

A photograph of a man in a blue cap and plaid shirt kneeling in a barn, feeding a black and white cow. The scene is set in a barn with other cows visible in the background. The text 'OIE#86SG' is overlaid on the top left of the image, with the number '86' in yellow and 'OIE' and 'SG' in white. Two yellow horizontal bars are positioned above and below the text.

OIE#86SG

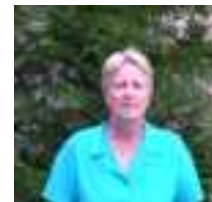


Report on Activities of the Biological Standards Commission 2017–2018

Beverly Schmitt
President

Members

- Beverly Schmitt (USA) – President
- Franck Berthe (France) – Vice-President
- Hualan Chen (China [PPR]) – Vice-President
- Tony Fooks (UK) – Member
- Mehdi El Harrak (Morocco) – Member
- Peter Daniels – (Australia) – Member

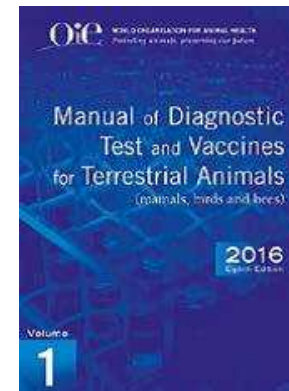


- Formal meetings:
 - 12–15 September 2017
 - 6–9 February 2018
- Email communications

- *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
- OIE Reference Centres (for terrestrial animals)
- *Ad hoc* Groups
- International Standardisation/Harmonisation
 - Standardisation programme
 - OIE Register of diagnostic kits
- Liaison with other Commissions

Activities

1. *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual)*



- Member Country comments are compiled by the OIE Secretariat
- The Consultant Editor reviews them and brings technical, controversial or conflicting comments to the attention of the BSC
- The BSC evaluates comments, approves changes or refers for further editing or input from subject matter experts
- 29 chapters and the glossary are being proposed for adoption

Chapters proposed for adoption

Glossary

- 1.1.3. Transport of biological materials
- 1.1.8. Principles of veterinary vaccine production
- 2.1.1. Anthrax
- 2.1.2. Aujeszky's disease (infection with Aujeszky's disease virus)
- 2.1.9 Heartwater
- 2.1.16 Q fever (vaccine section)
- 2.1.17 Rabies (infection with rabies virus)
- 2.1.19 Rinderpest (infection with rinderpest virus)
- 2.1.24 West Nile fever

Chapters proposed for adoption

- 2.2.5 Infestation with *Aethina tumida* (small hive beetle)
- 2.2.6 Infestation of honey bees with *Tropilaelaps* spp.
- 2.3.1 Avian chlamydiosis
- 2.3.2 Avian infectious bronchitis
- 2.3.7 Duck virus enteritis
- 2.3.11 Fowl typhoid and Pullorum disease
- 2.4.10 Enzootic bovine leukosis
- 2.4.14 Malignant catarrhal fever
- 2.4.15 Theileriosis
- 2.4.16 Trichomonosis
- 2.4.17 Animal trypanosomoses (including Tsetse-transmitted, but excluding surra and dourine)
- 2.5.2 Contagious equine metritis

Chapters proposed for adoption

- 2.5.4 Epizootic lymphangitis
- 2.5.11 Glanders and Meliodosis
- 2.7.4 Contagious agalactia
- 2.7.6 Enzootic abortion of ewes (Ovine chlamydiosis)
- 2.8.2 Atrophic rhinitis of swine
- 2.8.8 Swine vesicular disease
- 3.4 The role of official bodies in the international regulation of veterinary biologicals
- 3.7.2 Minimum requirements for the production and quality control of vaccines

Improved transparency regarding chapter comments

- Member Country and expert comments on draft chapters
- Have added a traceability table showing chapter by chapter BSC actions in response to comments
- When making comments on draft chapters, please submit rationale for proposed changes to the text and include references where relevant

Other *Terrestrial Manual* issues

- BSC received a number of requests to add additional references for minor statements. The *Terrestrial Manual* is not intended to provide comprehensive literature review
 - Intended to provide key references as an entry point to further literature review
- Chapters 1.1.8 and 2.7.2 regarding vaccine production have been amended to eliminate references to the target animal batch safety test where other quality control measures are in place

- In the future, revised chapters will contain the sentence:
“Safety tests in target animals are not required by many Regulatory Authorities for the release of each batch or serial. Where required, standard procedures are generally conducted using fewer animals than are used in the safety test required for licensing.”

