REPORT OF THE MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 12–15 February 2019

The OIE Biological Standards Commission met at the OIE Headquarters from 12 to 15 February 2019. Dr Matthew Stone, OIE Deputy Director General for International Standards and Science, welcomed the Commission: Prof. Emmanuel Couacy-Hymann, President, Dr John Pasick, Second Vice-President, Dr Ana Nicola and Dr Joseph O’Keefe, members of the Commission. Dr Franck Berthe, First Vice-President, and Prof. Ann Cullinane, member, could not attend.

1. Welcome

Dr Matthew Stone presented the new Performance Management Framework to the Commission. He explained that the object of the framework is continuous improvement of the work of all four OIE Specialist Commissions and the OIE Secretariats to meet expectations and for the benefit of the OIE Member Countries. He noted that the process includes regular meetings between Commission members and the Deputy Director General, the Presidents and the Director General, and a brief review at the end of each Commission meeting. Following the penultimate meeting prior to the next election, feedback on the work of the Commissions and individual members will be provided to the Director General and the Council.

Prof. Emmanuel Couacy-Hymann welcomed the Performance Management Framework, which will bring transparency to the processes and improve efficacy.

2. Adoption of Agenda

The proposed agenda was presented and adopted.

The Agenda and List of Participants are given at Annexes 1 and 2, respectively.


For this Agenda Item, the Commission was joined by the Consultant Editor of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (Terrestrial Manual), Dr Steven Edwards.

3.1. Update from September 2018 meeting: review of a validation dossier for a quantitative real-time PCR¹ method for detection of *Taylorella equigenitalis* directly from swabs

This item was postponed to September 2019 to give the Reference Laboratory experts time to complete a reproducibility study on PCRs including the above-mentioned PCR.

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¹ PCR: polymerase chain reaction
3.2. **Update on glanders issues: follow-up from the September 2018 meeting**

At the meeting in September 2018, the Commission discussed a number of agenda items relating to glanders and referred their conclusions to the two OIE Reference Laboratory experts for their consideration. One of the items the Commission had reviewed was the final report of a validation study on serological assays for glanders. The experts agreed that the *Terrestrial Manual* chapter should include some text and a reference to this study. The Commission acknowledged this and recommended that the authors amend the chapter accordingly, and that the study be published as soon as possible in the scientific literature.

Regarding the request to consider removing the mallein test from the *Terrestrial Manual* chapter on glanders on animal welfare grounds, the experts responded that the test remains useful in remote areas where blood samples cannot be transported properly, and therefore should be kept in the chapter. The Commission agreed to the experts’ advice noting that the text in the chapter covers the concerns raised: “The test is not generally recommended because of animal welfare concerns, however it can be useful in remote endemic areas where sample transport or proper cooling of samples is not possible.”

Finally, the experts agreed to include the validation study undertaken by a group led by Panaftosa in the *Terrestrial Manual* chapter. The Commission acknowledged this and recommended that the authors amend the chapter accordingly, and that the study be published as soon as possible in the scientific literature.

3.3. **Request from a Member Country regarding the chapter on bovine tuberculosis**

A Member Country requested amending the *Terrestrial Manual* Chapter 2.4.6 *Bovine tuberculosis* by inserting a recommendation for the use of heat-concentrated synthetic medium (HCSM) tuberculin for skin testing in cattle, as an acceptable alternative to purified protein derivative (PPD) tuberculin. Following consultation with the OIE Reference Laboratories for bovine tuberculosis, the Commission noted that PPD tuberculin is widely used and accepted in many countries. Therefore, the Commission concluded that, in the interest of standardisation of tuberculin testing reagents for international trade, the *Terrestrial Manual* should continue to recommend use of PPD bovine tuberculin as the preferred reagent for intradermal skin testing. However, the Commission acknowledged that, for domestic tuberculosis surveillance programmes, individual Member Countries may elect to use tuberculosis testing reagents other than those that are recommended in the *Terrestrial Manual*, provided these reagents are appropriately validated and calibrated in comparison with established reference standards.

It was noted that the *Terrestrial Manual* chapter would be updated once the new International Standard Bovine Tuberculin has been adopted by Member Countries (see agenda item 5.2). The expected date for proposal for adoption is the General Session in 2021.

3.4. **Improving Table 1 of the disease-specific chapters on tests available rated against purpose**

It was noted that some contributors to the disease-specific chapters of the *Terrestrial Manual* have difficulty understanding Table 1. *Test methods available and their purpose* and how to fill it in. The Commission agreed to add explanatory notes to the instructions for authors, stressing that the six columns under the heading “Purpose” relate to chapter 1.1.6 of the *Terrestrial Manual* entitled *Principles and methods of validation of diagnostic assays for infectious diseases*. The Commission also amended the text to clarify the rating system (what is meant by “+++” and “++” and “+”, etc.) to assist contributors to better rate the tests.
3.5. Review of Member Country comments received on draft chapters and their endorsement for circulation for second-round comment and proposal for adoption in May 2019

The Commission reviewed the comments that had been received on the 12 draft chapters that had been sent for first-round Member Country comment in October 2018, and approved 11 for circulation, some subject to clarification of certain points by the experts, for second-round Member Country comment and eventual proposal for adoption by the Assembly in May 2019.

The chapter on dourine (interim version) was put on hold following the proposal from the ad hoc Group on Animal African Trypanosomoses to develop three chapters in the Terrestrial Code: Infection with animal trypanosomes of African origin excluding infection with T. evansi and T. equiperdum; Infection with T. evansi (surra in all species); and Infection with T. equiperdum (dourine in horses) (see agenda items 3.8 and 9.1.1). The ad hoc Group will be given the comments and requested to update the chapters.

The 11 chapters and a brief summary of the main amendments made in response to Member Country comments are:

2.1.5. Echinococcosis (infection with Echinococcus granulosus and with E. multilocularis): minor editorial amendments were made and some references were updated; agreed to add a sentence and reference on the role of domestic cats in transmission of echinococcosis; and the decision to delete the section on diagnosis of Echinococcus in environmental samples was reversed as the tests are considered important. The OIE Reference Laboratory expert was asked to address technical comments on coproantigen tests, evidence of the zoonotic potential of some of the Echinococcus species; ratings of some of the tests in Table 1; the correct name of an Echinococcus species given in Table 4 and the possibility of giving a temperature range rather than a specific temperature in the test protocols.

2.1.13. New World screwworm (Cochliomyia hominivorax) and Old World screwworm (Chrysomya bezziana): minor amendments were made and references to a commercial reagent were deleted. One technical comment on the first instars was referred to the expert.

