



REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Virtual meeting, 7–11 February 2022

PART A – Texts to be proposed for adoption in May 2022

A virtual meeting of the OIE Biological Standards Commission was held from 7 to 11 February 2022. The list of participants can be found at [Annex 1](#).

Considering the ongoing COVID-19 pandemic, the 89th Annual General Session will be held in a semi-hybrid format from Monday 23 to Thursday 26 May 2022. 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 2022 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 89th General Session; and Part B (to be published in April 2022) will provide information about other topics discussed at the Commission's February 2022 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 89th General Session, the OIE will once again organise information webinars to ensure that Members are 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 89th General Session, and in particular the process for the adoption of standards.

1. Welcome

Dr Montserrat Arroyo, Deputy Director General (International Standards and Science) welcomed the members of the Biological Standards Commission. She thanked all members for their contributions, noting the efforts to maintain outputs of high quality despite the significant challenges posed by the COVID-19 pandemic. She also extended her appreciation to the members' employing institutions and national governments. Dr Arroyo briefed the members on the ongoing process to prepare the 2022 OIE General Session, including the planning of pre-General Session webinars that will be conducted by the OIE Specialist Commissions to inform Members on the revised and new standards being proposed for adoption. The Biological Standards Commission webinar will be held on 12 April 2022 from 1.00 to 3.00 pm local time in Paris. She also informed the Commission that the Technical Item would be on OIE and Veterinary Services engagement in global, regional and national Emergency Management Systems. Dr Arroyo summarised ongoing work on the OIE standards development and review system, including the development and planning for digital tools. Finally, she informed the Commission of an 'after-action review' conducted by the OIE in response to the COVID-19 pandemic.

Dr Monique Eloit, the OIE Director General, met the Commission later in the week and thanked its members for their support and commitment to achieving OIE objectives. She recognised the Commission's efforts and adaptability to develop new ways of working to sustain the OIE standard-setting process despite the challenges imposed by the COVID-19 pandemic. Dr Eloit provided an update on the 89th OIE General Session preparation and informed the Commission of new initiatives to review the OIE Science system.

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)*.

3.1. Review of Member comments received on draft chapters and their endorsement for circulation for second-round comment and proposal for adoption in May 2022

The Commission reviewed the comments that had been received on the 20 draft chapters that had been sent for first-round Member comment in October 2021. The Commission approved 19 for circulation, some subject to clarification of certain points by the experts, before presenting them for adoption by the Assembly in May 2022.

Comments had been received from: Australia, Brazil, China (People's Rep. of), European Union, Japan, New Zealand, United Arab Emirates, United Kingdom and United States of America.

The 19 chapters and a summary of the main amendments made in response to Member comments are provided below:

Glossary: deleted “eggs” and “avian” from the definition of specific antibody negative (SAN) so that it refers to animals including their eggs.

- 1.1.8. Principles of veterinary vaccine production: no comments received on the text circulated, which will be put forward for adoption. One Member had submitted comments on another section of the chapter: the Commission agreed to include the chapter in the next review cycle (2022/2023) so that these comments could be addressed.
- 2.3.4. Minimum requirements for the production and quality control of vaccines: added “where alternative methods exist” to the proposed new text for clarification.
- 3.1.4. Brucellosis (infection *Brucella abortus*, *B. melitensis*, *B. suis*): in the *Summary*, clarified that clinical signs include infertility and that the organisms are also excreted in urine and semen as well as milk and uterine discharges; this point was reiterated in Section A.1.1 *Infection with Brucella in cattle* where a sentence was added stating that *Brucella abortus* can be shed in semen, seminal fluid and urine; updated Section A.1.4 *Infection with Brucella in other domestic, captive-wild or wild species* to correct the scientific name of elk/wapiti and to include sika deer (*Cervus nippon*) as a species where brucellosis is observed, added *B. abortus* in wood bison in Canada as a third reservoir of infection in wild ruminants, and added that the sporadic reports of *B. melitensis* isolation from dogs are associated with contact with infected sheep or goats or ingestion of placenta or aborted fetuses; in Section B.1.2.3 *Collection and culture of samples* added that milk culture can be valuable for screening individual animals as well as herds; in Section B.1.4 *Nucleic acid recognition methods*, clarified that both the updated Bruce-ladder PCR protocol and the modified multiplex PCR assay described by Kang *et al.* (2011)¹ can discriminate between *B. suis* and *B. canis*, and allows the differentiation of *B. microti*; in Section B.2.5 *Enzyme-linked immunosorbent assays*, agreed that the study by Praud *et al.* (2012) on porcine serological tests does not support the text on the sensitivity and specificity of the indirect ELISA² and RBT³ for porcine samples and replaced it with supporting references; in Section B.3.1 *Brucellin skin test*, removed reference to the brucellin INRA preparation as it is no longer available; in Section C. *Requirements for vaccines*, replaced references to authorisation,

