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Biological Standards Commission

Biological Standards Commission
Standards proposed for adoption
- *Terrestrial Manual* chapters

89th General Session of the World Assembly of the OIE
Paris (France), 25 May 2022



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1. Introduction
2. Texts to be proposed for adoption at the 89th General Session (GS)



1. Introduction



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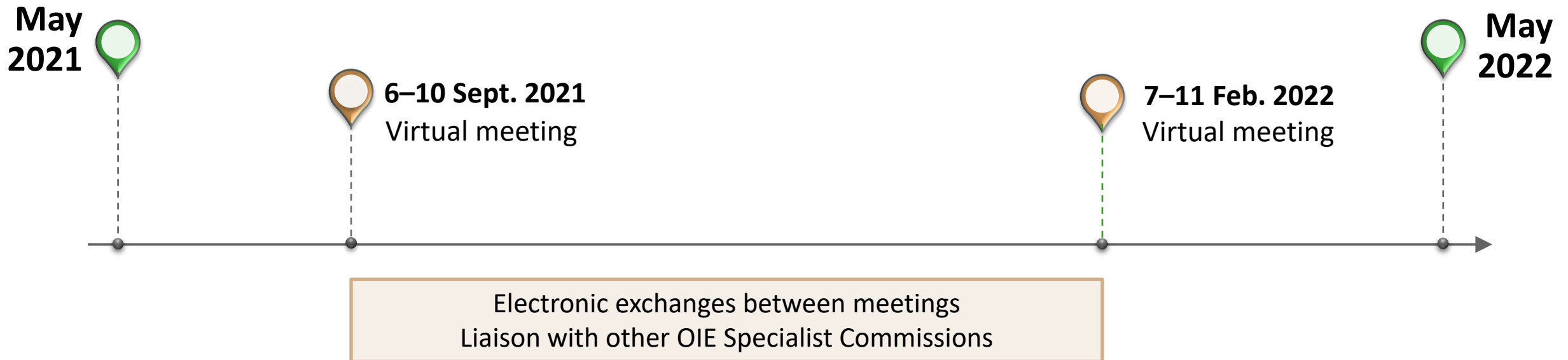
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Liaison with other OIE Specialist Commissions (BSC)

Since May 2021, the BSC had two virtual meetings:





2. Texts to be proposed for
adoption at the 89th GS
Doc. 89 SG/10/CS2



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- The February 2022 meeting report of the BSC was distributed in two parts:
 - Part A provides information on the new and revised texts for the *Terrestrial Manual* that will be proposed for adoption at the 89th General Session (Doc. 89 SG/10 CS2)
 - Part B provides information on other topics including the new applications for Reference Centre status to be proposed for adoption, as well as other topics for information.

Chapters proposed for adoption

- A total of 19 chapters and the revised glossary of terms proposed for adoption at the 89th General Session
- The chapters are available through a link in the BSC report Part A:
http://web.oie.int/download/Terr_Manual/MAILING_MARCH_2022.zip
- The chapters are also available on the Delegates website and on the BSC web page:
<https://www.oie.int/en/what-we-do/standards/standards-setting-process/biological-standards-commission/#ui-id-2/>



Comments on the proposed Standards submitted using the App

- The Biological Standards Commission would like to thank the following Members that submitted comments using the App: Canada, China (People's Rep. of), Hungary, India, Iran, Japan, Mexico, Singapore, Turkey, United Kingdom, United States of America and the 27 Member States of the European Union
- In preparation for the 89th General Session and to facilitate adoption of the chapters, the Commission reviewed the comments and proposes some amendments to the chapters to address the concerns expressed

Texts to be proposed for adoption



Chapter number	Title and year version adopted	Level of amendments	Major changes
x.x.xx	<i>Title of the chapter (year version last adopted)</i>	Minimal or Moderate or Extensive	Significant changes made to the chapter mentioned. For detailed edits refer to the actual chapter

Texts to be proposed for adoption (Glossary of terms)