2.5.1. African horse sickness (infection with African horse sickness virus): a sentence on virus inactivation was added; text and a reference on the role of dogs in disease transmission was added; text and a reference on the suspicion of vector transmission was added; a sentence on the use of cut-off values and test interpretation was added; and a sentence stating that serotypes 5 and 9 are not included in vaccines was added; a proposal to add two tests to Table 1 was rejected as no rationale was provided. A technical comment on a primer sequence was referred to the experts.

2.5.5. Equine encephalomyelitis (Eastern, Western and Venezuelan) (NB: merged version): minor amendments were made. The Commission agreed that RT-PCR is reverse transcription PCR and not reverse transcriptase PCR; for consistency this correction will be made throughout the Terrestrial Manual.

2.5.6. Equine infectious anaemia: many minor amendments were made clarifying the text. A request for a reference to support the claim that nucleic acid sequence comparisons have demonstrated a marked relatedness among viruses in Lentivirus genus was referred to the Reference Laboratory experts. The proposal to change the ratings of the ELISA² in Table 1 was not accepted as no rationale was given. The Commission agreed that information concerning one Member Country’s licensed test is not useful and should be deleted and replaced with generic text.

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² ELISA: enzyme-linked immunosorbent assay
2.5.7 Equine influenza (infection with equine influenza virus): minor editorial amendments were made; the text on the competitive/blocking ELISA was strengthened including some of its ratings in Table 1 because the assay has proven to be robust and useful for specific purposes, especially where large numbers of samples are to be tested; a paragraph on and a reference for a competitive/blocking ELISA were added.

2.7.10 Peste des petits ruminants (infection with peste des petits ruminants virus [PPRV]): the Commission did not agree to delete a statement that PPR was responsible for mass mortality of Mongolian siaga antelope as the OIE Reference Laboratory experts reiterated that the outbreak had been confirmed as PPRV (Shatar et al. [2017], Arch. Virol., 162, 3157–3160); in the agent identification section of Table 1, the penside test ratings were degraded for the three purposes: individual animal freedom from infection prior to movement, contribute to eradication policies and confirmation of clinical cases as the reliability of the test is not described in the chapter and it should not be used for these purposes; the OIE Reference Laboratory experts reviewed a recently published paper on detection of PPRV antibody using a penside test and considered that it is not yet validated for general use or widely available and thus did not include it in Table 1; the experts did not recommend inclusion of a description of a real-time RT-PCR, but did recommend users looking to implement an assay to contact one of the OIE Reference Laboratories to get the latest advice.

2.8.1. African swine fever (infection with African swine fever virus [ASF]): many minor amendments were made clarifying the text; the paragraph on distribution of ASF was shortened to refer to regions rather than individual countries; virus isolation was added to Table 1; the OIE Reference Laboratory experts were asked to re-examine the ratings in the serology section of Table 1; in the section on identification of the agent, a Member Country proposed addition of virus isolation in porcine bone marrow cells along with a protocol as it is mentioned elsewhere in the chapter.

2.8.3. Classical swine fever (infection with classical swine fever virus) (NB: Vaccine Section only): Some comments were received on the diagnostic testing part of this chapter: these were put on hold for the present as comments had been requested on the vaccine section only. Minor comments received and accepted.

2.9.7. Mange: one minor comment received and accepted.

3.1. Laboratory methodologies for bacterial antimicrobial susceptibility testing: many minor amendments were made clarifying the text. The OIE Reference Laboratory expert was asked to consider comments regarding laboratories undertaking a dilution method, the reinstatement of a sentence on the reliability of agar dilution, the description of non-wild type bacterial species as microbiologically resistant and the use of the term “breakpoint” method in Table 1. The Commission agreed to the standards and guidelines for antimicrobial susceptibility testing and subsequent interpretive criteria listed in the chapter should be international rather than national.

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

The chapters can be downloaded from the following address:

3.6. Selection of chapters for update in 2019/2020 review cycle

The Commission examined the status of chapters that had previously been identified for update in the 2019/2020 review cycle. The Commission decided to add to the list chapters that had last been updated in 2014. The following chapters have thus been identified:
2.1.2 Biotechnology in the diagnosis of infectious diseases
2.1.3 Managing biorisk: examples of aligning risk management strategies with assessed biorisks
2.3.1 The application of biotechnology to the development of veterinary vaccines
3.1.3 Bluetongue (infection with bluetongue virus)
3.1.5 Crimean–Congo haemorrhagic fever
3.1.7 Epizootic haemorrhagic disease (infection with epizootic haemorrhagic disease virus)
3.1.10 Japanese encephalitis
3.1.11 Leishmaniosis
3.1.12 Leptospirosis
3.1.15 Paratuberculosis (Johnne’s disease)
3.1.X Infection with Trypanosoma evansi (surra in all species)
3.2.1 Acarapisosis of honey bees (infestation of honey bees with Acarapis woodi)
3.2.4 Nosemosis of honey bees
3.2.7 Varroosis of honey bees (infestation of honey bees with Varroa spp.)
3.3.3 Avian infectious laryngotracheitis
3.3.5 Avian mycoplasmosis (Mycoplasma gallisepticum, M. synoviae)
3.3.6 Avian tuberculosis
3.3.14 Newcastle disease (infection with Newcastle disease virus)
3.3.15 Turkey rhinotracheitis (avian metapneumovirus)
3.4.1 Bovine babesiosis
3.4.4 Bovine genital campylobacteriosis
3.4.5 Bovine spongiform encephalopathy
3.4.7 Bovine viral diarrhoea
3.4.8 Contagious bovine pleurpneumonia (infection with Mycoplasma mycoides subsp. mycoides SC)
3.4.10 Haemorrhagic septicaemia (Pasteurella multocida serotypes 6:b and 6:e)
3.4.16 Infection with animal trypanosomes of African origin excluding infection with Trypanosoma evansi and T. equiperdum
3.5.3 Infection with Trypanosoma equiperdum (dourine in horses)
3.5.8 Equine piroplasmosis
3.5.10 Equine viral arteritis (infection with equine arteritis virus)
3.6.1 Myxomatosis
3.7.4 Contagious caprine pleuropneumonia
3.7.8 Ovine pulmonary adenomatosis (adenocarcinoma)
3.8.10 Transmissible gastroenteritis
3.9.1 Bunyaviral diseases of animals (excluding Rift Valley fever and Crimean–Congo haemorrhagic fever)
3.9.2 Camelpox
3.9.5 Cysticercosis
3.9.6 Listeria monocytogenes
3.9.10 Verocytotoxogenic Escherichia coli

The OIE Reference Laboratory or other experts, where necessary, would be asked to undertake the revisions.
3.7. New taxonomy for contagious bovine pleuropneumonia

The Commission was informed that the causative agent of contagious bovine pleuropneumonia, *Mycoplasma mycoides* subspecies *mycoides* SC (MmmSC) has been reclassified and reference to small colony (SC) has been removed. The OIE Reference Laboratories would be asked to confirm this change, and to update the chapter if necessary.

