaction

3 MAT: microscopic agglutination test

3.3.4. Avian influenza (including infection with highly pathogenic avian influenza viruses): agreed to leave the title of the chapter unchanged as *Terrestrial Manual* chapters are titled by disease name (avian influenza) and in parenthesis the title of the corresponding revised chapter in the *Terrestrial Code*, which is the name of the infection; added a sentence regarding zoonotic potential of avian influenza viruses in the introduction; revised the texts to harmonise the information on sampling and initial testing in both the avian influenza and Newcastle disease chapters so that they are identical; deleted the information on notification obligations for the disease and inserted a reference to the *Terrestrial Code* chapter; elaborated the information to clearly state that the presence of multiple basic amino acids at the cleavage site remains the genotypic standard for designating high pathogenicity; removed references to specific biosafety containment levels from the chapter as these should be determined by biological risk analysis; made a number of editorial changes to address various comments on different sections of the chapter.

3.3.14. Newcastle disease (infection with Newcastle disease virus): amended the taxonomy throughout the chapter based on several Member comments and reverted to the use of virus names and not species – therefore, the term "avian paramyxovirus" has been used and a statement has been included in the introduction to reflect the new nomenclature; revised the texts to harmonise the information on sampling and initial testing in both the avian influenza and Newcastle disease chapters so that they are identical; deleted the information on notification obligations for the disease and inserted a reference to the *Terrestrial Code* chapter; made other editorial changes as received.

3.4.4. Bovine genital campylobacteriosis: did not agree to add a sentence and reference to Section B *Diagnostic techniques* referring to a genomic island that can be used to discriminate *Campylobacter fetus* subsp. *venerealis* from *C. fetus* subsp. *fetus* as the experts published a paper showing that this island can also be present in *C. fetus* subspecies *fetus* strains; added text to Section B.1.9 *Molecular identification of* Campylobacter fetus *subspecies* clarifying that PCR is not recommended for primary diagnosis, but that it is possible to perform it from Thomann's transport and enrichment medium after enrichment; did not accept a proposal to add a new PCR and a reference to Table 3 *Sensitivity and specificity of* C. fetus (*sub*)*species identification of PCR assays* as only two *C. hyointestinalis* strains, the strain that cross reacts the most with *C. fetus*, had been tested; added text to Section B.2 *Serological tests – antibody detection* that the ELISA[4] is not considered validated; a significant Member comment on role and identification of *C. fetus* ssp. *venerealis* biovar intermedius (Cfvi) and on the methods of identification used for the *C. fetus* group will be addressed when the chapter is next updated.

3.5.3. Infection with *Trypanosoma equiperdum* (dourine in horses): did not agree to delete evidence of sexual transmission from the paragraph in the summary on definitive diagnosis as it is consistent with the rest of the chapter; added text to Section A *Introduction* clarifying that though nagana, surra and dourine all may present with similar chronic clinical signs, dourine initially often presents with the venereal clinical signs that progress to neurological and more chronic disease; deleted from the summary and from Section B.1.1 *Overview of parasitological methods* mention of diagnosis depending on evidence of sexual transmission as it is an epidemiological observation and not a test method; reinstated a sentence in Section B.1.1 on detection of trypanosomes in vaginal and urethral mucus samples as it provides important timing details that need to be considered in sample collection to improve testing sensitivity; in section B.2.1.1.2 *Antigen preparation from* in-vivo *propagated parasites*, replaced "trypanosome bodies" with "trypanosomes"; in Section B.2.4 Other serological tests, did not agree to reinstate traditional tests, such as radioimmunoassay, agar gel immunodiffusion and card agglutination, as they are not fit for purpose; deleted Section B.3 Confirmation of dourine cases as case definitions should be included in the *Terrestrial Code* rather than the *Terrestrial Manual*.