	Level of amendments	Major changes
Glossary of terms	Minimal	Two new terms added: <ul style="list-style-type: none">• Seroconversion• Specific antibody negative (SAN)



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Texts to be proposed for adoption (Introductory chapters)

Chapter number	Title and year version adopted	Level of amendments	Major changes
1.1.8.	Principles of veterinary vaccine production (2018)	Minimal (one paragraph)	To take account of VICH guidelines on harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use (VICH: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products)
2.3.4.	Minimum requirements for the production and quality control of vaccines (2018)		



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Texts to be proposed for adoption (Disease chapters)

Chapter number	Title and year version adopted	Level of amendments	Major changes
3.1.4.	Brucellosis (infection with <i>Brucella abortus</i> , <i>B. melitensis</i> , <i>B. suis</i>) (2016)	Moderate	<ul style="list-style-type: none"> Updated the description of the disease and technical aspects of some of the diagnostic tests Added information on the disease in camels and wildlife species
3.1.6.	Echinococcosis (infection with <i>Echinococcus granulosus</i> and with <i>E. multilocularis</i>) (2019)	Minimal (diagnostic tests), Extensive (vaccine section)	<ul style="list-style-type: none"> Updated to incorporate the latest internationally agreed terminology and taxonomy Thoroughly updated the vaccine section A comment was received relating to vaccination of the dog host using recombinant proteins

Texts to be proposed for adoption (Disease chapters): Discussion

Interventions on the following texts:

Chapter no.	Chapter title
	Glossary of terms
1.1.8	Principles of veterinary vaccine production
2.3.4.	Minimum requirements for the production and quality control of vaccines
3.1.4.	Brucellosis (infection with <i>Brucella abortus</i> , <i>B. melitensis</i> , <i>B. suis</i>)
3.1.6.	Echinococcosis (infection with <i>Echinococcus granulosus</i> and with <i>E. multilocularis</i>)

Proposed to the Assembly for adoption

Chapter no.	Chapter title
	Glossary of terms
1.1.8	Principles of veterinary vaccine production
2.3.4.	Minimum requirements for the production and quality control of vaccines
3.1.4.	Brucellosis (infection with <i>Brucella abortus</i> , <i>B. melitensis</i> , <i>B. suis</i>)
3.1.6.	Echinococcosis (infection with <i>Echinococcus granulosus</i> and with <i>E. multilocularis</i>)

Texts to be proposed for adoption (Disease chapters)

Chapter number	Title and year version adopted	Level of amendments	Major changes
3.1.8.	Foot and mouth disease (infection with FMD virus) (2021)	Minimal (Summary and Table 1 only)	<ul style="list-style-type: none"> Clarified in Table 1 and Section B.1 that it is essential to confirm the presence of FMDV following virus isolation by antigen or nucleic acid detection test
3.1.X.	Mammalian tuberculosis (infection with <i>Mycobacterium tuberculosis</i> complex) [replaces Bovine tuberculosis (2009)]	Extensive: new chapter	<ul style="list-style-type: none"> Broadened the scope to include specific information on cattle, goats and camelids Updated and expanded the diagnostic tests section including interpretation of results in different species Added some information on vaccines and updated the section on production of tuberculin



Texts to be proposed for adoption (Disease chapters)

Chapter number	Title and year version adopted	Proposed amendments following comments received on the App during the commenting period
3.1.X.	Mammalian tuberculosis (infection with <i>Mycobacterium tuberculosis</i> complex) [replaces Bovine tuberculosis (2009)]	<p>Following Member comments, the Commission proposes to:</p> <ul style="list-style-type: none"> • Delete the following text from line 9 of the Summary: “It is a major infectious disease of cattle, other domesticated animals, and certain wildlife populations, and is a barrier to trade.” • In Section B.2.2.2.1 <i>The single cervical test</i>, amend lines 465-466 to: The reaction is considered inconclusive if the increase in skin-fold thickness is <u>more than</u> between 2 mm and <u>less than</u> 4 mm and considered positive if there is an increase of 4 mm or more • In Section B.2.2.2.2 <i>The comparative cervical test</i>, amend line 484 to: The reaction is considered inconclusive if <u>the reaction to PPD-B is 2 mm or more, and is greater than the PPD-A reaction by 4 mm or less</u> there is a difference in skin thickness of ≥ 2.0 mm and <4 mm and a reaction to PPD-B of 2 mm or more. <p>And amend Table <i>Interpretation of the comparative cervical test</i> accordingly</p>