3.8. Feedback from the OIE ad hoc Group on Animal African Trypanosomoses

The ad hoc Group on Animal African Trypanosomoses advised that *Terrestrial Manual* Chapter 3.4.16 *Animal trypanosomoses (including tsetse-transmitted, but excluding surra and dourine)* should be amended to clearly indicate the fitness for purpose and limitations of the different laboratory diagnostics methods and to ensure correct alignment between the two chapters. The Commission had identified the chapter for update in the 2019/2020 review cycle taking into account this comment and the ad hoc Group’s proposal to develop three chapters: Infection with animal trypanosomes of African origin excluding infection with *T. evansi* and *T. equiperdum*; Infection with *T. evansi* (surra in all species); and Infection with *T. equiperdum* (dourine in horses) (see agenda items 3.5 and 9.1.1).

4. OIE Reference Centres

4.1. Annual reports of Reference Centre activities in 2018

As of 27 February 2019, 204 out of 214 (95%) Reference Laboratories and all 53 (100%) Collaborating Centres had submitted annual reports for 2018 to the OIE. In accordance with the adopted Procedures for designation of OIE Reference Laboratories (the SOPs) (http://www.oie.int/en/scientific-expertise/reference-laboratories/sops/) and the Procedures for designation of OIE Collaborating Centres (http://www.oie.int/en/scientific-expertise/collaborating-centres/sops/), the Commission agreed to review all the reports, noting in particular the performance of each Reference Centre with regard to fulfilling the Terms of Reference (ToR) to the benefit of OIE Member Countries. The Commission expressed its appreciation for the continued support and expert advice given to the OIE by the Reference Centres.

In accordance with the SOPs, those Reference Centres that were not complying with the performance criteria will be asked to provide an explanation of their situation; the Delegate will be in copy of all correspondence.

The activities relevant to the Terms of Reference of OIE Reference Centres for terrestrial animals are summarised in the following graphics:

![2018 Collaborating Centre Activities](image)
4.2. **Applications for OIE Reference Centre status**

The Commission recommended acceptance of the following applications for OIE Reference Centre status:

**OIE Reference Laboratory for Brucellosis** (Brucella abortus, B. melitensis and B. suis)
National Reference Laboratory for Animal Brucellosis (NRLAB), Department of Diagnostic Technology, China Institute of Veterinary Drug Control (IVDC), No.8 Zhongguancun South Street, Beijing 100081, CHINA (PEOPLE’S REP OF)
Tel.: (+86-10) 61.25.53.27
Email: dingjiabo@126.com
Designated Reference Expert: Prof. Jiabo Ding.

**OIE Reference Laboratory for Cysticercosis**
Helminthosis Laboratory, 1 Xujiapiing, Yanchangbu, Lanzhou 730046, Gansu Province CHINA (PEOPLE’S REP OF)
Tel.: (+86-931) 834.27.16; Fax: (+86-931) 834.09.77
Email: caixuepeng@caas.cn / caixp@vip.163.com
Designated Reference Expert: Prof. Xuepeng Cai.

**OIE Reference Laboratory for Avian mycoplasmosis** (Mycoplasma gallisepticum, M. synoviae)
Pendik Veterinary Control Institute, Bati mahallesi, Erol Kaya caddesi 1, 34890 İstanbul TURKEY
Tel.: (+90-216) 390.12.80; Fax: (+90-216) 354.76.92
Email: uozdemir@outlook.com; Website: https://vetkontrol.tarimorman.gov.tr/pendik
Designated Reference Expert: Dr Ümit Özdemir.
OIE Reference Laboratory for Contagious caprine pleuropneumonia
Pendik Veterinary Control Institute, Bati mahallesi, Erol Kaya caddesi 1, 34890 İstanbul TURKEY
Tel.: (+90-216) 390.12.80; Fax: (+90-216) 354.76.92
Email: uozdemir@outlook.com; Website: https://vetkontrol.tarimorman.gov.tr/pendik
Designated Reference Expert: Dr Ümit Özdemir.

OIE Collaborating Centre for Health of Marine Mammals
Tel.: (+39-011) 26.86.296
Email: credima@izsto.it; Website: www.izsto.it
Contact Point: Dr Cristina Casalone.

University Research Institute of Animal Health and Food Safety (IUSA-ULPGC), University of Las Palmas de Gran Canaria (ULPGC) Atlantic Center for Cetacean Research (ACCR), Campus de Cardones Trasmontaña s/n 35416, Arucas Las Palmas de Gran Canaria, SPAIN
Tel.: (+34-928) 45.97.11/12
Email: direccion_iusa@ulpgc.es; Website: www.iusa.eu
Contact Point: Prof. Antonio Jesús Fernández Rodríguez.

The Commission had consulted the OIE Working Group on Wildlife, which gave a favourable opinion on this application. The applicants will be asked which institute will be the initial “leader” of this consortium.

An application had been received for an OIE Reference Laboratory for trichinellosis. The Commission requested more information on the amount of diagnostic testing the laboratory undertakes, on their ability to receive samples from abroad, and further information on research projects that have been completed by the applicants. The Commission would review any supplementary information submitted at the next meeting in September 2019.

An application had been received for an OIE Collaborating Centre for Animal Welfare. The Commission consulted the Terrestrial Animal Health Standards Commission (the Code Commission), which has expertise in the domain of animal welfare, for an opinion on this application. The Code Commission gave a favourable review and noted the importance for the OIE of enlarging its network of expertise in the area of animal welfare. The Biological Standards Commission therefore accepted the application. In accordance with the Internal Rules for OIE Collaborating Centres, the application needs to be endorsed by the Regional Commission for Europe. Should the outcome be positive, the Centre would need to form a consortium with other Centres in Europe having a similar specialty.

An application had been received for an OIE Collaborating Centre for Traditional Veterinary Medicine. Before taking a decision on the technical aspects of the application, the Commission agreed to seek the view of the OIE Council on the principle of the OIE designating Centres on traditional medicines. The Commission also agreed to ask the candidate Centre to provide representative publications so that it can better understand the candidate Centre’s assessment of veterinary products. The applicants would also be asked to review the proposed title and scope as it currently implies that it covers practices that do not fall with the scope of the Main Focus Area “veterinary products”.