4 ELISA: enzyme-linked immunosorbent assay

3.5.5. Equine encephalomyelitis (Eastern, Western and Venezuelan): replaced the term "Old World" with a region-specific description; rejected a proposal that the effect of climate change on the vector populations and thus on the prevalence and distribution of mosquito-borne diseases should also be covered in this chapter because climate changes is beyond the scope of the *Terrestrial Manual*, which focuses on diagnosis; deleted information on Old World alphaviruses as it is not relevant for this chapter about equine encephalomyelitis; added a sentence and a reference on the potential transmission of Eastern equine encephalomyelitis virus (EEEV) from horses with a transient EEE viraemia to mosquitoes, which could allow them to play a role in ongoing transmission; in Section B.1.1 In-vitro *and* in-vivo *culture* deleted text on the use of newly hatched chickens for virus isolation; in Section B.1.2.2 *Real-time reverse-transcription PCR*, Table 3, added primer/probe sequences for Venezuelan equine encephalomyelitis along with a reference; in Section B.2.1 *Complement fixation*, added a sentence that the effectiveness of the antigen inactivation treatment should be confirmed before working with the antigen.

3.6.1. Myxomatosis: amended the name of the Shope fibroma virus to rabbit fibroma virus, throughout the chapter, which is approved by the International Committee on Taxonomy of Viruses; added a sentence and references to the introduction on the new genetic variant of *Myxoma* virus isolated from the European brown and Iberian hares; updated Section B.1.6 *Molecular methods – detection of nucleic acid* to include a real-time PCR; in Section C *Requirements for vaccines*, added a sentence and a reference to a licensed novel trivalent recombinant attenuated vaccine.

3.8.6. Porcine reproductive and respiratory syndrome (PRRS): included text on evidence that highly pathogenic strains of PRRS virus are also able to infect endothelial cells in lung, heart and brain, an attribute that may be of value in characterising new strains; added real-time RT-PCR to the summary and to Table 1 *Test methods available and their purpose* as the test had already been included in Section B *Diagnostic techniques;* reinstated the immunohistochemistry method and *in-situ* hybridisation in Table 1 as such tests can also provide additional information on the pathogenesis of a particular strain; in Section B.1.3 *Other methods* added text indicating that restriction fragment length polymorphism has been largely discredited as a reliable epidemiological tool for PRRS due to the highly error-prone nature of PRRSV replication; also in Section B.1.3 *Other methods* added text on the advantages and drawbacks of ORF5 sequencing, along with a protocol for an ORF5 PCR; in Section B.2 *Serological tests* clarified the text on the limited diagnostic value of serological tests as results can be influenced by maternal antibodies or previous vaccination: to diagnose active infection in an individual animal, acute and convalescent serum samples can be tested to demonstrate seroconversion; in Section C2.1.1 *Biological characteristics* included the recommendation to determine the full genome sequence of the PRRS master seed virus and to use this reference sequence to control the genetic stability of the PRRS modified live virus during the production process or during the serial *in-vivo* passages; in Section C2.1.2 *Quality criteria* (*sterility*, *purity*, *freedom from extraneous agents*) added that the PCR might also be used, as a complement to culture, to detect extraneous virus that could be present in the PRRS master seed virus; in Section C.2.3.2 *Efficacy requirement* specified that the interference of maternally derived antibody with the efficacy of modified live vaccines needs to be evaluated.

3.9.6. *Listeria monocytogenes:* added hedgehogs to *Table 1. Species with reported isolation of* Listeria monocytogenes; in the introduction, added text on the presence of the bacterium in environmental niches, including soil, water and plants, and qualified that HACCP[5] as one food preparation method to reduce the risk of listeriosis in humans; deleted MALDI-TOF MS[6] from Table 1. *Test methods available and their purpose* as it is not a test method on its own but

5 HACCP: hazard analysis critical control points
6 MALDI-TOF MS: matrix-assisted laser desorption ionisation–time of flight mass spectrometry

rather an identification method for isolates; clarified the text in Section B.1.1. *Bacterial isolation methods* on the principles of the ISO 11290 Part 1 method; in Section B.1.2 *Culture-based identification methods* added information on the hybrid sub-lineage of the major lineage II (HSL-II) of *L. monocytogenes;* in Section B.1.6.1 *Serotyping and genoserotyping* (*PCR group*) amended the number of *L. monocytogenes* serovars to include a newly identified serovar and added text and a reference to a PCR method that can detect it; in Section C Requirements for vaccines, added text on safety concerns regarding the use of *L. monocytogenes* vectored vaccines in dogs.

3.9.11. Zoonoses transmissible from non-human primates: updated the reference to the Federation of European Laboratory Animal Science Associations; in Section 1. *Tuberculosis,* added a sentence clarifying that tuberculins prepared for use in humans are not of sufficient potency to elicit a response in non-human primates; in Section 4. *Macacine herpesvirus 1* (*Simian herpes B virus, Cercopithecine herpesvirus 1*) clarified that PCR cannot identify latently infected macaques not actively shedding virus.