Texts to be proposed for adoption (Disease chapters)

Chapter number	Title and year version adopted	Level of amendments	Major changes
3.1.14.	Nipah and Hendra virus diseases (2015)	Extensive	<ul style="list-style-type: none"> • Included statements on the zoonotic potential of these viruses • Updated the section on diagnostic tests including updating Table 1 <i>Test methods available for the diagnosis of henipaviruses and their purpose</i> and inserting protocols for indirect and blocking ELISAs • Updated information on genetic characterisation of Nipah virus • Highlighted the variable and nonspecific clinical signs that horses infected with Hendra virus (HeV) can display
3.1.22.	Tularemia (2016)	Moderate	<ul style="list-style-type: none"> • Inserted information on how the disease spreads and how humans can acquire it • Updated Table 1 including adding conventional PCR and clarified that serology is of limited use • Added a paragraph and a reference on MALDI-TOF MS and updated the description of how to culture the antigen for the agglutination test

Texts to be proposed for adoption (Disease chapters)

Chapter number	Title and year version adopted	Proposed amendments following comments received on the App during the commenting period
3.1.22.	Tularemia (2016)	<p>Following Member comments, the Commission proposes to:</p> <ul style="list-style-type: none"> In Section A <i>Introduction</i>, line 94, add a new sentence and a reference: “Species that are moderately susceptible to tularemia, and maintain the infection for a prolonged time, may serve as reservoirs of infection to others (Hestvik <i>et al.</i>, 2015). HESTVIK G., WARNS-PETIT E., SMITH L.A., FOX N.J., UHLHORN H., ARTOIS M., HANNANT D., HUTCHINGS M.R., MATTSSON R., YON L. & GAVIER-WIDEN D. (2015). The status of tularemia in Europe in a one-health context: a review. <i>Epidemiol. Infect.</i>, 143, 2137–2160. doi: 10.1017/S0950268814002398. Section A <i>Introduction</i>, line 96 after the second sentence, add a new sentence: “Hunters opening carcasses of lagomorphs in the wild are at risk of infection.”

Texts to be proposed for adoption (Disease chapters): Discussion

Interventions on the following texts:

Chapter number	Chapter title
3.1.8.	Foot and mouth disease (infection with FMD virus)
3.1.X.	Mammalian tuberculosis (infection with Mycobacterium tuberculosis complex)
3.1.14.	Nipah and Hendra virus diseases
3.1.22.	Tularemia

Proposed to the Assembly for adoption

Chapter number	Chapter title
3.1.8.	Foot and mouth disease (infection with FMD virus)
3.1.X.	Mammalian tuberculosis (infection with <i>Mycobacterium tuberculosis</i> complex)
3.1.14.	Nipah and Hendra virus diseases
3.1.22.	Tularemia

Texts to be proposed for adoption (Disease chapters)

Chapter number	Title and year version adopted	Level of amendments	Major changes
3.2.1.	Acarapisosis of honey bees (infestation of hone bees with <i>Acarapis woodi</i> (2008)	Extensive	Thorough update as the chapter was last adopted in 2008: <ul style="list-style-type: none">• Added new diagrams and Table 1 <i>Test methods available and their purpose</i>• Fully updated the diagnostic tests section including the addition of a new section on PCR, both conventional and real-time• Deleted the section on the ELISA
3.3.9.	Fowl cholera	Minimal	<ul style="list-style-type: none">• Updated the diagnostic tests section, in particular by adding molecular methods, deleting somatic typing and clarifying that animal inoculation is no longer recommended• Clarified that it is now known that a killed vaccine provides protection only against isolates with identical or near to identical LPS structure