1 KANG S.I., HER M., KIM J.W., KIM J.Y., KO K.Y., HA Y.M. & JUNG S.C. (2011). Advanced multiplex PCR assay for differentiation of *Brucella* species. *Appl. Environ. Microbiol.*, **77**, 6726–6728.

2 ELISA: Enzyme-linked immunosorbent assay

3 RBT: rose bengal test

registration or licensing with “regulatory approval” to be consistent with the other chapters; added a new Section C.1.1.5 *Vaccination in other species*.

In Section B.2 *Serological tests*, the Commission did not agree to add that the complement fixation test can be impacted by anti-complementary activity with non-inactivated serum because anti-complementary activity in serum is not just due to non-inactivated serum.

In Section B.2.3.1.2 *Antigen standardisation*, did not agree to change the “highest” to the “lowest” and *vice versa* in text stating that the dilutions (in negative goat serum) of the International standard anti-*Brucella melitensis* Serum (ISaBmS) that must give a positive result and negative result have been established at 1/16 and 1/200. The intent of the sentence is to convey that the highest dilution (most dilute) that must be positive is 1/16, i.e. must always be positive. A higher dilution may also be positive but this is not a must. A 1/8 dilution must also be positive, but this is not the highest dilution that must be positive (it is lower). Likewise, a 200-fold dilution (1/200) must be negative. A 1/100, a lower dilution, can also be negative, but this is not a must. The 1/200 is the lowest dilution that must be negative. The statement is about the thresholds for the serum standard being positive or negative and these are the minimum standards for analytical sensitivity and specificity with this standard.

In Section C.1.1.4 *Vaccination in pigs*, the Commission did not accept a proposal to include a section on *Brucella suis* strain S2 vaccine, as the majority of OIE Reference Laboratory experts felt there was insufficient evidence at this time to include additional information or recommendations on the S2 vaccine. The chapter will be proposed for adoption in May, and this issue will be further discussed at the next meeting in September 2022.

- 3.1.6. Echinococcosis (infection with *Echinococcus granulosus* and with *E. multilocularis*): agreed to use *Echinococcus granulosus sensu lato* (*E. granulosus s.l.*) and *E. granulosus sensu stricto* (*s.s.*) throughout the chapter in accordance with the international consensus on terminology to be used in the field of echinococcosis, and to remove most instances of the term “hydatid” from the chapter; in the *Summary*, clarified that the coproantigen approach is valuable for epidemiological screening programmes; added that diagnosis in animals can be confirmed by DNA sequencing as well as PCR⁴; in the *Summary* and *Introduction* correctly referred to genotypes and not strains of *Echinococcus*; in the *Introduction*, added a statement that the current view is that there are nine species in the genus *Echinococcus*, and clarified the current molecular phylogeny and taxonomy of the G2 genotype and the species *E. canadensis*; also in the *Introduction*, deleted *E. equinus* as a species where there is no evidence of infections in humans as there are reports of human infection with this species; in Table 1. *Useful characteristics for identification of Echinococcus species* amended “polycystic” cysts to “unicystic cysts in the column covering metacestode for *E. oligarthra*”; in Section A.1 *Echinococcus granulosus (sensu lato)* replaced “specificity” with “predilection” as *Echinococcus* species are not specific to intermediate hosts; corrected the description of *Echinococcus vogeli* in Section A.4 from “polycystic echinococcosis” to “neotropical echinococcosis” as usually presents as a single cyst; added “and identification” after “Detection” [of the agent] to the heading in Table 2 *Test methods available for the diagnosis of echinococcosis and their purpose* and added a footnote highlighting that meat inspection may not include confirmation that cysts are due to *E. granulosus* infection; added text to Section B.1.2.1 Necropsy indicating that tissues should be deep frozen before necropsy to kill any eggs and that *E. multilocularis* can survive in liquid nitrogen for 35 years and still be infective; updated Table 3. *PCR primers used for coproDNA detection* to include more recent methods and references; in Section C1.1 *Intermediate hosts*, replaced “reduce transmission of cystic echinococcosis to humans” by “reduce human exposure to cystic echinococcosis”, as the parasite is transmitted not the disease.
- 3.1.8. Foot and mouth disease (infection with foot and mouth disease virus): in the *Summary*, added Seneca Valley virus infection to complete the list of vesicular diseases that cannot be differentiated clinically from FMD; added “detection and” to the section on identification of the agent in the *Summary*, and amended Table 1 *Test methods available for the diagnosis of*