NB: All amendments made in response to Member comments are highlighted in yellow in the chapters.

The chapters can be downloaded from the following address:
http://web.oie.int/downld/Terr_Manual/MAILING_MARCH_2021.zip

Reminder: extract from the report of the September 2020 meeting of the Biological Standards Commission. The following 24 chapters are also proposed for adoption:

3.1. Review of comments received on chapters that would have been proposed for adoption in May 2020

As a result of the COVID-19 pandemic, the OIE Council decided, in agreement with the Director General, that alternative procedures to address key institutional and administrative matters would be instigated. As a consequence, no new or amended chapters for the *Terrestrial Manual* were proposed for adoption in 2020. Chapters that were to be proposed for adoption in 2020 will be proposed for adoption in May 2021. All relevant texts that were to be proposed for adoption in May 2020, which had been circulated in the February 2020 report, were open for one additional round of comments. Only substantial comments that had not been submitted before were considered. As stated in the February 2020 report, texts (incorporating any revisions resulting from this process) will be circulated with the February 2021 report as the versions to be proposed for adoption in May 2021.

Comments had been received from: China (People's Rep. of), Chinese Taipei, European Union, India, New Zealand, Switzerland.

The Commission reviewed the comments and approved the chapters for proposal for adoption at the 88th General Session in May 2021. A summary of the main amendments are provided below:

2.1.2. Biotechnology in the diagnosis of infectious diseases: the advantages and strengths of isothermal amplification were deleted from Section A.3 as they are described in the previous two paragraphs; the Commission agreed that the techniques described in Section A.4. *Diagnosis by restriction fragment length polymorphisms* (*RFLP*) *and related DNA-based approaches* are not front-line diagnostic tools and so changed the title to "*Analysis by restriction fragment length polymorphisms* (*RFLP*) *and related DNA-based approaches*". In Section C.5.1 *Coxiella burnetii* was added as the causative agent of Q fever.

3.1.7. Epizootic haemorrhagic disease (infection with epizootic haemorrhagic disease virus): in the summary, the number of non-structural proteins coded for by the EHD virus was changed from "five" to "at least four", and the time period post-exposure for antibodies to be detectable was changed from "between 10 and 14 days" to "from 8 days"; still in the summary a request to change serogroup-specific "RT-PCR" to "real-time RT-PCR" as one of the assays for detection of EHD virus was rejected as "RT-PCR" covers both conventional and real-time assays and the Commission did not want to limit the list to real-time RT-PCR; in Sections B.1.2.1 and B.1.2.2, the target genes of the PCR methods described were corrected; a sentence in Section C *Requirements for vaccines* was deleted as it referred to bluetongue and not EHD.

3.1.8. Foot and mouth disease (infection with foot and mouth disease virus) (Method of [vaccine] manufacture only): no comments received.

3.1.10. Japanese encephalitis (vaccine section): one Member requested reinstatement of the mouse inoculation test, but the Commission reconfirmed its removal as effective *in-vitro* methods exist and the absence of a method from the *Terrestrial Manual* does not mean that it cannot be used rather that it is not recommended by the OIE.

3.1.11. Leishmaniosis: minor editorial amendments to improve clarity; included a sentence and a reference to LAMP[7] as an alternative method for genetic analysis; added text and a reference to cross reactions found in dogs with *Trypanosoma* spp. using ELISA.

3.1.15. Paratuberculosis (Johne's disease): in the summary reinstated microscopy as one of the methods for confirming a diagnosis of paratuberculosis as faecal Ziehl–Neelsen staining is included in Table 1 *Test methods available for diagnosis of paratuberculosis and their purpose*; removed mention of the complement fixation test from the summary, and kept mention of the agar gel immunodiffusion test clarifying that it remains a valuable test for the detection of paratuberculosis in sheep; maintained deletion of the CFT from Table 1 but added text to Section 2.2. explicitly stating that the CFT works well on clinically suspect animals, but does not have sufficient specificity to enable its use in the general population for control purposes. Thus, the CFT is not recommended for control purposes nor for individual animal testing prior to international movement.