Other *Terrestrial Manual* issues

- Based on outcome of a Technical Workshop for Thermotolerant PPR vaccines, the BSC has suggested guidance for characterising thermotolerance properties of vaccines and to highlight the importance of maintaining and monitoring the required cold chain temperatures during storage and transport
- Will be added to Chapter 1.1.8 *Principles for Veterinary Vaccine Production* which has been circulated for review

Other *Terrestrial Manual* issues

- An SOP for antigen preparation for the dourine complement fixation test was accepted by the BSC and has been submitted to the experts updating the chapter for next cycle
- Use of bovine tongue epithelium for production of foot and mouth disease vaccine will remain in the chapter. However, given:
 - Concerns regarding purity of product
 - Concern regarding increased levels of non-structural proteins
- BSC reaffirmed that method cannot be recommended in an OIE Standard test and would be proposed for deletion at the General Session in 2020

- The BSC has reviewed and accepted the report of a validation study for a real-time reverse transcriptase PCR for equine influenza. Chapter will be updated to include primer sets and cycling parameters with review by equine influenza reference laboratories
- The BSC will expand the title of Chapter 2.9.4 Cysticercosis to: Cysticercosis (including infection with *Taenia solium*) and ask experts to expand the section on *T. solium*

Other *Terrestrial Manual* issues: *ad hoc* Groups

- Rabies AHG was tasked with updating the *Terrestrial Manual* chapter on Rabies with a focus on incorporating newly developed validated tests, deleting obsolete tests and updating sections on oral vaccination of dogs and manufacturing methods for vaccines.
- The chapter was circulated a second time after the BSC February meeting. Following comments received from the European Union, the BSC, in consultation with the ten OIE Reference Laboratories for rabies, proposes the following amendments:

CHAPTER 2.1.17.

**RABIES (INFECTION WITH RABIES VIRUS
AND OTHER LYSSAVIRUSES)**

SUMMARY

...

Serological tests: Virus neutralisation (VN) and enzyme-linked immunosorbent (ELISA) assays are suitable tests for monitoring the antibody response of vaccinated animals in the framework of rabies control. For the purposes of measuring antibody responses to vaccination prior to international animal movement and trade, only VN methods, e.g. (FAVN test and RFFIT) tests are acceptable, as well as ELISAs validated as fit for this purpose. Serological tests should not be used for primary diagnosis.

Amendments to chapters proposed for adoption: Rabies

Table 1. Test methods available for the diagnosis of rabies and their purpose

Method	Purpose					
	Population freedom from infection	Individual animal freedom from infection prior to movement	Contribute to eradication policies	Confirmation of clinical cases	Prevalence of infection – surveillance	Immune status in individual animals or populations post-vaccination
Agent identification						
RIAD (antigen detection)	++	n/a	++	++	++	n/a
Sellers staining** (histological staining for 'Negri bodies')	+	n/a	+	+	+	n/a
MIT (virus isolation)	n/a	n/a	+++ ±	+++ ±	+++ ±	n/a
Detection of immune response						
ELISA	n/a	n/a ++	+++	n/a	n/a	+++

Key: +++ = recommended method, validated for the purpose shown; ++ = suitable method but may need further validation; + = may be used in some situations, but cost, reliability, or other factors severely limits its application; – = not appropriate for this purpose; n/a = purpose not applicable.

RIAD = rabies immunoperoxidase antigen detection; MIT = mouse inoculation test;

ELISA = enzyme-linked immunosorbent assay.

**See Section 1.3.3. Sellers staining is no longer recommended for routine diagnosis.

Amendments to chapters proposed for adoption: Rabies

- Delete Section B.1.3.1.
- ~~iv) Rabies immunoperoxidase antigen detection (RIAD)~~
- ~~As an alternative antigen detection method, the RIAD uses polyclonal rabies antibody with a widely available horseradish peroxidase-conjugated secondary antibody (Rahmadane *et al.*, 2017).~~
- ~~RAHMADANE I., CERTOMA A.F., PECK G.R., FITRIA Y., PAYNE J., COLLING A., SHELL B.J., BEDDOME G., WILSON S., YU M., MORRISSY C., MICHALSKI W.P., BINGHAM J., GARDNER I.A. & ALLEN J.D. (2017). DEVELOPMENT AND VALIDATION OF AN IMMUNOPEROXIDASE ANTIGEN DETECTION TEST FOR IMPROVED DIAGNOSIS OF RABIES IN INDONESIA. [PLOS NEGL. TROP. DIS.](#), 11 (11):E0006079. DOI: 10.1371/JOURNAL.PNTD.0006079.~~

■ Section B.2. Serological tests

The main application of serology for rabies is to determine responses to vaccination in domestic animals, particularly in connection with international travel, or for monitoring mass vaccination campaigns in dogs and other wildlife reservoir species. The measurement of rabies antibodies has typically involved virus neutralisation (VN) tests to detect rabies virus neutralising antibodies ELISAs are now also recognised as acceptable tests to detect binding antibodies. A strong but not strict correlation in levels is observed between these two different antibody detection methods. Depending on the nature of the ELISA, there can be variable sensitivity and specificity. In contrast to the ELISA, poor quality sera can cause cytotoxicity in VN tests, which could lead to false-positive results. Depending on the intended purpose, both tests are useful for detecting responses to vaccination if appropriate cut-offs are used. However, ELISAs are currently not applicable to international movement of animals or trade.

