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Dr Patrick Bastiaensen Programme Officer OIE Sub-Regional Representation for Eastern Africa

Terrestrial and Aquatic Manuals and the mechanism of standard adoption

Presented during the Regional Workshop for OIE National Focal Points for Veterinary Products (5th Cycle) Ezulwini, Swaziland 6-8 December, 2017

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- The OIE Terrestrial and Aquatic Manuals
- Case study : CBPP
- The mechanism of standard adoption
- Additional sources of information

Chapter 1

The OIE Terrestrial and Aquatic Manuals

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What is the purpose of the Manuals?

- Describe internationally agreed laboratory methods for disease diagnosis
- Enable the requirement for health certification in connection with trade to be met
- The *Terrestrial* Manual also covers the production and control of biological products e.g. vaccines

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The achievement of harmonisation of diagnostic testing and vaccination procedures :

- Avoids differences in interpretation of results
- Ensures the quality of diagnostic tests and vaccines

The OIE Standards



Published every 4 – 5 years



Published every year

The OIE Standards



Annual online updates

Published every year

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The OIE Standards



www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/

Abreviations, contributors, glossary,....

Part 1 : General Information (all updated between 2013 – 17)

- Management of veterinary diagnostic laboratories
- Collection, submission and storage of diagnostic specimens
- Transport of specimens of animal origin
- Biosafety and biosecurity in the veterinary labs and animal facilities
- Quality management in veterinary testing laboratories
- Principles and methods of validation of diagnostic assays
- High throughput sequencing, bioinformatics, computational genomics
- Principles of veterinary vaccine production

C Vaccine banks

• Sterility and (...) contamination of biological materials intended for veterinary use



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Abreviations, contributors,....

- Part 1 : General Information
- Management of veterinary diagnostic laboratories





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Part 2 : Disease – specific Information (almost all updated since 2012)

- Multiple species
- Apinae (bees)
- Aves (birds)
- Bovinae (bovines)
- Equidae (equids)
- Leporidae (rabbits)
- Caprinae (goats and sheep)
- Suidae (pigs)
- "Other diseases"



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- "Other diseases"

- Anthrax, FMD,...
- American foulbrood, varroosis,...
- Avian influenza, fowl cholera,...
- Bovine Tb, CBPP,...
- African horse sickness, glanders,...

CCP Africa

Myxon

Camelpo



12 Nipah, cysticercosis,

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Part 2 : Disease – specific Information

- Amphibians
- Crustaceans
- Fish
- Molluscs



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Part 2 : Disease – specific Information

- Amphibians
- Crustaceans
- Fish
- Molluscs

- Batrachochytrium dendrobatidis, ranavirus (2)
- White spot disease, Taura syndrome virus, ...
- Infectious salmon anaemia, Koi herpes virus, .
- Abalone herpesvirus, ...





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Part 3 : Specific Recommendations

- Laboratory methodologies for bacterial antimicrobial susceptibility testing
- Biotechnology in the diagnosis of infectious diseases
- The application of biotechnology to the development of vet. Vaccines
- The role of official bodies in the international regulation of vet. biologicals
- Aligning risk management strategies with assessed biorisks
- Recommendations for validation of diagnostic tests (antibody detection, antigen detection, nucleic acid detection, statistics, reference samples, wildlife,....)
- Recommendations for the manufacture of vaccines (minimum requirements for the organisation and management of a vaccine manufacturing facility, for the production and quality control of vaccines, for aseptic production in vaccine manufacture.



www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/

Part 4 : OIE Reference Experts and Disease Index

- List of OIE Reference Laboratories
- Alphabetical list of diseases



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Part 3 : Specific Recommendations

None

Part 3 : OIE Expertise

- Reference Experts and Laboratories for diseases of aquatic animals
- List of Collaborating Centres for diseases of aquatic animals



Chapter 2

Case study : Contagious bovine pleuropneumonia (CBPP) Infection with *Mycoplasma mycoides subsp. mycoides SC*



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Chapter 2.4.8. (last version May 2014)

www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/

NB: Version adopted by the World Assembly of Delegates of the OIE in May 2014

CHAPTER 2.4.8.