3.1.21. *Trypanosoma evansi* infection (surra in all species): added deer to the list of susceptible species; added a sentence and a reference stating that *Trypanosoma evansi* was considered a malignancy of *T. brucei* as this is an important characteristic of *T. evansi*; a proposal to delete the formol gel test was not accepted as it is the method of choice for camels.

3.3.3. Avian infectious laryngotracheitis: one comment received regarding a typo.

3.3.5. Avian mycoplasmosis (*M. gallisepticum, M. synoviae*): In Section B. 1.3.2. *16s-rDNA-PCR and denaturing gradient gel electrophoresis* a sentence regarding the method's suitability for use on DNA extracts from clinical specimens has been reinstated.

3.4.2. Bovine babesiosis: minor editorial amendments to improve clarity; a request to add more up-to-date molecular methods for detection of *B. bovis* and *B. bigemina* was put on hold as these methods are not sufficiently validated.

3.4.5. Bovine spongiform encephalopathy: amended text reference to EU legislation and included a hyperlink.

7 LAMP: loop-mediated isothermal amplification

3.4.8. Contagious bovine pleuropneumonia (infection with *Mycoplasma mycoides* subsp. *mycoides*): a suggestion to consult OIE WAHIS interface[8] for latest disease situation was included as the *Terrestrial Manual* is not appropriate place to list the countries that are recognised by the OIE as officially free of CBPP through adoption of an annual resolution.

3.4.10. Haemorrhagic septicaemia (*Pasteurella multocida* serotypes 6:b and 6:e): deleted Section B.1.2.7 because antimicrobial sensitivity testing is not a serotyping method and is not used to identify HS strains; made minor amendments to the PCR protocols.

3.4.12. Lumpy skin disease (LSD): a request to delete electron microscopy from Table 1 was not accepted as the text reflects its deficiencies; deleted text in Section B.1.31 referring to PCR-based methods to distinguish between field and vaccine strains because emerging recombinant vaccine strains may not be recognised using these methods.

3.4.16. Animal trypanosomes of African origin (excluding infection with *Trypanosoma evansi* and *T. equiperdum*): the Commission noted that the taxonomy of Trypanosomes of African origin remains controversial and acknowledged that some studies considered that *T. evansi* and *T. equiperdum* evolved separately and therefore did not accept the proposal to consider *T. evansi* and *T. equiperdum* as a subspecies of *T. brucei*; a request to add a sentence on the high sensitivity and specificity of PCR methods was rejected as it applies to all PCRs and does not need to be restated here; added text and a reference to an FAO publication regarding the occurrence of *T. ingens* in domestic animals; did not agree to the proposal to state that *Trypanosoma lewisi* can be found in *Rattus* rodents as it is a parasite of other rodents.

3.5.8. Equine piroplasmosis: no comments received.

3.6.2. Rabbit haemorrhagic disease: text was added to the introduction to specify the susceptible host species in North America; a description was added to Section B.1.5 *Immunostaining* on findings in bone marrow and one reference was reinstated as it includes a description of renal mesangial cell positivity.

3.7.4. Contagious caprine pleuropneumonia: no comments received.

3.7.8. Ovine pulmonary adenomatosis (adenocarcinoma): no comments received.

3.7.9. Peste des petits ruminants (infection with small ruminant morbillivirus) (vaccine section only): no comments received.

3.8.1. African swine fever (infection with African swine fever virus): a sentence that had been inserted to recognise the existence of moderately virulent strains was modified to remove mention of the chronic form of the disease; the Commission did not agree to reinstate text on the role of the carrier and persistently infected wild pigs in eradication programmes as deletion of this text had been proposed in consultation with the Scientific Commission in September 2019 and no Member had commented on it then; as stated in the paragraph, the biological basis for the persistence of ASFV is still not well understood, nor is it clear what role persistence plays in the epidemiology of the disease; and finally the issue of disease control is not covered in the *Terrestrial Manual*.

3.9.2. Camelpox: no comments received.

3.9.5. Cysticercosis (including infection with *Taenia solium*): proposals to add text and references to genus-specific assays, along with the suggestion to add a new section on detection of taeniid eggs in environmental samples, food and water were deferred to the next update. Some discrepancies between the summary and the main text regarding vaccine registration were corrected, text on signs in pigs and immunocompromised human patients infected with various *Taenia* species was included in the introduction; technical points on meat inspection were updated or corrected; missing and updated references were added.