Amendments to chapters proposed for adoption: Rabies

- Section B.2.3. Enzyme-linked immunosorbent assay (ELISA)
- ELISAs provide a rapid serological test that avoids the requirement to handle live rabies virus. Those tests detect antibodies that can specifically bind to rabies virus antigens, primarily the rabies virus glycoprotein and nucleoprotein. ~~The test can be used to determine antibody responses in individual dog and cat serum specimens following vaccination prior to international movement, provided the specific assay formulation has been validated as fit for this purpose, including a comparison with neutralisation tests, and is internationally accepted.~~ None of the available direct, indirect or competitive ELISAs are validated for international animal movement or trade (Wasniewski *et al.*, 2014). However, ELISAs are ~~also~~ a useful tool for monitoring rabies vaccination campaigns in wildlife species provided they are properly validated for this purpose. A commercial ELISA has been recommended for monitoring rabies vaccination campaigns in foxes and raccoon dogs (Wasniewski *et al.*, 2016).

Activities

2. Reference Laboratories and Collaborating Centres

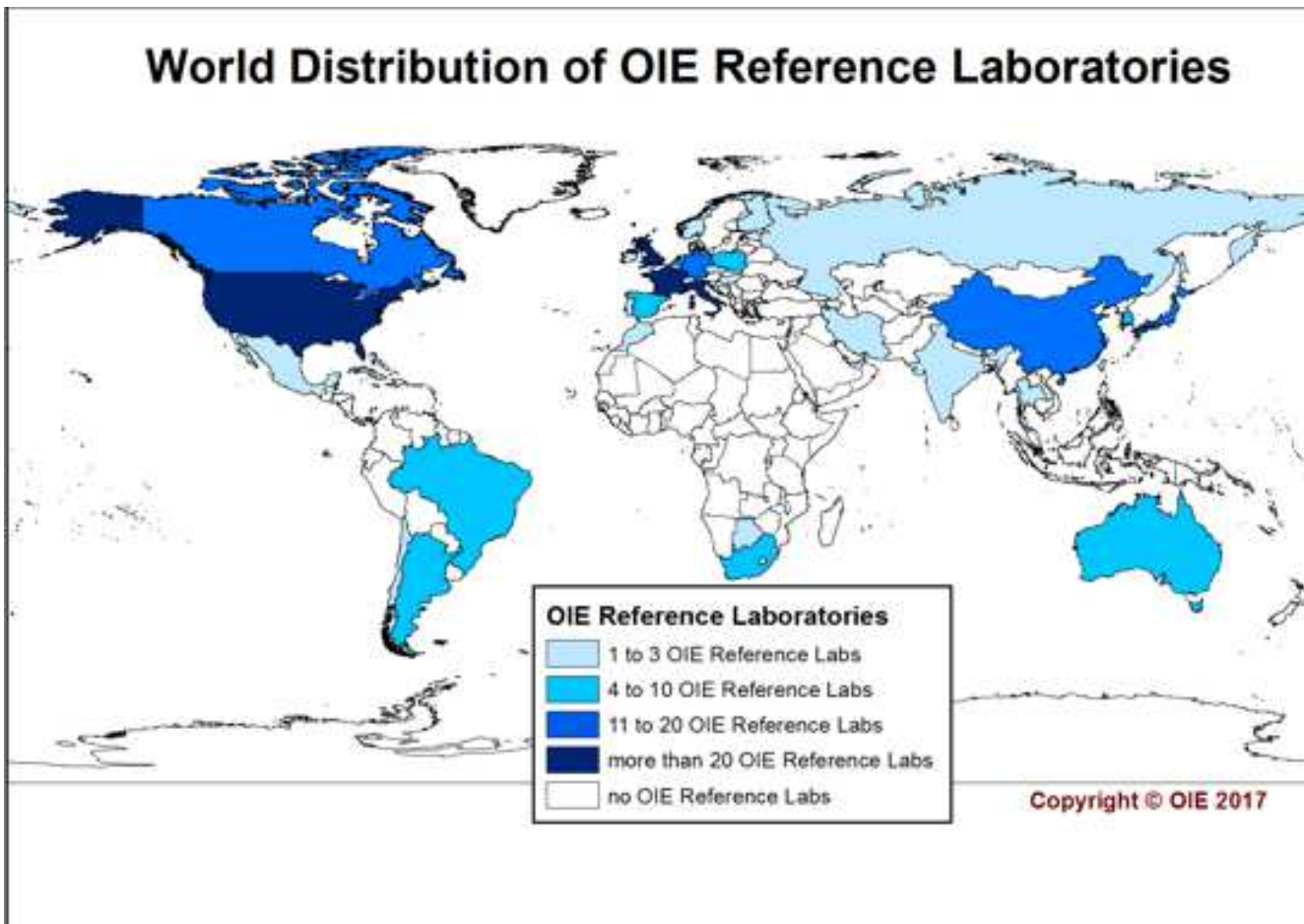


OIE Reference Laboratories and Collaborating Centres in 2017

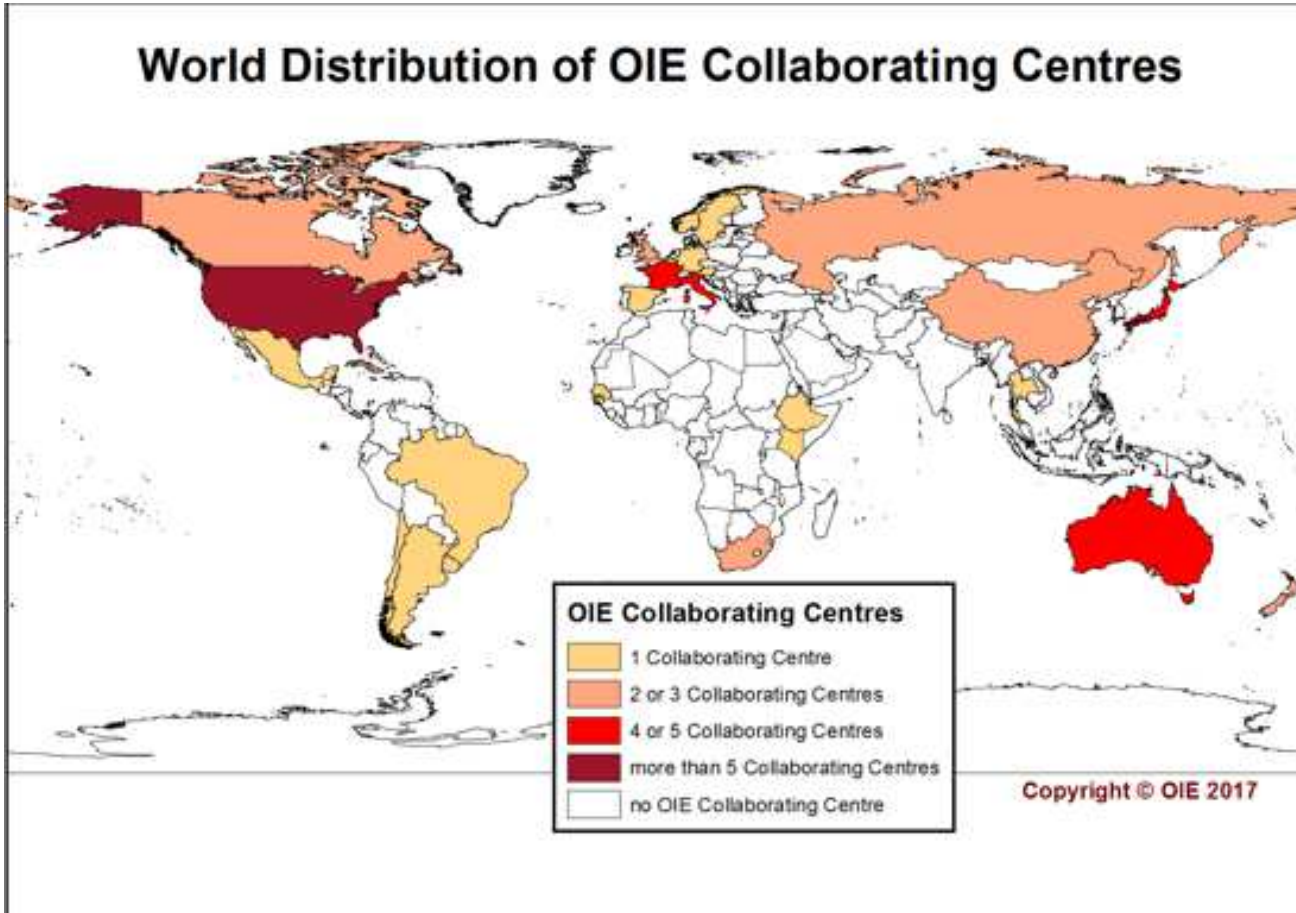
	Reference Laboratories	Collaborating Centres	Total
Number	267	55	322
Countries	38	28	46*
Diseases/Topics	118	49	-
Experts	194	-	-

* *Countries hosting both Reference Laboratories and Collaborating Centres are not counted twice.*

