

Dr Patrick Bastiaensen

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



Agenda

- 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



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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- Describe internationally agreed laboratory methods for disease diagnosis
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The achievement of harmonisation of diagnostic testing and vaccination procedures :

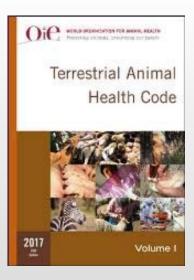
- Avoids differences in interpretation of results
- Ensures the quality of diagnostic tests and vaccines

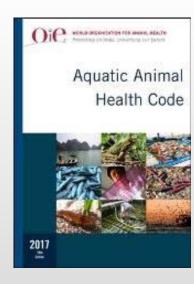


The OIE Standards

CODES

- Terrestrial
- Aquatic

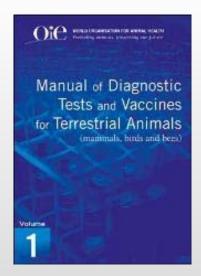


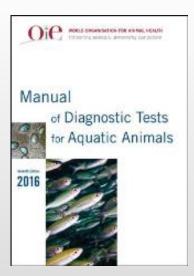


Published every year

MANUALS

- Terrestrial
- Aquatic





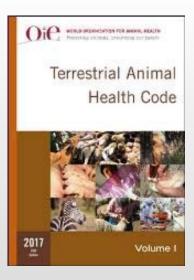
Published every 4 – 5 years

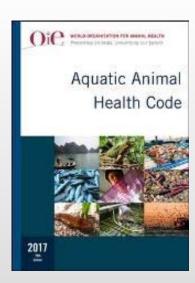


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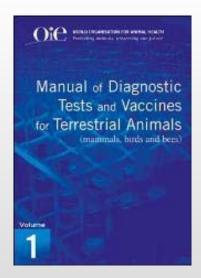




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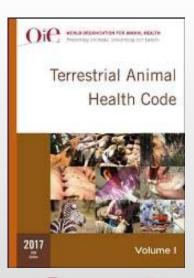
Annual online updates

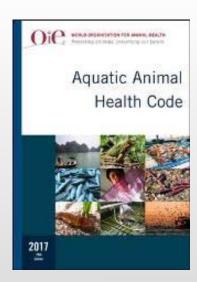


The OIE Standards

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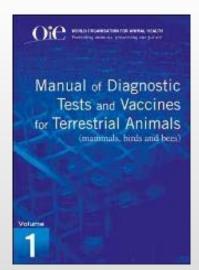






MANUALS

- Terrestrial
- Aquatic











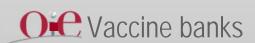


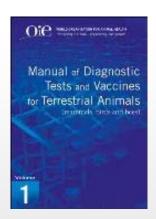
www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/

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



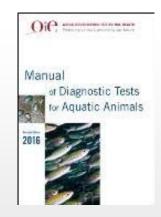


www.oie.int/en/international-standard-setting/aquatic-manual/access-online/

Abreviations, contributors,....

Part 1: General Information

Management of veterinary diagnostic laboratories



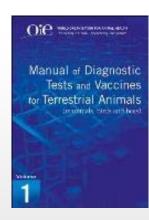
Quality management in veterinary testing laboratories



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

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"





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

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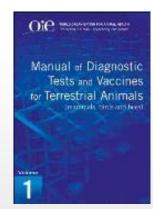
- Anthrax, FMD,...
- American foulbrood, varroosis,...
- Avian influenza, fowl cholera,...
- Bovine Tb, CBPP,...
- African horse sickness, glanders,...



CCP s, PPR, SGP,

Africa Nipah, cysticercosis,...

Camelpo cter, toxoplasmosis,



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

Part 2 : Disease – specific Information

- Amphibians
- Crustaceans
- Fish
- Molluscs





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

Part 2 : Disease – specific Information

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



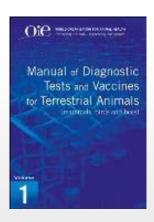




www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/

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.

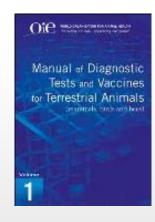




www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/

Part 4 : OIE Reference Experts and Disease Index

- List of OIE Reference Laboratories
- Alphabetical list of diseases





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

Part 3 : Specific Recommendations

None

Part 3 : OIE Expertise

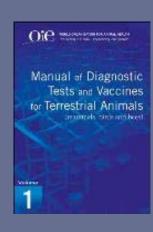
- Reference Experts and Laboratories for diseases of aquatic animals
- List of Collaborating Centres for diseases of aquatic animals





Chapter 2

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





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 necropsy

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.