Finally an application had been received for an OIE Collaborating Centre for Continuing Education and Veterinary Capacity Building. Before the Commission could reach a decision, the applicant would be asked to provide more information on the staff at the institution, the number of trainings it has provided and the countries involved, and a full list of publications.
4.3. Changes of experts at OIE Reference Centres

The Delegate of the Member concerned had submitted to the OIE the following nomination for changes of experts at OIE Reference Laboratories. The Commission recommended their acceptance:

*Aujeszky’s disease, vesicular stomatitis and swine influenza,*
Dr Sabrina Swenson to replace Dr John Schiltz at the National Veterinary Services Laboratories, Ames, Iowa, UNITED STATES OF AMERICA

*Classical swine fever*
Dr Katsuhiko Fukai to replace Dr Shunji Yamada at the National Institute of Animal Health, Tokyo, JAPAN

*Bovine babesiosis and equine piroplasmosis*
Prof. Naoaki Yokoyama to replace Prof. Ikuo Igarashi at the Obihiro University of Agriculture and Veterinary Medicine, JAPAN

*Aujeszky’s disease*
Dr Marie-Frédérique Le Potier to replace Dr André Jestin at Anses Ploufragan, Laboratoire de Ploufragan-Brest, FRANCE

*Leptospirosis*
Dr Scott Craig to replace Dr Lee Smythe at the Queensland Health Scientific Services, AUSTRALIA

4.4. Review of new and pending applications for laboratory twinning

Dr Mariana Marrana from the OIE Programmes Department updated the Commission on the OIE Laboratory Twinning programme. As of February 2019, 50 projects have been completed, 28 projects are underway and 8 are awaiting funding before beginning.

Four new twinning proposals were presented to the Commission for technical review.

i) **United States of America – Thailand** for developing diagnostic and surveillance capacity for wildlife: the Commission observed that the concerns raised during the last meeting about the epidemiological situation of wildlife-associated disease in animal and public health in Thailand and the region had been addressed. The proposal now had detailed information on the targeted diseases and diagnostic techniques as well as a detailed plan for building capacity in this domain. The Commission supported the technical contents of this project.

ii) **Belgium – Burundi** for foot and mouth disease (FMD): the Commission noted that the comments made during the last meeting had been taken into consideration and therefore the length of the project and the number of trainings had been reduced. It was also confirmed that the main staff members involved in the project have permanent positions. The Commission supported the technical contents of this project.

iii) **France – Guinea** for brucellosis: the Commission supported the objectives and work plan of the project and highlighted the importance of brucellosis in the West African Region.

iv) **South Africa – Uganda** for Rift Valley fever: the Commission recognised the importance of Rift Valley fever diagnostics in the East African Region. However, the project proposal was not in line with the Guidelines for OIE Laboratory Twinning Projects. The Commission encouraged the parent and candidate laboratories to work with the OIE to shorten the timeline, add detail to the work plan (especially regarding sample collection, role of sentinel animals, and diagnostic techniques), clarify the role of each laboratory mentioned in the proposal and reduce the budget.
4.5. Development of procedures for the establishment and maintenance of OIE Reference Laboratory networks

The OIE currently has a small number of Reference Laboratory networks (FMD, OFFLU, bluetongue, and non-tsetse transmitted animal trypanosomoses), each operating according to its own model. The Commission noted that some of the networks, such as OFFLU and FMD, have remained functional and successful for a number of years while others, such as bluetongue, seem to have gradually become inactive. It would appear that the success of each network depends on having a highly motivated leader, a priority disease, a clear goal and well defined objectives.

With this in mind and to advance this project, the Commission identified three priority diseases that are of current global importance for which OIE Reference Laboratory networks could be established, namely African swine fever, PPR and rabies. The Commission then identified a potential leader among the OIE Reference Laboratories for these diseases, referring to the analysis made of six questions from the annual Reference Laboratory reports for 2017, and requested the Secretariat to contact the experts concerned to see if they would consider establishing a network.

The aim for the OIE and the Commission in establishing OIE networks is to attract experts from beyond the OIE Reference Laboratory network, e.g. from national laboratories, research institutions and universities. Once they have accepted the task, the lead experts would be asked to develop a compelling purpose and clear objectives to motivate potential partners to join the network. The Secretariat and the OIE Focal Points for Laboratories will assist in the task of identifying potential members of the network such as national laboratories. The proposed goals and objectives for the three networks, along with the identified partners, will be reviewed at the September 2019 meeting of the Commission.

In parallel, the Commission would examine the current Guidance for the Management of OIE Reference Centre Networks (http://www.oie.int/en/scientific-expertise/reference-laboratories/reference-centre-networks/) to see if they already provide a complete framework for OIE network or if they could be further developed into SOPs for eventual proposal for adoption by the Assembly in May 2020. The member would provide their feedback for review at the September 2019 meeting of the Commission.

4.6. Implementation of the new procedures for designation of OIE Collaborating Centres: mapping the existing Centres against the list of main focus areas and specialties

Following the September 2018 meeting, the Commission had agreed to continue the analysis of the activities of the existing Collaborating Centres and the mapping exercise, proposing into which main focus area and specialty3 each Centre falls. The Commission reviewed the analysis and agreed which Collaborating Centres had potential overlapping specialties and thus may need to form consortia. The Secretariat was tasked with further evaluating the activity reports to verify the situation. Once satisfied that there are overlapping activities, the Collaborating Centres in question would be informed of the outcome of the analysis. Of a total of 53 Collaborating Centres for terrestrial animal health issues, potential overlapping activities were identified in two Centres in the Africa region, eight in the Americas region, two in the Asia–Pacific region and four in the European regions. If confirmed that one of the Collaborating Centres is active in all the domains given in its title, the Centre may be asked to split into more than one OIE Collaborating Centre. In accordance with the timeline established during the September 2018 meeting, the Commission’s proposals would be sent to each Collaborating Centre for consideration and feedback for the September 2019 meeting.

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3 http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/A_List_of_focus_areas_and_specialties_for_OIE_Collaborating_Centers.pdf
5. **Ad hoc Groups**

- **Update on activities of past ad hoc Group meetings**

5.1. **Ad hoc Group on MERS-CoV (Middle East respiratory syndrome – coronavirus)**

Dr Gounalan Pavade from the OIE Science Department updated the Commission on the meeting of the **ad hoc** Group on MERS-CoV, which was held from 22 to 24 January 2019.