CONTAGIOUS BOVINE PLEUROPNEUMONIA (INFECTION WITH MYCOPLASMA MYCOIDES SUBSP. MYCOIDES SC)

SUMMARY

Contagious bovine pleuropneumonia (CBPP) is a disease of ruminants (Bos and Bubalus genuses) caused by Mycoplasma mycoides subsp. mycoides SC (MmmSC; SC = small colony). It is manifested by anorexia, fever and respiratory signs such as dyspnoea, polypnoea, cough and nasal discharges in bovines. Diagnosis requires the isolation of the aetiological agent. The main problems for control or eradication are the frequent occurrence of subacute or subclinical infections, the persistence of chronic carriers after the clinical phase and the lack of extensive vaccine coverage.



Identification of the agent: Samples to be taken from live animals are nasal swabs and/or broncho-alveolar washings or pleural fluid obtained by puncture. Samples to be taken at percopsy.

Chapter 2.4.8. (last version May 2014)

www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/

A. INTRODUCTION

Contagious bovine pleuropneumonia (CBPP) is an infectious and contagious respiratory disease of *Bovidae* caused by *Mycoplasma mycoides* subsp. *mycoides* "small colony" (*Mmm*SC) with a major impact on livestock production and a potential for rapid spread. As a result, CBPP-infected countries are excluded from international trade of live animals.

*Mmm*SC is a mycoplasma, i.e. a wall-less bacteria (mollicute), belonging to the so-called "mycoides cluster" that groups five mycoplasma species that are ruminant pathogens (Manso-Silván *et al.*, 2009). These five mycoplasmas share phenotypic and genotypic characteristics that cause cross-reactions in conventional

diagnostic techniques. The closest relative to MmmSC is M. mycoides susbp capri (Mmc), which is usually found in goats.

In natural conditions, *Mmm*SC affects only the ruminants of the *Bos* genus, i.e. mainly bovine and zebu cattle but also the yak (*Bos grunniens*) and water buffaloes (*Bubalus bubalis*) (Santini *et al.*, 1992). *Mmm*SC has been isolated from sheep and goats in Africa, in Portugal and in India (Srivastava *et al.*, 2000). Among wild animals, one single case has been reported in American buffaloes (*Bison bison*) and none in African buffaloes (*Syncerus caffer*) or other wild ruminants. Small ruminants and wild animals do not play a role in the epidemiology of the disease, and CBPP is not a zoonotic agent.

The incubation period for naturally infected animals can range from 3 weeks to 6 months. The clinical manifestations in cattle range from hyperacute through acute, subacute and chronic forms.

Chapter 2.4.8. (last version May 2014)

www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/

B. DIAGNOSTIC TECHNIQUES

Clinical diagnosis of CBPP is unreliable as initial signs may be slight or non-existent and may be indistinguishable from any severe pneumonia. Therefore, CBPP should be investigated by pathological, microbiological, molecular or serological diagnostic methods. As the pathological lesions of CBPP are distinctive, and pathognomonic, abattoir surveillance for CBPP involving lung examination is a practical method for disease monitoring.

It is recommended to isolate and identify the causative organism in order to confirm an outbreak. Table 1 lists the laboratory methods used for the diagnosis of CBPP.

	Purpose								
Method	Population freedom from infection	Individual animal freedom from infection prior to movement	Contribution to eradication policies	Confirmation of clinical cases	Prevalence of infection – surveillance	Immune status in individual animals or populations post-vaccination*			
Agent detection and identification ¹									
In-vitro culture isolation (followed by species identification tests)	+++	-	-	+++	-	-			
Direct molecular test (PCR)	-	-	-	++	-	-			

Table 1. Laboratory methods currently used for diagnosis of CBPP and their purpose

Di

B. Diagnostic techniques

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Article 1 : Identification of the agent (direct diagnosis)

- Samples
- In-vitro culture
- Biochemical and immunological identification tests
- Molecular identification and typing (PCR)

Article 2 : Serological tests (indirect diagnosis)

- Complement fixation
- C-ELISA
- Immuno-blotting

B. Diagnostic techniques

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Article 3 : Requirements for vaccines

- Background
- Outline of production and minimal requirements

Characteristics of the seed (MmmSC strains T1/44 and T1sr).