MmmSC 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 *Mmm*SC 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.

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

	Purpose									
Method	Population freedom from infection	Individual animal freedom from infection prior to movement	Contribution to eradication policies	of clinical of infection – in 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)	-	-	-	++	-	-				



B. Diagnostic techniques

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

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

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

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





- 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)



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



Global experts

 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).



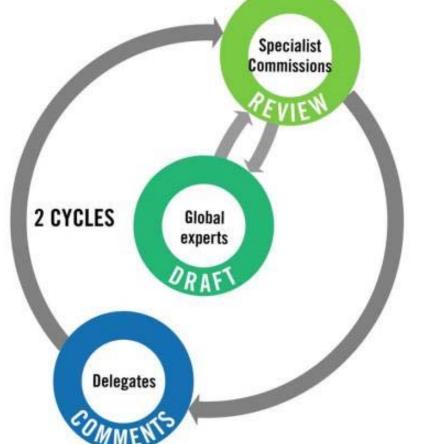
- Commission reports and draft standards are sent to the OIE Delegates twice per year
- 60 day window for comments



Also increasingly transparency on the OIE website (portals of the four Specialised Commissions)



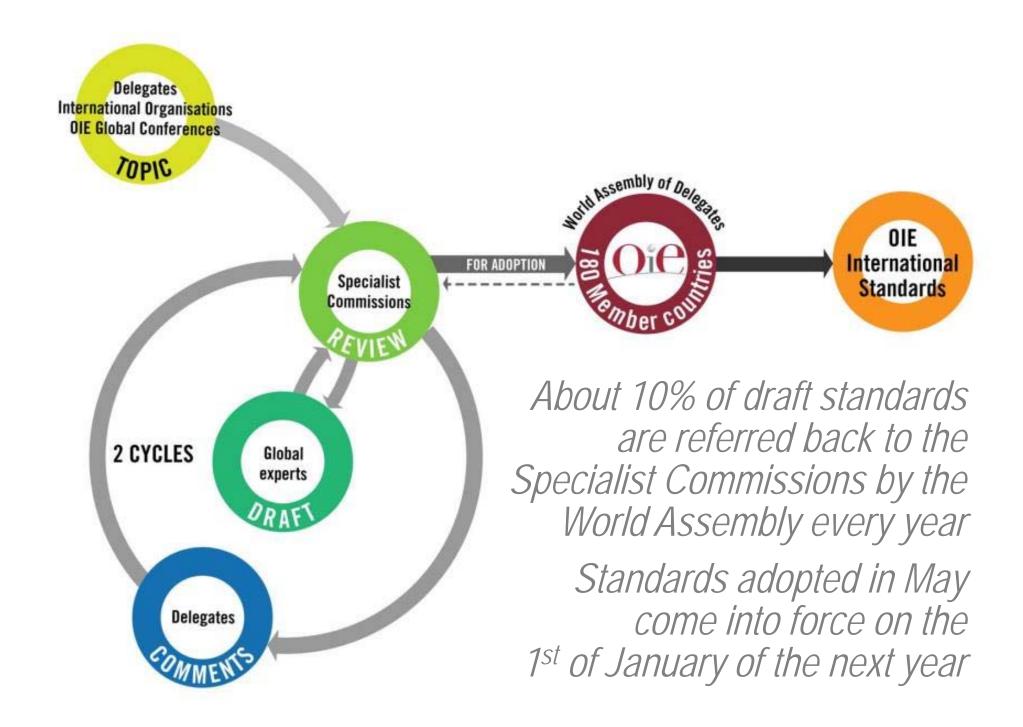
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Importation or transit of aquatic animals and aquatic animal products for any purpose regardless of the <u>infection</u> with SYCV spring viraemia of carp status of the exporting country, zone or compartment

- 1) Competent Authorities should not require any conditions related to SVCV, regardless of the infection with SVCV status of the exporting country, zone or compartment, when authorising the importation or transit of the following aquatic animal products derived from the a species referred to in Article 10.9.2. that which are intended for any purpose and which-comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or equivalent that has been demonstrated to inactivate SVCV);
 - pasteurised fish products that have been subjected to heat treatment at 90°C for at least ten minutes (or any time/temperature equivalent which that has been demonstrated to inactivate SVCV);
 - mechanically dried eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes or any time/temperature equivalent which that has been demonstrated to inactivate SVCV);