4 PCR: polymerase chain reaction

FMD and their purpose and Section B.1 accordingly, to qualify that it is essential to confirm the presence of FMDV following virus isolation; deleted footnote 1 from Table 1 and harmonised the style of the remaining two footnotes; in Section B.1 added heart muscle from cases with myocarditis to the sample types, and deleted part of the last sentence referring to the need for viral isolate for certain tests and studies as it was out of context.

Two Members had submitted comments on other parts of the chapter that had not been circulated. These comments would be addressed by the experts when they review the entire chapter in the next review cycle.

- 3.1.x. Mammalian tuberculosis (infection with *Mycobacterium tuberculosis* complex): in the *Summary*, added a statement that mammalian tuberculosis is a barrier to trade, added the full name of spoligotyping (spacer oligonucleotide typing), and added mycobacterial interspersed repeat units – variable number tandem repeat (MIRU-VNTR) as it is a commonly used genotyping method; also in the *Summary*, clarified that vaccination of cattle is prohibited in many countries as the vaccine may sensitise animals to the tuberculin skin test and other tuberculin-based immunological tests; added text in the *Introduction* stating that *Mycobacterium microti* has also been found widespread in wild boar and that the microscopic test can often give negative results, even in sick animals, due to the limited presence of mycobacteria; in Table 1 *Test methods available for use in cattle, goats, and camelids and their purpose* amended the ratings of the tests for detection of immune response in goats and camelids, including rating the lateral flow antibody test “+” for all species (cattle, goats and camelids); deleted text from Section B.2.2.2.1. *Single cervical test* on situations where a high false positive rate is expected because it is beyond interpretation of the test itself to its use in the context of control/eradication, which is not in the remit of the *Terrestrial Manual*; corrected the figures in the interpretation of the results of the *Comparative cervical test* (Section B. 2.2.2.2); added a section on interpretation of test results in camelids; in Section 3.2. *Serology for detection of specific antibodies* indicated that serology is used as a complementary test to the skin test and 15–30 days after skin testing in camelids.

The Commission did not agree to include another multiplex real-time PCR proposed by one Member because, as mentioned in the text, a number of PCR protocols have been reported using different targets, primers or methods. In reply to a Member that proposed changing the word “anthroponoses”, the Commission noted that the word “zoonosis” tends to be used for infections from animals to humans and that “anthroponosis” (also known as “reverse zoonosis” or “zooanthroponosis”) can be accepted to describe human-to-animal transmission.

- 3.1.14. Nipah and Hendra virus diseases: in the *Summary*, added text to highlight the variable and nonspecific clinical signs that horses infected with Hendra virus (HeV) can display, and text clarifying the role of contact with urine, saliva or birth products from infected flying-foxes in transmission to horses and direct contact with bodily fluids for transmission between horses; also in the *Summary*, added that human-to-human transmission of Nipah virus (NiV) has been seen in outbreaks in India as well as Bangladesh, and updated the information on the recent genetic characterisation of NiV; in the *Introduction*, clarified the occurrence of HeV cases in horses within the geographical range of the *Pteropus* bats in Australia, added information and a reference on clinical signs in humans, specified the likely route of transmission from the wildlife reservoir to humans in the Bangladesh outbreaks, and pointed out that two henipa-like viruses have been isolated from shrews in the Korea (Rep. of); in Section B.2.1.1 *Sampling and submission of specimens* added a statement that in pregnant animals or in cases of abortion, uterus, placenta and fetal tissues should be included because it has been deleted from the *Summary*; in Table 3 *Primers used for conventional PCR and sequencing of HeV*, added a footnote to clarify that the HeV-P gene semi-nested conventional PCR also detects HeV-g1 and HeV-g2, but with much lower sensitivity for HeV-g2; in Section B.4.2.2. *Hendra B-ELISA method*, emphasised that other ELISA protocols for henipavirus diagnostics in pigs have been published; in Section 4.3 *Bead-based assays*, deleted a sentence on the more stringent biological risk management required for ELISAs as all ELISA protocols are now established with recombinant antigen, which is not associated with any biosafety risk; in Section C. *Requirements for vaccines*, added a statement that there is no vaccine approved for the prevention of HeV in humans.