The **ad hoc** Group on MERS-CoV was convened by the OIE Director General primarily to draft a chapter for the OIE Terrestrial Manual that would set laboratory standards and provide validated internationally agreed upon procedures to be used for MERS-CoV confirmatory diagnosis in animals. The **ad hoc** Group began the draft chapter by agreeing on the assays and their ratings to be included in Table 1 **Test methods available and their purpose**. The Commission approved the proposed table with an amendment. The full draft **Terrestrial Manual** chapter detailing the diagnostic tests listed in Table 1 will be prepared by the **ad hoc** Group for review at the next Commission meeting in September 2019.

The **ad hoc** Group’s assessment of MERS-CoV against the listing criteria in Chapter 1.2 of the **Terrestrial Code**, the amended case definition and the update of the MERS-CoV Question and Answers document published on the OIE website was reviewed by the Scientific Commission on Animal diseases during its February 2019 meeting (see report of the meeting: Doc 87 SG/12/CS3 B).

The **ad hoc** Group report was endorsed and is attached as Annex 3.

5.2. **Ad hoc Group on Replacement of the International Standard Bovine Tuberculin**

Dr Glen Gifford from the OIE Antimicrobial Resistance and Veterinary Products Department updated the Commission on the ongoing OIE project to replace the International Standard Bovine Tuberculin (ISBT).

An OIE **ad hoc** Group of bovine tuberculosis experts is coordinating a project to develop and evaluate a replacement for the ISBT. The project involves evaluation and calibration of two candidate tuberculins in comparison with the current international standard. It is being carried out in three phases: (i) initial selection of two tuberculin candidates based on an evaluation of the manufacturers’ documentation (completed in December 2017), (ii) a preliminary laboratory evaluation conducted in two OIE Reference Laboratories for Bovine tuberculosis (completed in August 2018), and (iii) a larger scale international collaborative study involving the three Reference Laboratories and fifteen other sites.

The international collaborative study is scheduled to conclude in June 2019, except for one cattle study that will be conducted in August 2019. In September 2019, the Commission will be given an interim update on the outcome of the study. The final report will be presented to the Commission in February 2020 for endorsement. If the results of the evaluation and calibration studies are satisfactory, a draft Resolution recommending adoption of a new ISBT will be presented to the OIE Assembly for adoption in May 2020. The new ISBT standard would then be maintained in secure storage at the NIBSC, made available for distribution to national regulatory agencies and tuberculin manufacturers for use in standardising national references and quality control of commercially manufactured tuberculins. In the third and fourth quarters of 2020, the **ad hoc** Group and collaborators will draft a manuscript for publication in a refereed scientific journal.

5.3. **Ad hoc Group on Veterinary Biobanking**

Dr Antonino Caminiti from the OIE Science Department updated the Commission on the progress that had been made with the project to develop an OIE Virtual Biobank. He informed the Commission that the OIE has been evaluating the first draft of the business plan for the development of the system, which has been proposed by the Istituto Zooprofilattico Sperimentale della Lombardia e dell’Emilia (Brescia, Italy), OIE Collaborating Centre for Veterinary Biobank. The finalisation of the business plan is expected shortly and will be followed by the organisation of the first meeting of participant laboratories and the project’s governance boards.

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4 NIBSC: National Institute for Biological Standards and Control (United Kingdom)
5.4. Ad hoc Group on High Throughput Sequencing and Bioinformatics and Computational Genomics (HTS-BCG)

Dr Caminiti updated the Commission on the progress that had been made with the project to develop an OIE Pathogen Genomic Platform. The funding application submitted to Wellcome Trust in 2018 by the OIE and the OIE Collaborating Centre for Viral Genomics and Bioinformatics, University of Glasgow Centre for Virus Research (Glasgow, UK) was not successful. Following a meeting between the OIE and Wellcome Trust at the end of 2018, the OIE decided to apply again in collaboration with the OIE Collaborating Centre. The preliminary application was submitted in early 2019 and received a positive evaluation from the selection panel of Wellcome Trust, which is now willing to consider a full application from the OIE. A decision on the full application by Wellcome Trust is expected by July 2019.

5.5. Ad hoc Group on Biological Threat Reduction in Relation to Identification, Assessment and Management of Dual Use in the Context of Responsible Conduct in Research

Dr Christine Uhlenhaut from the OIE Programmes Department updated the Commission on the work of the OIE ad hoc Group on Biological Threat Reduction in relation to Identification, Assessment and Management of Dual Use in the Context of Responsible Conduct in Research. The Group was established, following a recommendation of the 2nd OIE Global Conference on Biological Threat Reduction in 2017 and met from 27 to 29 November 2018. The Commission had provided comments and suggestions on the draft Guidelines for responsible conduct in veterinary research identifying, assessing and managing dual use, which had been finalised at the end of January. Once translated into French and Spanish, the Guidelines will be made available on the OIE website.

The ad hoc Group report was endorsed and is attached as Annex 4.

6. International Standardisation/Harmonisation

- Diagnostic tests

6.1. OIE Register of diagnostic kits

6.1.1. Update and review of new applications or renewed applications

Dr Máriá Szabó from the OIE Antimicrobial Resistance and Veterinary Products Department updated the Commission on the status of the kits in the registry and the new applications that are currently under review. At present, there are 11 registered kits; 5 new applications, including one with an extended claim, were received in 2018 and are in various stages of review. Two new applications have been received so far in 2019.

The Commission was informed that evaluation of a dossier should soon be completed. If the expert report concludes that the kit is satisfactory, the Commission agreed to consider reviewing the experts’ recommendations on a priority basis and endorsing the report as soon as possible so it could be presented for final decision by the Director General with a view to presenting a Resolution for adoption at the General Session in May 2019.

One kit, which was first registered in 2014, is due for its 5-year renewal in 2019. The OIE Newcastle disease experts had been consulted regarding their experience with the kit and its fitness for purpose, and their advice had been requested on whether or not the kit should be renewed. The Commission was provided with a brief report summarising the experts’ comments and recommendations. After consideration, the Commission agreed to endorse the proposal for renewal. A draft Resolution will be presented at the General Session in May 2019; if adopted by the Assembly, the kit will be renewed for the period from 2019 to 2024.

6.2. Standardisation programme

6.2.1. Update on project to extend the list of OIE-approved reference reagents

Dr Caminiti updated the Commission on the progress that had been made with the project to extend the list of OIE-approved international reference reagents.
Regarding the request for inclusion in the list of reagents for trichinellosis by the OIE Reference Laboratory for trichinellosis in Italy, the Commission assessed the results of the proficiency test that was conducted in collaboration with the other OIE Reference Laboratory for trichinellosis in Canada, and compiled the data in a single table for ease of review. The Commission gave a positive evaluation of the results. However, it was not always possible to associate unequivocally all the results of the tests to each participant laboratory. The Commission also pointed out that it would be important to know which type of ELISA was used by the participant laboratories (in-house, etc.) for a final decision on the inclusion of the reagents in the list. For this reason, a member of the Commission would be put in contact with the OIE Reference Laboratory in Italy to clarify the attribution of certain data and advance the process for inclusion in the list.