 - e) fish meal
- 2) When authorising the importation or transit of aquatic animals and aquatic animal products of a species when autonising the importation or transic or equation are equation arrange products on a spectrum referred to in Article 10.9.2., other than those referred to in point 1 of Article 10.9.3., Competent Authorities renered to the August 10.9.2., other than those referred to in point 1 of August 10.9.2., Competers Augustiness should require the conditions prescribed in Articles 10.9.7. to 10.9.121 relevant to the infection with SVCV
- 3) When considering the importation or transit of aquatic animals and aquatic animal products of a species not When considering the importation or transit or aquatic animals and aquatic animal products or a species not covered referred to in Article 10.9.2, but which could reasonably be expected to pose a risk of transmission covered referred to in Article 10.9.2. but which could reasonably be expected to pose a risk of items of SVCV_, the Competent Authority should conduct a risk analysis in accordance with the spread of SVCV, the Competent Authority should conduct a risk analysis in accordance with the recommendations in Chapter 2.1. The Competent Authority of the exporting country should be informed of



Chapter 4

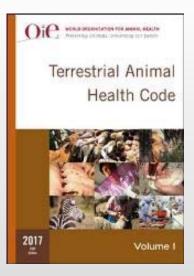
Additional sources of information

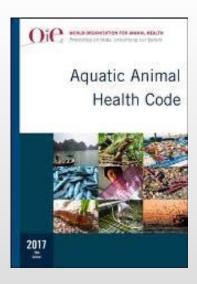


Codes and Manuals : a perfect match?

CODES

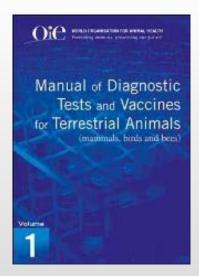
- Terrestrial
- Aquatic

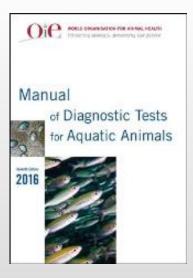




MANUALS

- Terrestrial
- Aquatic







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

Nairobi sheep disease

"No" nr 2

Some diseases are listed by the OI

Bovine viral diarrhoea, trypanosomiasis

"No" nr 3

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

Vesicular stomatitis, spherical baculovirus

"No" nr 4

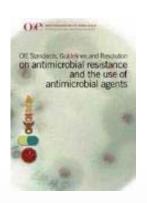
The "prescribed tests for internation

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....