- 3.1.22. Tularemia: In the *Summary*, added a statement on the cause of oropharyngeal and pneumonic infections along with information on how the disease spreads and how humans can acquire it because this information is relevant to work-safety issues in the laboratory and the potential use of *Francisella tularensis* as a biological agent; in the *Introduction*, added a statement that Type B has been found in possums in Australia; also in the *Introduction*, deleted reference to the living bacteria occurring in faeces and expanded the statement on how infection can occur to include contact with sick animals, infected tissues, consumption of infected animals, drinking or direct contact of contaminated water; mention of the OIE Reference Laboratory was deleted as currently there is none; in Table 1. *Test methods available for the diagnosis of tularemia and their purpose*, the rating for the real-time PCR was changed from “+++” to “+” and the rating of the conventional PCR was changed from “++” to “+”, both for the purpose “Population freedom from infection” as it is only useful in very limited circumstances (e.g. in ticks or other arthropods), but has little or no relevance for screening subclinically infected animals, the rating for the conventional PCR was changed from “-“ to “+++” for the purpose “Confirmation of clinical cases” as PCR is a reliable confirmatory tool as pointed out in the text, and added a footnote emphasising that serology is of limited value in susceptible animals, which usually die before development of specific antibodies; in Section B.1.3.3 *Identification of isolates*, added a paragraph and a reference on MALDI-TOF MS⁵ because MALDI-TOF MS is a quick and reliable method for the identification of these bacteria; in Section B.2.1 *Agglutination tests*, updated the description of the how the antigen is cultured as antigen preparation more typically uses formalin and safranin instead of ethanol and crystal violet.

One Member had proposed adding a new section on molecular epidemiology for outbreak investigations. The Commission felt that the proposal related not just to this chapter but to the *Terrestrial Manual* in general. The Commission decided to put this comment on hold for the present and to consider at the next meeting in September if they would like the topic of molecular epidemiology to be covered in the *Terrestrial Manual*.

- 3.2.1. Acarapisosis of honey bees (infestation of honey bees with *Acarapis woodi*): changed “infection” to “infestation” throughout the chapter; in the *Summary*, added that the mites can also be found at the base of the bee’s wings, and corrected the maximum number of eggs that mites lay from 20 to 14; in the *Summary* and *Introduction*, clarified that the mite being described is the adult female mite, *Introduction*, added a sentence on the effects of heavy mite infestations in winter months; added “detection and” to the section on identification of the agent in the *Summary*, and amended Table 1 *Test methods available and their purpose* and Section B.1 accordingly; clarified that though drones can be found to have a higher abundance of mites per bee, the most significant caste affected by *Acarapis woodi* is the worker bee population, which is present in the colony throughout the entire year, including the seasons when a colony is most vulnerable: winter and early spring; in Section B.1.1 *Microscopy – dissection of individual bees*, changed the freezing interval from ‘24 hours’ to ‘48 hours’, to ensure that bees have been euthanised.
- 3.3.9. Fowl cholera: in the *Summary*, clarified the names of eight LSP⁶ genotypes: L1–L8; in Section C. *Requirements for vaccines*, replaced references to authorisation, registration or licensing with “regulatory approval” to be consistent with the other chapters.
- 3.3.15. Turkey rhinotracheitis (avian metapneumovirus): in the *Summary* added that vaccines are available for both turkey rhinotracheitis (TRT) and swollen head syndrome (SHS); in the *Introduction*, corrected the statement referring to two new isolates reported from North America – the original text referred to genotypes; added a sentence and a reference on co-infection with other viruses and fungi; included some information on clinical signs in chickens; in Section C. *Requirements for vaccines*, replaced references to authorisation, registration or licensing with “regulatory approval” to be consistent with the other chapters.
- 3.6.2. Contagious equine metritis (CEM): in Section A.1 *Description and impact of the disease*, removed the mention of vaccination as there are no vaccines available for CEM; in Section A.3 *Differential diagnosis*, added clitoral fossa, clitoral sinuses and endometrium as they are