8 http://www.oie.int/en/animal-health-in-the-world/the-world-animal-health-information-system/the-world-animal-health-information-system/

3.x.xx Middle East respiratory syndrome (infection of dromedary camels with Middle East respiratory syndrome coronavirus): deleted text from the summary referring to notification as this issue is not covered in the *Terrestrial Manual*; also in the summary deleted speculative text on the risk of spill-over transmission to humans; deleted the text in Section C. *Requirements for vaccines* as it is speculative and replaced with text on available candidate vaccines; nomenclature: the Commission agreed to leave the title of the chapter unchanged as *Terrestrial Manual* chapters are titled by disease name (Middle East respiratory syndrome) and in parenthesis the title of the corresponding chapter in the *Terrestrial Code*, which is the name of the infection.

NB: All amendments made in response to Member comments are highlighted in yellow in the chapters.

The chapters can be downloaded from the following address:
http://web.oie.int/downld/Terr_Manual/MAILING_MARCH_2021.zip

To recap, below is a list of the 38 chapters that are proposed for adoption at the 88th General Session in May 2021. The chapters can be downloaded from the following address:

http://web.oie.int/downld/Terr_Manual/MAILING_MARCH_2021.zip

The chapters are also available on the Delegates website and on the website of the Biological Standards Commission.

1. 1.1.1. Management of veterinary diagnostic laboratories
2. 2.1.2. Biotechnology in the diagnosis of infectious diseases
3. 3.1.3. Bluetongue (infection with bluetongue virus)
4. 3.1.7. Epizootic haemorrhagic disease (infection with epizootic hemorrhagic disease virus)
5. 3.1.8. Foot and mouth disease (infection with foot and mouth disease virus)
6. 3.1.10. Japanese encephalitis (vaccine section)
7. 3.1.11. Leishmaniosis
8. 3.1.12. Leptospirosis
9. 3.1.15. Paratuberculosis (Johne's disease)
10. 3.1.21. *Trypanosoma evansi* infection (surra in all species)
11. 3.1.23. Vesicular stomatitis
12. 3.2.7. Varroosis of honey bees (infestation of honey bees with *Varroa* spp.)
13. 3.3.3. Avian infectious laryngotracheitis
14. 3.3.4. Avian influenza (including infection with high pathogenicity avian influenza viruses)
15. 3.3.5 Avian mycoplasmosis (*M. gallisepticum*, *M. synoviae*)
16. 3.3.14. Newcastle disease (infection with Newcastle disease virus)
17. 3.4.2. Bovine babesiosis
18. 3.4.4. Bovine genital campylobacteriosis
19. 3.4.5. Bovine spongiform encephalopathy
20. 3.4.8. Contagious bovine pleuropneumonia (infection with *Mycoplasma mycoides* subsp. *mycoides*)
21. 3.4.11. Haemorrhagic septicaemia
22. 3.4.12. Lumpy skin disease
23. 3.4.16 Animal trypanosomes of African origin (excluding infection with *Trypanosoma evansi* and *T. equiperdum*)
24. 3.5.3. Infection with *Trypanosoma equiperdum* (dourine in horses)
25. 3.5.5. Equine encephalomyelitis (Eastern, Western and Venezuelan)
26. 3.5.8. Equine piroplasmosis
27. 3.6.1. Myxomatosis
28. 3.6.2. Rabbit haemorrhagic disease
29. 3.7.4. Contagious caprine pleuropneumonia
30. 3.7.8. Ovine pulmonary adenomatosis (adenocarcinoma)
31. 3.7.9. Peste des petits ruminants (**NB:** Vaccine section only)

32. 3.8.1. African swine fever (**NB:** Introduction only)
33. 3.8.6. Porcine reproductive and respiratory syndrome
34. 3.9.2. Camelpox
35. 3.9.5. Cysticercosis (including infection with *Taenia solium*)
36. 3.9.6. Listeria monocytogenes
37. 3.9.11. Zoonoses transmissible from non-human primates
38. 3.x.xx Middle East respiratory syndrome (infection of dromedary camels with Middle East respiratory syndrome coronavirus)

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.../Annexes

Annex 1

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 8–9, 11–12 February 2021

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Annex 2

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 8–9, 11–12 February 2021

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Agenda

1. Welcome

2. Adoption of Agenda

3. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*

3.1. Review of Member comments received on draft chapters and their endorsement for circulation for second-round comment and proposal for adoption in May 2021