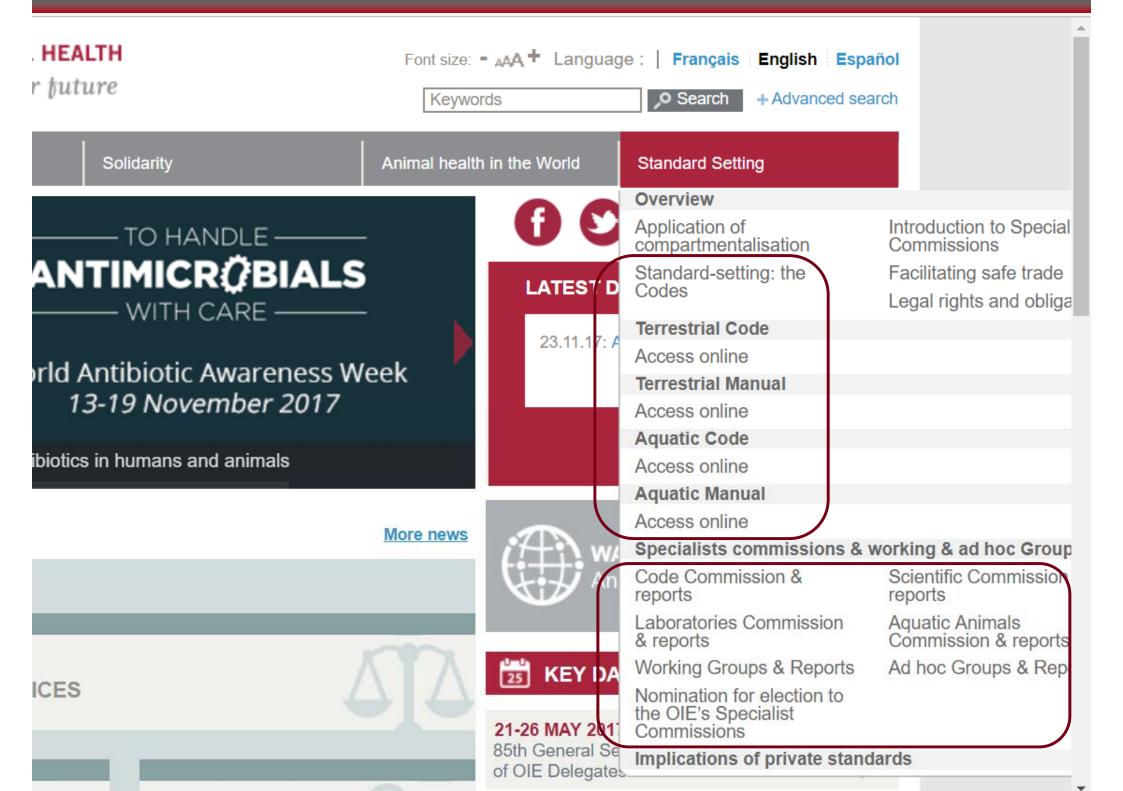












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cting animals, preserving our future

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Veterinary products

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85th General Session of the World

of OIE Delegates

Keywords



	Scientific expertise	Solidarity	Animal health	n in the World Standard Setting
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	Proficiency testing	Criteria and internal rules		
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	Biological threat reduction		More news	WAHIS PORTAL
	OIE Biological threat reduction strategy			Animal Health Da
	OFFLU, the animal influenza	as network		
	CMC-AH, The Crisis Manage	ement Centre-Animal Health		
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	Background information	Procedure for submission		- NET 5/1120
	Download application form	The register of diagnostic kits		21-26 MAY 2017 85th General Session of the World

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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	(ir
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 AI Antibody test kit	User's manual	ALI
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	AS IQ 2000	User's manual	RT
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WORLD ORGANISATION FOR ANIMAL HEALTH Protecting animals, preserving our future







lotifications

13/10/2017 Namibia: Anthrax (hippopotamus) 10/10/2017 Cote D'Ivoire : African swine fever 22/09/2017 Tanzania : Anthrax (hippopotamus)

21/09/2017 Botswana Foot and mouth disease (serotype pending)







Representations

Regional Commission

OIE delegates

OIE focal points

Veterinary councils

Veterinary training

OIE mandates

Transparency

Veterinary services

Scientific information

International solidarity

Sanitary safety in trade

Food safety

Animal welfare

Reference centres

Regional programmes

Library

Contacts

Links



News

11,2017 Harmonisation of registration of vet. personnel in the SADC re 11,2017 We need YOU to handle antimicrobials with care I 11.2017 Position of Project Coordinator Southern Africa (Gaborone) 10.2017 Launch of the OIE's EBO-SURSY Project website (Bamako) 10.2017 Position of PRAPS Project Executive Secretary (Bamako) fr. 10.2017 Training workshop on the capture and tagging of difficult dogs

10.2017 Improving the rabies national control plan in Tunisia 09.2017 ■ The VETGOV Programme comes to a close

09.2017 2017 World Rabies Day : zero by 30

09.2017 New OIE Bulletin for download (pdf)

09.2017 Jocelyn Merot leaves OIE Tunis office, returns to France 09.2017 Claudia Schoene appointed in Gaborone

news archives since 2007 1

Featured Vou Tube presentation

Barnako, 13 November 2017. Misuse and overuse of antimicrobials increase resistance risk, endangering both animal and human health and welfare. But YOU can HELP, particularly as a member of the Veterinary Services. Indeed, you have a role to play in fighting antimicrobial resistance....

Appointments of OIE Delegates in Africa

24/11/2017 Kenya: Dr Obadiah Njagi

21/11/2017 Algeria: Dr Mohamed Abdelhafid Henni

06/11/2017 Malawi : Dr Patrick Chikungwa 07/00/0047 I thus - Dr Zalovia Mahamaa



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Sanitary safety

Safeguard world trade by publishing health standards for international trade in animals and animal products



The OIE develops normative documents relating to rules that Member Countries can use to protect themselves from the introduction of diseases and pathogens, without setting up unjustified sanitary barriers. The main normative works produced by the OIE are: the Terrestrial Animal Health Code, the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, the Aquatic Animal Health Code and the Manual of Diagnostic Tests for Aguatic Animals.

OIE standards are recognised by the World Trade Organization as reference international sanitary rules.

They are prepared by elected Specialist Commissions and by Working Groups bringing together internationally renowned scientists, most of whom

are experts within the network of about 300 Collaborating Centres and Reference Laboratories that also contribute towards the scientific objectives of the OIE.