5 MALDI-TOF MS: Matrix assisted laser desorption ionisation time of flight mass spectrometry

6 LSP : Lipopolysaccharide

the recommended swabbing sites for mares; added “and identification” to Table 1 *Test methods available for the diagnosis of contagious equine metritis and their purpose* and added “Detection and” to the title of Section B.1; added a section on MALDI-TOF; in Section B.1.4 *Molecular methods*, added a sentence clarifying that a minimum of five suspect colonies be taken for confirmation by PCR to reduce the possibility of selecting the wrong colony; in Section B.1.4.1 *Real-time PCR*, added two references; in Section B.1.4.2 *Other PCRs*, emphasised that other PCRs can only be used if they have been validated to OIE Standards (Chapter 1.1.6) as fit for use for defined purposes; in Section B.1.5.2 *Semen testing*, added text and a reference stating that growth of the organism is not always inhibited by antibiotics in semen extender.

- 3.8.11. Scrapie: in the *Summary*, clarified that epidemiological data suggest atypical scrapie does not present like an infectious disease but instead it has a sporadic distribution; still in the *Summary* section on detection of PrP^{Sc} in lymphoreticular tissues, included rectoanal mucosa-associated lymphoid tissue, third eyelid biopsies and palatine tonsil as they are the important tissue samples for biopsies in live animals, while emphasising that such testing is not appropriate for detection of atypical scrapie as there is little or no involvement of the lymphoreticular system or of a proportion of classical scrapie cases, so they can be used only to confirm the presence of infection and cannot be used to prove its absence; in Section A.2. *Host genetic factors*, clarified that there is some evidence suggesting that certain codons may be associated with susceptibility to the disease in goats and updated the European Food Safety Authority (EFSA) reference; in Section B.3 *Genetic screening for resistance*, added text stating that while a breeding programme for resistance in goats may not be feasible due to the low abundance of resistant polymorphisms, screening programmes at the local level can help to identify resistant goats to restock affected herds after the application of genetically-based selective culling, as it has been applied for decades in sheep.

In the *Summary*, a suggestion to include text stating that variations at some codons can affect susceptibility to atypical scrapie was rejected as it was vague and confusing and did not add to the context of the paragraph. Also in the *Summary*, the proposal that diagnosis is confirmed by vacuolation **and** immune-detection was not accepted as in many countries only one method is required: it was agreed to specify that vacuolation is TSE-specific. Finally in the *Summary*, the proposal to change “brain” to “brainstem” was rejected because “brain” includes the cerebellum, which is necessary for the detection of atypical scrapie, so “brainstem” is incomplete. In Section A.2. *Host genetic factors*, a proposal to add a table grouping alleles by level of susceptibility with an explicit indication of the resistance associated to ARR allele was rejected as it was felt to be beyond the scope of the *Terrestrial Manual*, which is for diagnostic tests and not for preventative medicine: the PrP genotype has no implication on the diagnostic procedure. Also in Section A.2, a proposal to include a reference to a case-control study in goats was rejected because the analysed samples were sourced from a restricted geographical area and given the genetic variability of the PrP in goats and how difficult it is to identify genetic resistance markers that are applicable universally to goat TSEs, it would be inappropriate to mention the reference in the *Terrestrial Manual* as it may mislead readers. In addition the information is of limited value as no Veterinary Authority would implement a preventative strategy to eliminate atypical scrapie – it is classical scrapie that they try to stamp out. In Section A.3 *Strain characterisation*, a Member commented that the chapter should be amended to reflect the biodiversity of classical scrapie strains. In reply, the Commission stressed that the field of strain typing in TSEs⁷ is a specialist subject and beyond the purpose of this *Terrestrial Manual*, which focuses on diagnosis of the disease. The chapter does not describe strain characterisation but discrimination between BSE⁸ and scrapie, which until a few years ago was referred to as strain discrimination. To address this, the title of the Section was changed to Discrimination between classical scrapie and BSE and the first sentence on strain characterisation was deleted. In Section B.1.1 *Specimen selection and preparation*, a proposal to add that CNS material is fixed in neutral buffered formalin was rejected as other fixatives may also be used. In Section B.1.2 *Histological examination*, a proposal to add that classical scrapie lesions frequently affect “the spinal tract nucleus of the trigeminal nerve”