3.2. Request to include instructional training videos in *Terrestrial Manual* chapters

3.3. Review of the instructions for authors

3.4. Update from February 2018 meeting: review of a validation dossier for a quantitative real-time polymerase chain reaction method for detection of *Taylorella equigenitalis* directly from swabs

3.5. *Terrestrial Manual* status: update on chapters selected for the 2021/2022 review cycle

4. OIE Reference Centres

4.1. Annual reports of Reference Centre activities in 2020

4.2. Applications for OIE Reference Centre status

4.3. Changes of experts at OIE Reference Centres

4.4. Review of new and pending applications for laboratory twinning

4.5. Consultation with the Council: follow-up on Council's suggestions

Reference Laboratories – Implementation of the SOPs

4.6. Follow-up September meeting: further feedback from the Laboratories that are not complying with the key ToR according to their 2018 annual report

4.7. Feedback from the Laboratories that are not complying with the key ToR according to 2019 annual report

4.8. Annual report for Reference Laboratories for Rinderpest: adapted template

4.9. Further develop SOPs to include provisions for suspending laboratories and labs temporarily with no expert

Collaborating Centres – Implementation of the SOPs

4.10. Postponed from September: feedback on the mapping exercise for the existing Centres against the list of main focus area and specialties

4.11. Follow-up September: feedback from the Centres that are not complying with the key ToR according to 2019 annual report

4.12. Follow-up September: feedback on the review of the 5-year work plans received from Collaborating Centres

5. *Ad hoc* Groups

Update on activities of *ad hoc* Groups

5.1. *Ad hoc* Group on Replacement of the International Standard Bovine Tuberculin (ISBT) and revision of the OIE *Terrestrial Manual* Chapter 3.4.6 Bovine tuberculosis

5.2. *Ad hoc* Group on Sustainable Laboratories

5.3. *Ad hoc* Group on the revision of *Terrestrial Code* chapters regarding the collection and processing of semen of animals, 9 November 2020 to 15 January 2021

6. International Standardisation/Harmonisation

6.1. OIE Register of diagnostic kits

6.1.1. Update and review of new or renewed applications

6.1.2. Endorsement of updated SOP for OIE Register of diagnostic kits

7. Resolutions for the General Session

8. Conferences, Workshops, Meetings

Future Conferences, Workshops, Meetings

8.1. WAVLD International Symposium, Lyon, France 2023

9. Liaison with other Commissions

9.1. Horizontal issues among the Specialist Commissions

9.1.1. Update on case definitions: dourine, equine influenza, surra and leishmaniosis

9.1.2. Standard Operating Procedure for determining if a pathogenic agent of terrestrial animals meets the OIE definition for an emerging disease

9.2. Scientific Commission for Animal Diseases

9.2.1. Feedback on review of Collaborating Centre application on Economics of Animal Health

9.3. Terrestrial Animal Health Standards Commission

9.3.1. Updates from the September 2020 Code Commission meeting

9.3.2. Questions on Chapter 12.7 *Infection with* Theileria equi *and* Babesia caballi (*equine piroplasmosis*)

9.3.3. Question on Chapter 8.3 *Infection with bluetongue virus*

9.3.4. Question on Chapter 11.10 *Infection with* Theileria annulata, T. orientalis *and* T. parva

9.3.5. Question on Chapter 10.4 *Infection with high pathogenicity avian influenza viruses*

9.3.6. Question on Chapter 12.2 *Infection with* Taylorella equigenitalis (*contagious equine metritis*)

9.4. Aquatic Animal Health Standards Commission

9.4.1. Feedback on review of Collaborating Centre application on Economics of Animal Health

10. Matters of Interest for Consideration or Information

10.1. Update on OFFLU

10.2. Update on rinderpest

10.3. Update on COVID-19

10.4. Global Laboratory Leadership Programme

10.5. Sustainable laboratories data analysis and advocacy paper

10.6. VICH: Brief report on the 39th VICH Steering Committee Meeting and 13th VICH Outreach Forum meeting (16–19 November 2020)

10.7. Biosafety research road map

10.9. Update on IAEA Zodiac Project

10.10. *Ad hoc* Group on alternative strategies for the control and elimination of *Mycobacterium tuberculosis* complex infection in livestock

11 Any Other Business

11.1. Work plan

11.2. Dates of the next Biological Standards Commission meeting