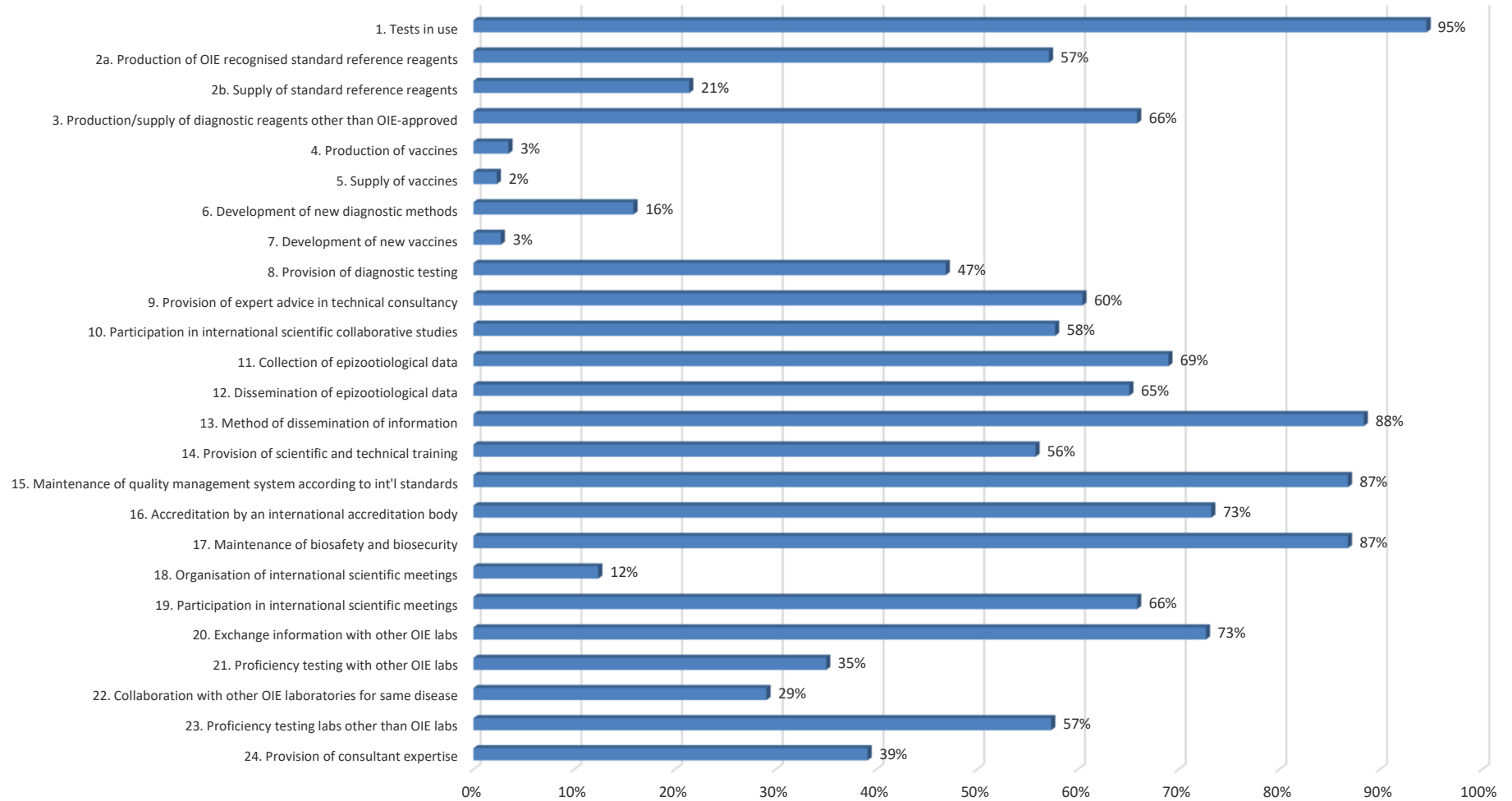
World Distribution of OIE Reference Laboratories