Methods of manufacturing

Requirements for authorisation, registration, licensing

Chapter 3

The mechanism of standard adoption



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- new scientific information e.g. from research or disease outbreaks
- new diseases emerging (Nipah)
- new approaches e.g. vaccination



- Identify the appropriate Commission
- Diagnostic for terrestrial diseases : Biological Standards Commission (the "laboratory" Commission)

Specialist Commissions REVIEN

> Diagnostic for aquatic diseases : *Aquatic Animal Health Standards Commission (the "aquatic" Commission)*



 Using (wildlife) working group and ad hoc groups for specialist tasks e.g. animal welfare, shipment of biological samples, BSE, FMD, epidemiology, avian influenza,...



 Using individual experts, experts affiliated (designated) to OIE Reference Laboratories, Collaborating Centres, representatives from organisations having signed an Agreement with the OIE (e.g. IDF).







Chapter 4

Additional sources of information

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Codes and Manuals : a perfect match ?



Codes and Manuals : a perfect match ?

"No" nr 1

Some diseases are listed by the OIE but have no Code standard and no Manual text

"No" nr 2

• Some diseases are listed by the OIE, have no Code standard but have a Manual text

"No" nr 3

 Some diseases were de-listed in the past and chapters removed from the Code, but kept in the Manual

"No" nr 4

• The *"prescribed tests for international trade",* not yet covered by individual Manual text

Codes and Manuals : a perfect match ?

"No" nr 1

Some diseases are listed by the OI

"No" nr 2

Some diseases are listed by the OI

"No" nr 3

 Some diseases were de-listed in th kept in the Manual

"No" nr 4

The "prescribed tests for internation

Nairobi sheep disease

Bovine viral diarrhoea, trypanosomiasis

Vesicular stomatitis, spherical baculovirus

Bovine TB, Newcastle, Aujeszky

Complements to standards : guidelines

- List of antimicrobials of veterinary importance
- Fit for purpose accreditation
- Quantitative and qualitative risk assessment
- Wildlife disease risk analysis
- Terrestrial / aquatic animal health surveillance
- Quality standard and guidelines for vet. laboratories
- Private standards
- And much more....









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D ORGANISATION FOR ANIMAL HEALTH Font size: - AAA + Language : | Français | cting animals, preserving our future Keywords Search Scientific expertise Solidarity Animal health in the World Standard Setting Overview **Collaborating Centres** Terms of reference List of Centres erence on Annual reports Map LATEST DISEASE ALERT Reduction Guidelines for applicants Criteria and internal rules ecurity for All 🖥 **Reference** Centre 20.11.17: Equine piroplasmosis Networks Reference Laboratories Terms of reference List of Laboratories awa, Canada Map and networks Annual reports R Criteria and internal rules Proficiency testing **Reference** Centre Guidelines for applicants 9 10 Networks More news Biological threat reduction WAHIS PORTAL **OIE Biological threat** Animal Health Da reduction strategy OFFLU, the animal influenzas network CMC-AH, The Crisis Management Centre-Animal Health Registration of diagnostic kits **KEY DATES** 25 Background information Procedure for submission Download application form The register of diagnostic 21-26 MAY 2017 kits 85th General Session of the World Contact of OIE Delegates Veterinary products

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egister of diagnostic kits certified by the OIE as validated as fit for purpose

for purpose' means that the kit has to be validated to such a level to show that the kit's results can be interpreted to have a defined meaning erms of diagnosis or another biological property being examined.