The Commission also proposed to create a standard form to be attached as an Annex to the guidelines for inclusion of antibodies, antigens and PCR reagents in the list. The purpose of this form is to facilitate the process of applying for inclusion of a reagent by applicant laboratories. One of the Commission’s members accepted to draft the form for evaluation and final adoption by the Commission at the next meeting in September 2019.

Finally, the inclusion of reagents in the list of OIE-approved international reference reagents is currently conditional to a successful proficiency test among OIE Reference Laboratories for the same disease. However, as there is a single OIE Reference Laboratory for certain OIE-listed diseases, the Commission proposed to update the guidelines and introduce the possibility of involving any OIE Reference Laboratories or other accredited laboratories in the proficiency test, provided that the laboratory is accredited for the specific test method.

7. Resolutions for the General Session

7.1. Resolutions that will be presented in May 2019

The Commission noted that the following resolutions would be proposed for adoption at the General Session in May 2019:

- A resolution proposing the adoption of the 11 draft chapters for the Terrestrial Manual;
- A resolution proposing the new OIE Reference Laboratories;
- A resolution proposing the new OIE Collaborating Centres in the terrestrial animal health domain;
- A resolution proposing the addition of one diagnostic kit to the OIE Register and the renewal of an already registered kit.

8. Conferences, Workshops, Meetings

- Past Conferences, Workshops, Meetings

8.1. 7th meeting of the International Expert Group of Biosafety and Biosecurity Regulators in Ottawa, Canada 18–20 September 2018

Dr Ana Maria Nicola updated the Commission on the above-mentioned meeting. The main topics discussed were how to regulate biosafety and biosecurity issues in universities and private laboratories, how to collect information on the agents worked on in such laboratories, how to designate containment levels, new technologies and trends, biosafety and biosecurity challenges, the importance of biosecurity capacity-building, concerns related to new emerging issues, global partnership against the spread of weapons and materials of mass destruction, trends and challenges in incident reporting, challenges with the implementation of the WHO GAPIII5 containment requirements for poliovirus, dual use, and joint external evaluation and performance of Veterinary Services.

5 WHO GAPIII: World Health Organization Global Action Plan to minimise poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use
8.2. Update on laboratory focal points and engagement from the Commission members

Ms Jennifer Lasley from the OIE Programmes Department presented an update from the second cycle of regional seminars of the National Focal Point Programme for Veterinary Laboratories. The seminars in the second cycle are composed of four main topics – transport of specimens, biological risk analysis, quality management, and systems-based approach to laboratory networking – and the theme of the seminar is “Towards a culture of safety and quality”. Members of the Commission were requested to attend the regional seminars planned in 2019 and 2020. The next seminar for Asia is tentatively planned for 17–19 June 2019 in Chiang Mai, Thailand, and for Europe for 27–29 August 2019 in Kiev, Ukraine; and the participation of a member of the Commission is requested at each seminar.

- **Future Conferences, Workshops, Meetings**

8.3. 19th WAVLD⁶ Symposium, 19–22 June 2019, Chiang Mai, Thailand: 1-day OIE Seminar (Friday 21 June): finalising the programme

Ms Lasley presented an update on the 1-day OIE Seminar to be held during the 19th WAVLD Symposium, 19–22 June 2019, Chiang Mai, Thailand. Invitation letters for speakers will be issued in March and the programme is near finalisation. The Commission was reminded that the OIE Seminar would be divided into two parts: the morning session on Laboratory Quality Management Systems: The Costs and Benefits of Quality and the afternoon session on Biobanking and Reference Materials. Given the recent spread of ASF in the region, a presentation entitled: African Swine Fever: Setting standard laboratory diagnostics and laboratory networking in Asia had been included in the programme.

9. Liaison with other Commissions

9.1. Horizontal issues among the Specialist Commissions

9.1.1. Proposal of the ad hoc Group on Animal African Trypanosomoses

The Commission noted that the ad hoc Group on Animal African Trypanosomoses proposed that three Terrestrial Code chapters be developed: Infection with animal trypanosomes of African origin excluding infection with T. evansi and T. equiperdum; Infection with T. evansi (surra in all species); and Infection with T. equiperdum (dourine in horses). The experts would be asked to update or develop corresponding chapters for the Terrestrial Manual.

9.1.2. Feedback from September: proposed definition of “new strain” for the purpose of disease notification

Dr Lina Awada from the OIE World Animal Health Information and Analysis Department joined the meeting for this agenda item. At the last meeting in September 2018, the Commission had been asked for assistance in drafting a definition of the term “new strain” that would clarify Member Country obligations to report immediate disease events in accordance with the relevant Articles of chapter 1.1 of the OIE Codes. Dr Awada informed the Commission that their advice “that a new strain would relate to a phenotypic change corresponding to a genotypic change that can be diagnosed consistently” was helpful and would be included in the notification guidelines.

In September 2018, the Commission had also advised that “the definition of new strain is somewhat addressed in the current definition of emerging disease provided by the Terrestrial and Aquatic Codes”. Following Dr Awada’s feedback, the Commission agreed that that advice was incorrect and could be deleted from their recommendation.

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⁶ WAVLD: World Association of Veterinary Laboratory Diagnosticians
9.2. **Scientific Commission for Animal Diseases**

*Matters from the Scientific Commission for Animal Diseases to the Biological Standards Commission*

None at this meeting.

9.3. **Terrestrial Animal Health Standards Commission**

*Matters from the Terrestrial Animal Health Standards Commission to the Biological Standards Commission*

The Biological Standards Commission provided the following advice to the Code Commission on technical comments from OIE Members on draft *Terrestrial Code* chapters.

9.3.1. **Advice on Member Country questions on Chapter 1.4 Animal health surveillance**

In reply to a request to clarify the scope of “testing” in the *Terrestrial Manual* and if it includes clinical observations, the Biological Standards Commission stated that the *Terrestrial Manual* definition of test method is: “Specified technical procedure for detection of an analyte (synonymous with assay)”. Clinical observation is therefore not a test in the context of the *Terrestrial Manual*.

The Biological Standards Commission added that often the definitions in the *Terrestrial Manual* and *Terrestrial Code* glossaries are different and this is appropriate because of the different purposes of the two publications call for contextual definitions.

In reply to a question on penside tests, the Biological Standards Commission confirmed that penside tests are sometimes included in the *Terrestrial Manual*. The Commission emphasised that, according to chapter 1.1.6 *Principles and methods of validation of diagnostic assays for infectious diseases*: “All diagnostic assays (laboratory and field assays) should be validated for the species in which they will be used.”