7 TSEs: transmissible spongiform encephalopathies

8 BSE: bovine spongiform encephalopathy

was rejected as the dorsal nucleus of the vagus nerve, which is mentioned, is the primary target area.

- 3.8.13. Theileriosis in sheep and goats (infection with *Theileria lestoquardi*, *T. luwenshuni* and *T. uilenbergi*): changed the rating of the IFAT⁹ and ELISA from “–” to “++” for the purpose “individual animal freedom from infection prior to movement” and added a footnote to clarify that for this purpose (animal movement) serology should not be used alone but always combined with an agent detection test.
- 3.9.3. Classical swine fever (infection with classical swine fever virus) (diagnostic section only): in Table 1. *Test methods available for the diagnosis of classical swine fever and their purpose*, clarified that the PCR is a reverse-transcription PCR; in Section C. Requirements for vaccines, replaced “authorised”, “licensed” and “registration” with “granted regulatory approval” and “approved” to be consistent with the other chapters.
- 3.10.1. Bunyaviral diseases of animals (excluding Rift Valley fever and Crimean–Congo haemorrhagic fever): for Cache Valley virus (CCVV), extended the geographical range from North America to the Americas and included goats as one of the main animal species affected; updated the information on prevalence including adding a more recent reference; for Akabane virus (AKAV), added the information that antibodies have been found in horses, donkeys, buffalo, deer, camels, and wild boar, but there are currently no descriptions of Akabane-associated illnesses in these species; added text and two references to multiplex RT-PCR methods that have been developed for rapid, sensitive detection of multiple arboviruses, including AKAV; for Schmallenberg virus (SBV) added cerebellar hypoplasia and enlarged thymus as clinical signs; and for Nairobi sheep disease virus (NSDV) added a statement that sheep are more susceptible than goats; expanded the information on and the protocol for the IFAT.

The Commission did not agree to increase the incubation period for the disease from 2–5 days to 2–15 days because though there are reports of infections where clinical signs have only appeared up to 15 days after the application of infected ticks to the animal, this appeared to be due to a delay in the tick establishing feeding, while in experimental inoculations, signs appear a maximum of 5 days after infection; neither did the Commission agree to add text stating the agent was transmitted transovarially in the tick according to Daubney & Hudson, 1934¹⁰: transovarial transmission, where larvae bred from infected adults are themselves infectious, has not been demonstrated in any species of tick except *Rhipicephalus appendiculatus*, and Daubney & Hudson (1934) specifically say that they did not observe this for *Ambylomma variegatum*.

A Member commented that the chapter lacks diagnostic details and test protocols. The Commission is aware of this situation and intends to address it. The Commission thus agreed to put the chapter forward for adoption in May this year, and to ask the contributing experts to further update the chapter by including Table 1 *Test methods available and their purpose* and protocols; the resulting updated chapter will be added the next review cycle (2022/2023).

- 3.10.4. Cryptosporidiosis: updated the number of *Cryptosporidium* species as well as the number of genotypes and included a recent reference on taxonomy and molecular epidemiology of *Cryptosporidium*; updated Table 1. *Some differences among species within the genus Cryptosporidium* by including information that was missing and adding new species; as potassium dichromate (K₂Cr₂O₇) is toxic, the recommendation to perform all procedures in a fume hood or a ducted Class II biosafety cabinet (ducted = vents externally to the room) was added; in Section 2.3.2.1 *Preparation of flotation solution*, added information on how long the solutions can be kept for once made.
- 3.10.6. Mange: moved Section 3 *Serological tests* to Section 1.3 *Serological tests* and added a sentence and references on the development of serodiagnostic methods based on recombinant proteins; added cats as a domestic host for *Sarcoptes scabiei*; added horses as a

9 IFAT = indirect fluorescent antibody test

10 DAUBNEY R. & HUDSON J.R. (1934). Nairobi sheep disease; natural and experimental transmission by ticks other than *Rhipicephalus appendiculatus*. *Parasitology*, **26**, 496–509.

species infected with Chorioptic mange; in Section B.2.2.1 *Demodecidae*, clarified that *Demodex gatoi* can be transferred between cats of any age while transfer between other hosts occurs only by very close contact between individuals; updated Section C. *Requirements for vaccines* including adding two references.