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Texts to be proposed for adoption (Disease chapters)

Chapter number	Title and year version adopted	Level of amendments	Major changes
3.3.15.	Turkey rhinotracheitis (avian metapneumovirus) (2009)	Moderate	<ul style="list-style-type: none"> Updated virus taxonomy, strain classification and host range Added Table 1 <i>Test methods available and their purpose</i> Thoroughly updated and reformatted Section C on requirements for vaccines <p>Following Member comments, the Commission proposes to:</p> <ul style="list-style-type: none"> Amend line 173 to stipulate that there is serological and molecular evidence that aMPV occurs in a variety of other avian species, but that there is no evidence of disease “except in pheasants”.
3.6.2.	Contagious equine metritis (2018)	Moderate	<ul style="list-style-type: none"> On the experts recommendations and following metanalysis of the published data, included two real-time PCR methods and emphasised that other PCRs can only be used if they have been validated to OIE Standards as fit for use for defined purposes Added a section on MALDI-TOF



Texts to be proposed for adoption (Disease chapters)

Chapter number	Title and year version adopted	Proposed amendments following comments received on the App during the commenting period
3.6.2.	Contagious equine metritis (2018)	<p>Following Member comments, the Commission proposes to amend line 178 as follows:</p> <p>Delete the sentence:</p> <p>“A minimum of five suspect colonies should be taken for confirmation by PCR”</p> <p>and replace with:</p> <p>“To mitigate the possibility of false negative results, it is recommended that, whenever possible, several colonies suspected of being of the <i>Taylorella</i> genus are selected for confirmation by PCR.”</p>

Texts to be proposed for adoption (Disease chapters): Discussion

Interventions on the following texts:

Chapter number	Chapter title
3.2.1.	Acarapisosis of honey bees (infestation of honey bees with <i>Acarapis woodi</i>)
3.3.9.	Fowl cholera
3.3.15.	Turkey rhinotracheitis (avian metapneumovirus)
3.6.2.	Contagious equine metritis

Proposed to the Assembly for adoption

Chapter number	Chapter title
3.2.1.	Acarapisosis of honey bees (infestation of honey bees with <i>Acarapis woodi</i>)
3.3.9.	Fowl cholera
3.3.15.	Turkey rhinotracheitis (avian metapneumovirus)
3.6.2.	Contagious equine metritis

Texts to be proposed for adoption (Disease chapters)

Chapter number	Title and year version adopted	Level of amendments	Major changes
3.8.11.	Scrapie (2016)	Moderate	<ul style="list-style-type: none"> • Clarified the information on classical and atypical scrapie throughout the chapter • Clarified that histological examination should not be used as a primary screening or confirmatory test • Changed the title of the section on <i>Strain characterisation to Discrimination between classical scrapie and BSE</i> as the chapter does not describe strain characterisation • Some editorial comments were received and the text will be amended accordingly
3.8.13.	Theileriosis in sheep and goats (infection with <i>Theileria lestoquardi</i> , <i>T. luwenshuni</i> and <i>T. uilenbergi</i>)	New chapter	<ul style="list-style-type: none"> • New chapter in anticipation of the listing of these agents by the OIE



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Texts to be proposed for adoption (Disease chapters)

Chapter number	Title and year version adopted	Level of amendments	Major changes
3.9.3.	Classical swine fever (infection with classical swine fever virus) (diagnostic section only) (2019)	Moderate	<ul style="list-style-type: none"> • Mentioned the existence of and difficulties caused by persistent infections • Included technical updates to the virus isolation procedure and the RT-PCR • Emphasised the existence of other ruminant pestiviruses and the need for reliable differentiation of CSFV from other pestiviruses; updated the ELISA
3.10.1.	Bunyaviral diseases of animals (excluding Rift Valley fever and Crimean–Congo haemorrhagic fever) (2014)	Moderate	<ul style="list-style-type: none"> • Updated the taxonomy of and information on these viruses: Schmallenberg virus, Nairobi sheep disease virus, Cache Valley virus and Akabane virus • Agreed to further update by adding diagnostic details and test protocols in the 2022/2023 cycle