In Article 1.4.3, Section 1. *Design of surveillance system*, point e bis) *Diagnostic tests*, a Member Country had proposed deleting the word “imperfect” from the sentence; “Imperfect sensitivity or specificity, as well as prevalence, will have an impact on the conclusions drawn from surveillance”. The Biological Standards Commission fully agreed to this deletion as the word unnecessarily limits the scope of the sentence.

In the same paragraph, the Biological Standards Commission agreed with some of the amendments proposed by a Member Country but believed that predictive values are essential to evaluating test performance and should not be deleted. The Commission proposed the following text amendments highlighted in yellow:

> The performance of a test at the *population* level (including field observations) may be described in terms of its sensitivity, specificity and predictive values. These parameters, together with imperfect sensitivity or specificity, as well as prevalence, will have an impact on the conclusions drawn from surveillance. Therefore, these parameters and should be taken into account in the design of surveillance systems and analysis of surveillance data.
In Article 1.4.3, Section 2. Implementation of the surveillance system, point a) Diagnostic tests, a Member Country had proposed replacing the words “each species in which they may be used” with “target species” in the sentence “The sensitivity and specificity values of the tests used should be specified for each species in which they may be used and the method used to estimate these values should be documented in accordance with Chapter 1.1.6 of the Terrestrial Manual”. The Biological Standards Commission agreed.

The Member proposed adding the following sentence to the paragraph: “Where validation data are lacking for non-target species, accuracy estimates should be provided by appropriate experts.” The Biological Standards Commission did not support inclusion of the proposed additional sentence The Commission stated that it is hard to give an estimation when a test has not been validated in a species. Some information on this issue is available in Terrestrial Manual Chapter 3.6.7 Principles and methods for the validation of diagnostic tests applicable to wildlife, in particular the issue is partly addressed in Figure 1: Flowchart of pathways and stages of test validation in wildlife when a previously validated test exists or does not exist.

9.3.2. Proposal from a Member Country to develop a chapter on laboratory diagnosis

In reply to a Member Country proposal to develop a Terrestrial Code chapter on laboratory diagnosis, the Biological Standards Commission understands that the Member Country is concerned that laboratories are not implementing or meeting the requirements of Terrestrial Manual Chapter 1.1.5 Quality management in veterinary testing laboratories. This issue is a critical part of an OIE project on sustainable laboratories managed by the OIE Programmes Dept. An ad hoc Group on Sustainable Laboratories will be convened shortly, which could discuss the need for additional guidelines on such topics.

9.4. Aquatic Animal Health Standards Commission

9.4.1. Joint meeting between the two Specialist Commissions

The Biological Standards Commission and the Aquatic Animals Commission held a joint meeting to share information and explore areas of common interest and ways of working together. Topics specifically addressed included: each Commission’s approach to and its work on the Terrestrial Manual and Aquatic Manual, respectively; Reference Centre activities, specifically how to collaborate on the development of procedures and joint decision making.

All agreed that it has been a useful meeting and as it would not always be possible to arrange a joint meeting, the two Commissions agreed to hold teleconference calls between meetings to progress relevant items, e.g. regarding the guidance under development for Reference Laboratory networks. The meeting had greatly contributed to strengthening the collaboration between the two Commissions.
10. Matters of Interest for Information

10.1. Update on OFFLU\(^7\)

Dr Pavade provided an update on OFFLU activities. The Commission was briefed on the OFFLU contribution of avian influenza (AI) data for the period February to September 2018 to WHO Consultation on the Composition of Influenza Virus Vaccines for the Northern Hemisphere.

A significant amount of genetic and antigenic data on zoonotic AI was shared with WHO at the September 2018 vaccine composition meeting in Atlanta, Georgia, United States of America. Animal health laboratories in 24 countries representing Africa, Asia, the Americas and Europe contributed sequence data for 195 H5, H7 and H9 and antigenic data for selected AI viruses.

The Commission was also updated on the results of the annual OFFLU proficiency testing coordinated by the Australian Animal Health Laboratory in Geelong. Ten laboratories including OIE Reference Laboratories, Collaborating Centre and a national laboratory participated in the exercise. The panel comprised 15 samples from Australia, Europe or the Asian region, which were tested for molecular detection of influenza A, H5 and H7 viruses and for pathogenicity analysis, as appropriate. Some of the laboratories experienced difficulties in detecting positive samples, and the causes for these problems would be investigated. The Commission recommended that the laboratories that failed to detect positive samples should review their methods to ensure appropriate competencies are maintained across the OFFLU network of laboratories.

10.2. Sustainable laboratories project

Ms Jennifer Lasley updated the Commission on the Sustainable Laboratory Biosafety and Biosecurity initiative at the OIE. With the support of Global Affairs Canada, the OIE has embarked on a 3-year project to address laboratory biosafety and biosecurity, innovation, and resource sustainability to reduce the threat of biological threats. The OIE will analyse PVS\(^8\) Pathway data to inform a position paper on the investment needs for sustainable laboratories and will hold a technical consultation to establish the research agenda for evidence-based biosafety in low-resource settings. The OIE is working on the development of a business plan to meet the demand for laboratory equipment calibration across sectors in the Africa region, potentially including a comparative analysis of donor-funded equipment investment and resource wastage versus investment in local supply chains for laboratory equipment calibration, maintenance, and repair and the development of an ‘essential’ list of laboratory equipment required for diagnostic to inform national investment priorities in laboratory equipment maintenance, repair and calibration. Informed by these projects, the OIE will expand the PVS Sustainable Laboratories toolbox for new users and new uses, support Laboratory Twinning Projects, and convene an Open Innovation Consortium. The Biological Standards Commission considers this area of work to be of critical need to Member Countries and therefore will advise on guidelines or additional standards to be developed as a result of the project, specifically on meeting minimum facilities and equipment requirements for veterinary diagnostic laboratory facilities. The ad hoc Group on Sustainable Laboratories, to be convened tentatively in late 2019 for the first time, will be able to advise the Biological Standards Commission on these topics.