- 3.10.7. Salmonellosis: amended the title of Section A.1 to include nomenclature; reinstated Grimont & Weill (2007)¹¹ as it includes relevant and current information on *Salmonella* species; clarified that modified semi-solid Rappaport Vassiliadis (MSRV) is an agar and that it has been validated for environmental samples; amended Sections B1.1.4 *Example test procedures for isolation of Salmonella from food, feedstuffs, faecal and environmental samples* and Section B.2.5.5 *Preparation of flagellar antigens*, to bring them in line with ISO 6579-1; in Sections B.1.2 *Quantification methods*, B.1.3 *Identification of suspect colonies*, and B.1.4 *Immunological and nucleic acid recognition methods*, corrected the ISO references; in Section C. *Requirements for vaccines*, replaced references to authorisation, registration or licensing with “regulatory approval” to be consistent with the other chapters.

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

To recap, below is a list of the 19 chapters that are proposed for adoption at the 89th General Session in May 2022. The chapters can be downloaded from the following address:

http://web.oie.int/downld/Terr_Manual/MAILING_MARCH_2022.zip

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

		Glossary
1.	1.1.8.	Principles of veterinary vaccine production
2.	2.3.4.	Minimum requirements for the production and quality control of vaccines
3.	3.1.4.	Brucellosis (infection with <i>B. abortus</i> , <i>B. melitensis</i> , <i>B. suis</i>)
4.	3.1.6.	Echinococcosis (infection with <i>Echinococcus granulosus</i> and with <i>E. multilocularis</i>)
5.	3.1.8.	Foot and mouth disease (infection with foot and mouth disease virus)
6.	3.1.14.	Nipah and Hendra virus diseases
7.	3.1.22.	Tularemia
8.	3.1.X.	Mammalian tuberculosis (infection with <i>Mycobacterium tuberculosis</i> complex)
9.	3.2.1.	Acarapisosis of honey bees
10.	3.3.9.	Fowl cholera
11.	3.3.15.	Turkey rhinotracheitis (avian metapneumovirus)
12.	3.6.2.	Contagious equine metritis
13.	3.8.11.	Scrapie
14.	3.8.13	Theileriosis in sheep and goats (infection with <i>Theileria lestoquardi</i> , <i>T. luwenshuni</i> and <i>T. uilenbergi</i>)
15.	3.9.3.	Classical swine fever (infection with classical swine fever virus)
16.	3.10.1.	Bunyaviral diseases of animals (excluding RVF fever and Crimean–Congo haemorrhagic fever)
17.	3.10.2.	Cryptosporidiosis
18.	3.10.6.	Mange
19.	3.10.7.	Salmonellosis

.../Annexes

¹¹ GRIMONT P.A.D. & WEILL F.-X. (2007). Antigenic Formulae of the *Salmonella* Serovars, Ninth Edition, World Health Organization Collaborating Centre for Reference and Research on *Salmonella*. Institut Pasteur, Paris, France.

MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION
Virtual meeting, 7–11 February 2022

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MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Virtual meeting, 7–11 February 2022