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Texts to be proposed for adoption (Disease chapters): Discussion

Interventions on the following texts

Chapter number	Chapter title
3.8.11.	Scrapie
3.8.13.	Theileriosis in sheep and goats (infection with <i>Theileria lestoquardi</i> , <i>T. luwenshuni</i> and <i>T. uilenbergi</i>)
3.9.3.	Classical swine fever (infection with classical swine fever virus) (diagnostic section only)
3.10.1.	Bunyaviral diseases of animals (excluding Rift Valley fever and Crimean–Congo haemorrhagic fever)

Proposed to the Assembly for adoption

Chapter number	Chapter title
3.8.11.	Scrapie
3.8.13.	Theileriosis in sheep and goats (infection with <i>Theileria lestoquardi</i> , <i>T. luwenshuni</i> and <i>T. uilenbergi</i>)
3.9.3.	Classical swine fever (infection with classical swine fever virus) (diagnostic section only)
3.10.1.	Bunyaviral diseases of animals (excluding Rift Valley fever and Crimean–Congo haemorrhagic fever)

Texts to be proposed for adoption (Disease chapters)

Chapter number	Title and year version adopted	Level of amendments	Major changes
3.10.2.	Cryptosporidiosis (2016)	Moderate	<ul style="list-style-type: none"> Updated the information on differences among species within the genus <i>Cryptosporidium</i> Updated the number of <i>Cryptosporidium</i> species as well as the number of genotypes and included a recent reference on taxonomy and molecular epidemiology of <i>Cryptosporidium</i> Revised the description and impact of the disease and its human health risk and zoonotic potential; updated the information on transmission, biosafety and biosecurity requirements
3.10.6.	Mange (2019)	Minimal	<ul style="list-style-type: none"> Minor updates, including addition of preliminary information on molecular methods and serology <p>Following Member comments, the Commission proposes to:</p> <ul style="list-style-type: none"> Amend lines 6 and 7 (<i>Summary</i>) and line 30 (Section A <i>Introduction</i>), to clarify that the term “scab” should be used in relation to <i>Psoroptes ovis</i>



Texts to be proposed for adoption (Disease chapters)

Chapter number	Title and year version adopted	Level of amendments	Major changes
3.10.7.	Salmonellosis (2016)	Moderate	<ul style="list-style-type: none">• Revised the sections on the nature and classification of the pathogen, the description and impact of the disease, and its zoonotic potential and biosafety and biosecurity requirements• Revised the example test procedures for isolation of <i>Salmonella</i> from food, feedstuffs, faecal and environmental samples and on immunological and nucleic acid recognition methods• Stressed that attenuation of live vaccines is essential to limit intestinal replication and persistence in the animals and environment, but such attenuation is unlikely to have no impact on the vaccinal response



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Texts to be proposed for adoption (Disease chapters): Discussion

Interventions on the following texts:

Chapter number	Chapter title
3.10.2.	Cryptosporidiosis
3.10.6.	Mange
3.10.7.	Salmonellosis

Proposed to the Assembly for adoption

Chapter number	Chapter title
3.10.2.	Cryptosporidiosis
3.10.6.	Mange
3.10.7.	Salmonellosis

WHEN INCLUDING AN OIE *TERRESTRIAL MANUAL* CHAPTER IN NATIONAL REGULATIONS:

- Only the most recently adopted version of an OIE standard is the version in vigour
- When referencing OIE Standards in national regulations, rather than giving a specific year, the regulations should refer to “the most recently adopted version of the OIE standard”

- **Draft Resolution No. 25:** Designation of OIE Reference Laboratories for terrestrial and aquatic animal diseases: presented for adoption before the General Session following the adapted procedure
- **Draft Resolution No. 26:** Designation of OIE Collaborating Centres for:
 - Antimicrobial Stewardship in Aquaculture (the Americas)
 - Camel Diseases (the Middle East)

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