These standards are adopted by the World Assembly of Delegates

Downloads and online versions of the OIE standards

Transp					_
Veteri	Terrestrial Animal Health Code Vol. 1	26th edition (2017)		4 Mb	\blacksquare
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Intern	Aquatic Animal Health Code	20th edition (2017)		2 Mb	$\overline{\Psi}$
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Anima	Aquatic Animal Health Code	20th edition (2017)	HTML	online	$\overline{\Psi}$
Reference					_
Regional	Manual of Diagnostic Tests and Vaccines for Terrestrial Animals	Latest edition	HTML	online	Ψ
Library	Terrestrial Animais				
Contacts	Manual of Diagnostic Tests for Aquatic Animals	Latest edition	HTML	online	\blacksquare
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	List of anti-microbials of veterinary importance	2014	7	0.2 Mb	Ψ



The WTO's Sanitary and Phyto-Sanitary (SPS) Agreement

The WTO's 2014 Trade Facilitation Agreement

■ The OIE's specialist commissions :

11 .

The Terrestrial Animal Health Standards Commission ("Code Commission")

The Scientific Commission for Animal Diseases ("Scientific Commission")

The Biological Standards Commission ("Laboratories Commission")

The Aquatic Animal Health Standards Commission ("Aquatic Animals Commission")

■ The specialist commission's members from the Africa region :



Dr Gideon Brückner (South Africa) Scientific Commission (President)



Dr Baptiste Dungu (Congo) Scientific Commission (Member)



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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 07/00/0047 I thus - D. Zalosia Mahasaa

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lotifications

13/10/2017 Namibia: Anthrax (hippopotamus) 10/10/2017 Cote D'Ivoire : African swine fever 22/09/2017 Tanzania : Anthrax (hippopotamus)

21/09/2017 Botswana Foot and mouth disease (serotype pending)





Representations

Regional Commission

OIE delegates

OIE focal points

Veterinary councils

Veterinary training

OIE mandates

Transparency

Veterinary services

Scientific information

International solidarity

Sanitary safety in trade

Food safety

Animal welfare

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News

11,2017 Harmonisation of registration of vet. personnel in the SADC re 11,2017 We need YOU to handle antimicrobials with care I 11 2017 Position of Project Coordinator Southern Africa (Gaborone) 10.2017 Launch of the OIE's EBO-SURSY Project website (Bamako) 10.2017 Position of PRAPS Project Executive Secretary (Bamako) fr. 10.2017 Training workshop on the capture and tagging of difficult dogs 10.2017 Improving the rabies national control plan in Tunisia 09.2017 ■ The VETGOV Programme comes to a close 09.2017 2017 World Rabies Day : zero by 30 09.2017 New OIE Bulletin for download (pdf) 09.2017 Jocelyn Merot leaves OIE Tunis office, returns to France 09.2017 Claudia Schoene appointed in Gaborone

news archives since 2007 1

Featured You Tube presentation

WE NEED YOU to handle antimicrob...





Appointments of OIE Delegates in Africa

24/11/2017 Kenya: Dr Obadiah Njagi

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A Section

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FAO Reference Laboratories EMPRES



Twinning with OIE Reference Laboratories



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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'.

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-Raborokowe

OIF delet Botswana National Veterinary Laboratory (BNVL), Off Gaborone - Francistown highway (A1). Sebele

OIE focal Private Bag 0035,

Veterinar Gaborone BOTSWANA

Tel: (267) 392.88.16. Fax: (267) 392.89.56

Veterinar Email: cmarobela-raborokgwe@gov.bw

Foot and mouth disease

Veterii Dr Onkabetse George Matlho

Botswana Vaccine Institute (BVI)

Scient Department of Animal Health and Production

Broadhurst Industrial Site

Intern Lejara Road

Sanita Private Bag 0031, Gaborone BOTSWANA

Food : Tel: (267) 391.27.11 Fax: (267) 395.67.98

Telex: 2535 BD

Anima Email: gmatlho@bvi.co.bw

Reference

Library

Regional Dr François Maree

Onderstepoort Veterinary Research

Transboundary Animal Diseases Programme

Contacts Private Bag X05, Onderstepoort 0110 Pretoria, SOUTH AFRICA

Tel: (27) 12 529 95 75 Fax: (27) 12 529 95 43

Appointments of OIE Delegates in Africa

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Thank you for your attention



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