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 2022
 - 3.2. Follow-up from the General Session: Chapter 3.4.12 *Lumpy skin disease*
 - 3.3. Follow-up from September 2021: conclusions and recommendations from the OIE *Scientific and Technical Review* issue on diagnostic test validation science
 - 3.3.1. Progress on development of a template of the validation data requested for addition to a future online list of validated tests
 - 3.3.2. Progress on development of a template for a new *Terrestrial Manual* section on the rationale behind the selection of tests included in Table 1. *Test methods available and their purpose*
 - 3.3.3. *Terrestrial Manual* validation chapters: chapter 1.6 *Principles and methods of validation of diagnostic assays for infectious diseases* and chapters 2.2.1 to 2.2.8 in Section 2.2 *Validation of diagnostic tests*
 - 3.4. Follow-up from September 2021: request to update Chapter 3.1.1 *Anthrax* to include a new easier to produce *Bacillus anthracis* capsule stain
 - 3.5. Member comments on chapters 2.3.1 *The application of biotechnology to the development of veterinary vaccines* and 3.1.17 *Rabies (infection with rabies virus and other lyssaviruses)*
 - 3.6. Correction to Table 1 *Test methods available for the diagnosis of peste des petits ruminants and their purpose* of Chapter 3.8.9 *Peste des petits ruminants (infection with small ruminant morbillivirus)*
 - 3.7. *Terrestrial Manual* status: update on chapters selected for the 2022/2023 review cycle
4. **Liaison with other Commissions**
 - 4.1. Horizontal issues among the Specialist Commissions
 - 4.1.1. Review of case definitions
 - 4.2. Scientific Commission for Animal Diseases
 - 4.2.1. Follow-up General Session: emerging recombinant lumpy skin disease virus strains, their correct diagnosis and notification)
 - 4.2.2. Review of assessments of diseases against listing criterion 3: delisting assessments
 - 4.3. Terrestrial Animal Health Standards Commission
 - 4.3.1. Updates from the September 2021 Code Commission meeting
 - 4.3.2. Technical questions on Chapter 11.10 *Infection with Theileria annulata, T. orientalis and T. parva*
 - 4.3.3. Technical questions on Chapter 8.8 *Infection with foot and mouth disease*
 - 4.4. Aquatic Animal Health Standards Commission
 - 4.4.1. Nothing for this meeting
5. **OIE Reference Centres**
 - 5.1. Annual reports of Reference Centre activities in 2021
 - 5.2. Applications for OIE Reference Centre status
 - 5.3. Changes of experts at OIE Reference Centres
 - 5.4. Review of new and pending applications for laboratory twinning

- 5.5. Inconsistencies among OIE Reference Laboratories in results obtained using the real-time RT-PCR for African horse sickness

Reference Laboratories – Implementation of the SOPs

- 5.6. Follow-up September meeting: further feedback from the Laboratories that are not complying with the key ToR according to their 2018 annual report
- 5.7. Follow-up September: feedback from the Laboratories that are not complying with the key ToR according to 2020 annual report
- 5.8. Further develop SOPs to include provisions for suspending laboratories and for handling laboratories that temporarily have no designated expert

Collaborating Centres – Implementation of the SOPs

- 5.9. Follow-up September meeting: feedback on the mapping exercise for the existing Centres against the list of main focus area and specialties
- 5.10. Follow-up September: feedback from the Centres that are not complying with the key ToR according to 2019 annual report
- 5.11. Follow-up September: feedback from the Centres that are not complying with the key ToR according to 2020 annual report
- 5.12. Follow-up September: feedback on the review of the 5-year work plans received from Collaborating Centres

Reference Centre networks

- 5.13. Update on the three Reference Laboratory networks (rabies, PPR and ASF)
- 5.14. Outcomes of OIE Reference Centre December 2021 meeting in SADC region
- 5.15. OIE Training Portal and OIE Training Platform activities: a good example of OIE Collaborating Centre collaboration
- 5.16. Request to change title of an OIE Collaborating Centre

6. Ad hoc Groups

Update on activities of past *ad hoc* Groups

- 6.1. *Ad hoc* Group on Replacement of the International Standard Bovine Tuberculin: update on the replacement ISBT

7. International Standardisation/Harmonisation

- 7.1. OIE Register of diagnostic kits:
 - 7.1.1. Update and review of new or renewed applications

8. Resolutions for the General Session

- 8.1. List of resolutions that will be presented in May 2022

9. Matters of Interest for consideration or information

- 9.1. Update on OFFLU
- 9.2. Update on rinderpest
- 9.3. Update on COVID-19
- 9.4. EuFMD/FAO project for a pre-qualification system for veterinary medicines
- 9.5. Update on Global Burden of Animal Diseases programme

10. Any other business

- 10.1. Workplan
- 10.2. Dates of the next Biological Standards Commission meeting: 5–9 September 2022

11. Meeting review