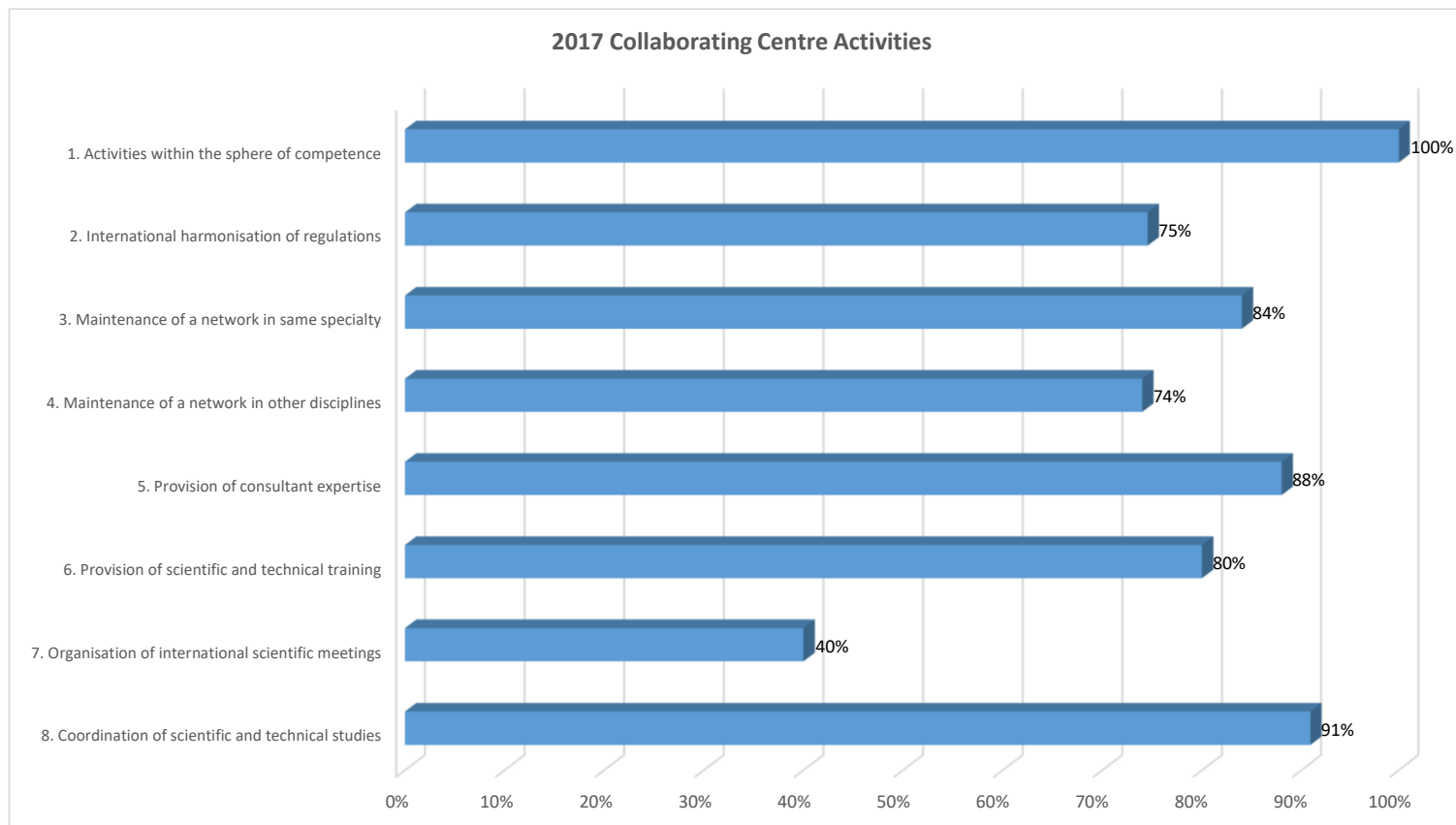
World Distribution of OIE Collaborating Centres



2017 OIE Reference Laboratory Activities



Activities of Collaborating Centres in 2017



Reference laboratory annual report summary

- Reports received from 227/228 Reference Laboratories and 53/53 Collaborating Centres
- In accordance with the SOP, adopted last year by the Assembly and implemented for the first time, the Delegate of institute that did not submit a report received a letter regarding interest in maintaining reference laboratory status

ISO 17025 or equivalent progress

- Laboratories that have not demonstrated having achieved ISO 17025 or equivalent accreditation will have OIE Reference Laboratory status suspended (Resolution No. 17)
- Possibility for reinstatement within 2 years if they achieve accreditation
- If laboratory does not achieve accreditation within 2 years they must re-apply for OIE Reference Laboratory status once accreditation is obtained
- 17 laboratories identified for suspension, three have requested withdrawal from list

New OIE Reference Laboratories recommended for adoption

Disease	Institution	Expert
Infectious bursal disease	Harbin Veterinary Research Institute, Chines Academy of Agricultural Sciences, Harbin, People's Republic of China	Dr Xiaomei Wang
Salmonellosis	Animal and Plant Quarantine Agency, Ministry of Agriculture, Food and Rural Affairs, Gimcheon-si, Gyeongsangbuk-do, Korea (Rep. of)	Dr Min-Su Kang
Chronic wasting disease	Norwegian Veterinary Institute, Oslo, Norway	Dr Sylvie Benestad
Highly pathogenic and low pathogenic avian influenza	Federal Centre for Animal Health, Vladimir, Russia	Dr Victor N. Irza
Newcastle disease	Federal Centre for Animal Health, Vladimir, Russia	Dr Victor N. Irza

OIE Reference Laboratories requested delisting

Disease	Institution	Expert
Avian chlamydiosis	Ghent University, Belgium	Prof. Daisy Vanrompay
Equine infectious anaemia	National Institute of Animal Health, Ibaraki, Japan	Dr Makoto Yamakawa
Tularemia	Hungarian Academy of Sciences, Budapest, Hungary	Dr Miklós Gyuranecz

Replacement experts at OIE Reference Labs

Disease	Country	Former expert	Replaced by
Bovine spongiform encephalopathy and scrapie	UK	Dr Marion Simmons	Dr John Spiropoulos
Aujeszky's disease	Netherlands	Dr Andre Bianchi	Dr Willie Loeffen
African horse sickness	UK	Dr Javier Castillo-Olivares	Dr Simon Carpenter
Bovine spongiform encephalopathy and scrapie	Argentina	Dr Francisco Javier Blanco Viera	Dr Fernando Oscar Delgado
Anthrax	Canada	Dr Elizabeth Golsteyn-Thomas	Dr Kingsley Amoako