sease	Name of the Diagnostic kit	Name of the Manufacturer	Contact	Type of kit	Purpose(s) validated	Date and Number of registration	Validation studies Abstract Sheet	Kit insert	i Set
an Influenza	BioChek Avian Influenza Antibody test kit	BioChek UK Ltd	info@biochek.com	ELISA	see Resolution No XXVII adopted in May 2008 by the World Assembly of the OIE Delegates	May 2008 Registration Number: 20080203	AS Biochek Al Antibody test kit	User's manual	ALEI
ite spot ease	IQ 2000 TM WSSV Detection and Prevention System	GeneReach Biotechnology Corp	sales@genereach.com	PCR	see Resolution No XXVII adopted in May 2008 by the World Assembly of the OIE Delegates	May 2008 Registration Number: 20080304	12 AS IQ 2000	User's manual	RTA alth D
vine ongiform	Prionics AG - Check Western		info@prionics.com	Western Blo	ot 🔁	May 2008 Registration 21-26	12 1/AY 2017	User's manual	
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3	Contact		kits			85th Ge	eneral Ses	sion of t	the Wo
	Veterinary proc	ducts				of OIE	Delegates		



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21/11/2017 Algeria : Dr Mohamed Abdelhafid Henni

06/11/2017 Malawi : Dr Patrick Chikungwa

07/00/0047 I thus - Dr Zahasia Mahasia



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Africa



FAO Reference Laboratories EMPRES

Twinning with OIE Reference Laboratories



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(c) P. Bastiaensen (oie) 2005

At present the expertise and diagnostic capacity provided through Reference Laboratories and Collaborating Centres is located mainly in developed countries. This tendency leads to a geographical distribution favouring the northern hemisphere.

There is a need for a more even spread both in terms of geography and countries' development status. Capacity and expertise needs to be extended to developing and in-transition countries so that they can become self-sufficient in effective surveillance prophylaxis and control, and that, when justified, reliable evidence and scientific justification can be provided to certify animals and animal products as 'safe for trade'.

Colondan of such

Africa-based OIE Reference laboratories

- African Horse Sickness African Swine Fever
- Bluetongue
- Contagious bovine pleuro-pneumonia
- Echinococcosis / Hydatidosis
- Foot-and-Mouth Disease
- Lumpy Skin Disease Sheep and goat pox
- Rabies
- Rift Valley Fever

Represen Contagious bovine pleuro-pneumonia

Regional	Dr (Ms) Chandapiwa Marobela-Raborokgwe
OIE deleg	Botswana National Veterinary Laboratory (BNVL),
	Off Gaborone - Francistown highway (A1), Sebele
OIE focal	Private Bag 0035,
	Ophonese DOTOMANIA
Hereinia	Gaborone BOT SWANA Tel: (267) 392.88.16. Fax: (267) 392.89.56
Veterinar	Email: cmarobela-raborokgwe@gov.bw

OIE man

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Foot and mouth disease

and the second	
Veterin	Dr Onkabetse George Matlho Botswana Vaccine Institute (BVI)
10000000	
Scient	Department of Animal Health and Production
and the second	Broadhurst Industrial Site
Intern	Lejara Road
a supervised	Private Bag 0031,
Sanita	Gaborone BOTSWANA
Food s	Tel: (267) 391.27.11 Fax: (267) 395.67.98
	Telex: 2535 BD
the sector of the	
Anima	Email: gmatlho@bvi.co.bw

Referen

Regional	Dr François Maree				
	Onderstepoort Veterinary Research				
Library	Transboundary Animal Diseases Programme				
1.2	Private Bag X05,				
Contacts	Onderstepoort 0110				
Links	Pretoria, SOUTH AFRICA				
CITICS	Tel: (27) 12 529 95 75 Fax: (27) 12 529 95 43				

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24/11/2017 Kenya : Dr Obadiah Njagi 21/11/2017 Algeria : Dr Mohamed Abdelhafid Henni 06/11/2017 Malawi : Dr Patrick Chikungwa

Thank you for your attention



Patrick Bastiaensen

p.bastiaensen@oie.int

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