Replacement experts at OIE Reference Labs

Disease	Country	Former expert	Replaced by
Salmonellosis	Canada	Dr Cornelis Poppe	Dr Gitanjali Arya
Classical swine fever	Canada	Dr John Pasick	Dr Aruna Ambagala
Highly pathogenic avian influenza	Canada	Dr John Pasick	Dr Yohannes Berhane
Theileriosis	Italy	Dr Santo Caracappa	Dr Alessandra Torina

Replacement of expert of OIE Reference Labs

Disease	Country	Former expert	Replaced by
Bluetongue, Equine infectious anemia, Equine encephalomyelitis, West Nile Fever	USA	Dr Eileen Ostlund	Dr Tracy Sturgill Samayoa
Rabies	Mexico	Dr Juan Antonio Montano Hirose	Dr Jose Alvaro Aguiar Setien
Aujeszky's disease, vesicular stomatitis, swine influenza	USA	Dr Sabrina Swenson	Dr John Schlitz

New Procedures for Designation of Centres (May 2018)

- Development of new procedures in collaboration with the Aquatic Animal Health Standards Commission
- Six main focus areas identified:
 1. Laboratory expertise
 2. Training and education
 3. Animal health management
 4. Animal production
 5. Veterinary products
 6. Wildlife health and biodiversity

New Procedures for Designation of Centres (May 2018)

- Future CC applicants will choose area of expertise from this list; existing CCs will be asked where their expertise lies within the list
- This approach assures that the OIE will have CCs for defined topics of strategic interest to the OIE
- CCs will be designated for a fixed 5-year term period with review at end of term
- A summary of achievements for the past 5 years and proposal for activities for forthcoming years will be required for renewal

New Procedures for Designation of Centres (May 2018)

- Five performance criteria for CC evaluations are proposed:
 - Lack of submission of an annual report
 - No response to or progress on specific collaboration projects
 - A pattern revealing lack of activity
 - No response to requests from OIE HQ for scientific expertise
 - Noncompliance with administrative obligations relating to transparency and confidentiality

New Procedures for Designation of Centres (May 2018)

- Any CC scoring negatively when measured against these criteria could progress down path to de-listing
- SOP includes procedure for failure to submit an annual report
- CC may be proposed for de-listing if the need for activities in the specific topic is no longer required. Proposal to be made by the Council and Regional Commission and voted on by General Assembly

TWINNING LABORATORIES

- Laboratory Twinning programme is functioning well
- Contributing to improving global disease control capacity
- Countries in all five OIE regions are benefiting
- Demand and interest remains high

- 47 projects completed
- 30 projects underway
- 9 projects pending (“in the pipeline”)

- Most popular topics
 - Avian influenza and Newcastle disease
 - Brucellosis
 - Rabies
 - Foot and mouth disease

Adopted (May 2012)

- RABIES – Changchun Veterinary Research Institute, China (People’s Rep. of)
- AVIAN MYCOPLASMOSIS – National Centre for Animal and Plant Health, Cuba
- CONTAGIOUS BOVINE PLEUROPNEUMONIA (CBPP) – National Veterinary Laboratory, Botswana

Adopted (May 2014)

- INFECTIOUS SALMON ANAEMIA – Aquaculture Pathology Laboratory, Chile
- OIE Collaborating Centre for VETERINARY EPIDEMIOLOGY AND PUBLIC HEALTH – China Animal Health and Epidemiology Centre (CAHEC), China (People’s Rep. of)

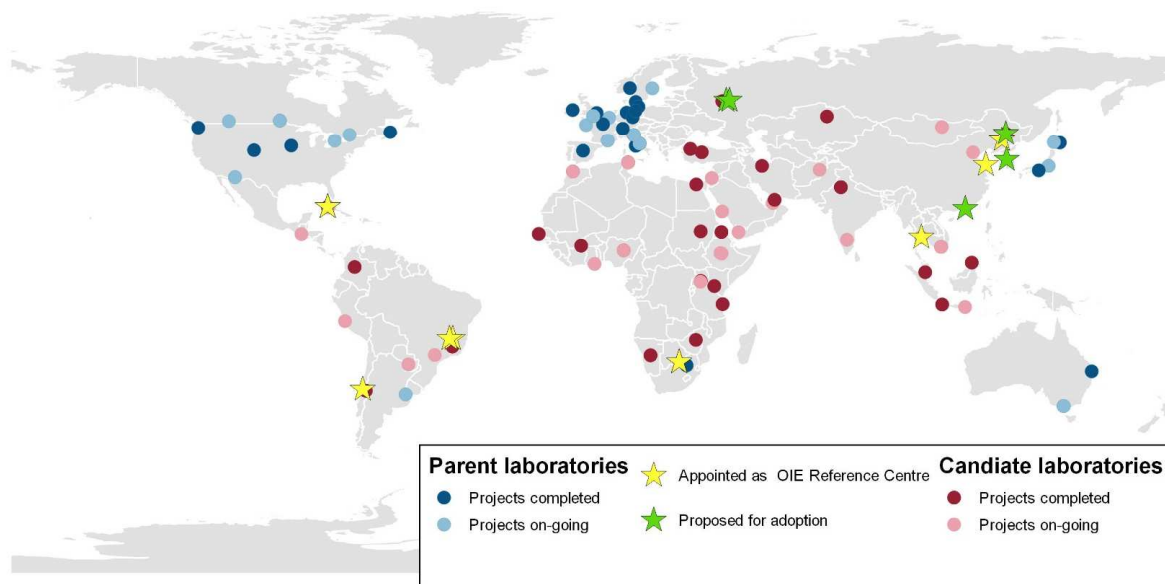
Adopted (May 2016)

- BRUCELLOSIS – National Institute of Animal Health, Thailand
- AVIAN INFLUENZA – Laboratório Nacional Agropecuário em Campinas – Lanagro-SP, Brazil
- NEWCASTLE DISEASE – Laboratório Nacional Agropecuário em Campinas – Lanagro-SP, Brazil

Proposed for adoption (May 2018)

- INFECTIOUS BURSAL DISEASE – Harbin Veterinary Research Institute, Chinese Academy of Agricultural Sciences, Harbin, China (People’s Rep. of)
- AVIAN INFLUENZA – Federal Centre for Animal Health (FGBI-ARRIAH), Vladimir, Russia
- NEWCASTLE DISEASE – Federal Centre for Animal Health (FGBI-ARRIAH), Vladimir, Russia
- INFECTIOUS HAEMATOPOIETIC NECROSIS - Animal and Plant Inspection and Quarantine Technical Centre, Guangdong Province, China (People’s Rep. of)
- VIRAL HAEMORRHAGIC SEPTICAEMIA - Aquatic Animal Quarantine Laboratory, National Fishery Products Quality Management Service, Ministry of Oceans & Fisheries, Korea (Rep. of)

OIE Laboratory Twinning Projects



Activities

3. *Ad hoc* Groups (AHG)



- The *ad hoc* Group on Transport of Biological Materials updated the *Terrestrial Manual* chapter
- The *ad hoc* Group on Replacement International Standard Bovine Tuberculin continues to update the BSC on its progress in developing and evaluating a replacement

Ad hoc Groups

- The *ad hoc* Group on High Throughput Sequencing, Bioinformatics and Computational Genomics has advanced the project to develop an OIE genomic platform; the OIE has submitted an application for funding
- Two *ad hoc* Groups are needed to develop an OIE Genomic Platform over the next 4 years
 - Define business processes, operations and main technical specifications.
 - Development of sub-modules for the diseases that have been selected for the pilot phase of the platform project (i.e. rabies, peste des petits ruminants, bluetongue, African horse sickness, Rift Valley fever)

- The BSC endorsed the draft OIE Guidelines for the Establishment, Operation and Networking of Veterinary Biobanks. In addition, the Commission endorsed the draft proposal for the pilot phase of the project
- The *ad hoc* Group on Veterinary Biobanking will review progress made by a core group of OIE Reference Laboratories charged with refining metadata schemes, quality requirements and testing system functionalities

Activities

4. International standardisation/harmonisation



- The BSC endorsed the document *International Reference Standards for Polymerase Chain Reaction*
- HPAI and Newcastle Reference Laboratories are undertaking a proficiency tests to evaluate possible reference serum
- The BSC has asked the Trichinellosis Reference Laboratories to organise a proficiency test with intent in generating International Reference standards
- The BSC approved listing a equine influenza (EI) reagent recommended by the EI Expert Surveillance Panel on vaccine strains

OIE Register of diagnostic kits:

- Renewal for an additional 5 years

Name of the diagnostic kit and target disease	Avian Influenza Disease Antibody Test Kit: avian influenza
Manufacturer	BioChek UK Ltd

Name of the diagnostic kit and target disease	Prionics® - Check WESTERN: bovine spongiform encephalopathy
Manufacturer	Prionics AG

OIE Register of diagnostic kits:

- Renewal for an additional 5 years

Name of the diagnostic kit and target disease	IQ 2000™ WSSV Detection and Prevention System: white spot disease
Manufacturer	GeneReach Biotechnology Corporation

Name of the diagnostic kit and target disease	IQ Plus™ WSSV Kit with POCKIT System: white spot disease
Manufacturer	GeneReach Biotechnology Corporation

Summary: Draft Resolutions

- No. 14:** Amendments to the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*
- No. 16:** Designation of OIE Reference Laboratories for terrestrial animal diseases
- No. 17:** Suspension of OIE Reference Laboratories for terrestrial animal diseases
- No. 18:** Procedures for the designation of OIE Collaborating Centres
- No. 19:** Register of diagnostic kits validated and certified by the OIE

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Thank you for your attention!