10.3. Open innovation competition for sustainable labs

Dr Keith Hamilton from the OIE Programmes Department updated the Commission on this initiative. During the OIE Consultation on sustainable laboratory biosafety and biosecurity, held in March 2018 at OIE Headquarters\(^9\), it was highlighted that innovative solutions were needed to tackle laboratory sustainability, and that these solutions may be found outside the traditional laboratory sector. It was agreed that one way to actively seek these innovative solutions would be to hold an Open Innovation competition, otherwise known as a Grand Challenge. The OIE had done some preliminary scoping work. This scoping work had framed three options for an Open Innovation competition; 1. Technology Challenge, e.g. power management, waste management, water management, cool storage, clean air, or design and engineering work; 2. Security Challenge, e.g. securing materials, detecting unwanted

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\(^7\) OFFLU: Joint OIE-FAO Network of Expertise on Animal Influenza

\(^8\) PVS: Performance of Veterinary Services

presence, monitoring premises, securing waste; 3. Laboratories Maintenance and Operations Challenge, e.g. calibration services, maintenance services, mobile technology for calibration. The OIE would do some further work to identify specific challenges (within options 1 and 3) that would be most amenable to an Open Innovation. The OIE would also work to engage a consortium of stakeholders (donors, end users, technical experts) in operationalising the concept.

10.4. Network of Collaborating Centres for Emergency response

Dr Hamilton presented a proposal that had been submitted to the OIE Director General by the OIE Collaborating Centre in Teramo, Italy, for three existing OIE Collaborating Centres to form a network on Veterinary Emergencies. The three Collaborating Centres were the OIE Collaborating Centre on Biological Threat Reduction (Institute for Infectious Animal Diseases, Texas, USA); OIE Collaborating Centre on Reduction of Risk of Disasters in Animal Health (Centro Nacional de Sanidad Agropecuaria, Cuba); OIE Collaborating Centre on Veterinary Training, Epidemiology, Food Safety, and Animal Welfare (Istituto Zooprofilattico Sperimentale dell’Abruzzo e del Molise [IZSAM], Teramo, Italy). The network had already agreed on Terms of Reference at its first meeting in November 2018. The application had been submitted by IZSAM (which had volunteered to take the first rotation as Secretariat to the network) on behalf of all three Centres. The Commission welcomed the application and noted its potential to support Member Countries. The Commission acknowledged that the network should expand to include other centres with relevant expertise in Asia and Africa. It was noted that expertise in emergency management could also be found within the National Veterinary Services themselves. The Commission was reminded that SOPs were being developed to formalise a process for establishing OIE Reference Centre networks. The Commission agreed nevertheless, that approval of this network should not be delayed, and approved the application.

10.5. Update on VICH10 activities

Dr Mária Szabó informed the Commission about the upcoming 6th VICH Public Conference entitled Unlocking Africa’s Potential, which takes place from 27 to 28 February 2019 in Cape Town, South Africa.

10.6. Feedback from the Second OIE Global Conference on Antimicrobial Resistance and Prudent Use of Antimicrobial Agents in Animals: Putting Standards into Practice, Marrakesh, Morocco, 29 to 31 October 2018

Dr Elisabeth Erlacher-Vindel, Head of the OIE Antimicrobial Resistance and Veterinary Products Department, informed the Commission of one of the recommendations to the OIE of the successful OIE Global Conference: “To explore the opportunity to develop standards or guidelines related to autogenous vaccines and other alternatives to antimicrobials, including guidance for quality, safety and efficacy, as tools to reduce the need to use antimicrobials”. The Commission agreed to consider ways to support this recommendation at its next meeting in September 2019.

10.7. Validation of reference lists for OIE-WAHIS: Diagnostic tests

The Commission noted the project to include links to the diagnostic tests included in the Aquatic and Terrestrial Manuals in the upgraded OIE-WAHIS database.

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10 VICH: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products
10.8. Update on activities on biological threat reduction

The Biological Standards Commission was informed about the activities related to Biological Threat Reduction. It was explained that these activities are cross-cutting within OIE and that they at the same time often involve stakeholders from other sectors, e.g. law enforcement, forensics experts or public health.

10.9. Update on rinderpest

The Global Rinderpest Action Plan (GRAP) was published in November 2018 and is available on the FAO\textsuperscript{11} and OIE websites. The FAO-OIE Joint Advisory Committee (JAC) for rinderpest met at the OIE Headquarters from 11 to 12 December 2018. The pending rinderpest holding facilities (RHF)s applications were discussed. It is expected that CIRAD\textsuperscript{12}, France, and the China Institute for Veterinary Drug Control will be proposed for designation as RHFs Category A and B by Resolution presented by the OIE Scientific Commission at the next General Session in May 2019. The Sequence and Destroy Project being undertaken by two OIE Reference Laboratories for Rinderpest (CIRAD, France and The Pirbright Institute, United Kingdom) will be concluded in March 2019, when all the sequenced materials will have been destroyed.

The OIE “Never Turn Back” communication and awareness campaign, including the Rinderpest Game, had been a success. More than two thousand players from over 80 countries played the game.

The annual survey on rinderpest virus containing materials (RVCM) held by countries is underway and the results will be presented by the President of the OIE Scientific Commission at the General Session in 2019. The Commission agreed with JAC’s recommendation to stop asking all OIE Member Countries for annual reports on RVCM and instead focus advocacy efforts on countries known to have or suspected of having RVCM outside of RHFs, which are now 10 or less.

10.10 Follow up from the OIE Consultation on Sustainable Laboratory Biosafety and Biosecurity: ad hoc Group on Veterinary Paraprofessionals

Ms Lasley provided an update of the OIE’s work on veterinary paraprofessionals (VPPs). She informed the Commission that pursuant to the plan to develop guidance for competencies and curricular requirements, the ad hoc Group has concluded its work on the OIE Curricula Guidelines for Veterinary Paraprofessionals, which will be published and released at the General Session in May 2019. It covers three tracks identified as important for VPPs working in the Veterinary Services: animal health, veterinary public health and laboratory diagnosis.

11. Any Other Business

11.1. Work plan

The updated work plan was agreed and can be found at Annex 5.

11.2. Dates of the next Biological Standards Commission meeting

The Commission noted the dates for its next meeting: 17–20 September 2019.

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\textsuperscript{11} FAO: Food and Agriculture Organization of the United Nations

\textsuperscript{12} CIRAD: Centre international en recherche agronomique pour le développement (agricultural research and international cooperation organization)
MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION

Paris, 12–15 February 2019

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Agenda

1. Welcome

2. Adoption of Agenda

   3.1. Update from September 2018 meeting: review of a validation dossier for a quantitative real-time PCR\textsuperscript{13} method for detection of \textit{Taylorella equigenitalis} directly from swabs
   3.2. Update on glanders issues: follow-up from September 2018 meeting
   3.3. Request from a Member Country regarding the chapter on bovine tuberculosis
   3.4. Improving Table 1 of the disease-specific chapters on tests available rated against purpose
   3.5. Review of Member Country comments received on draft chapters and their endorsement for circulation for second-round comment and proposal for adoption in May 2019
   3.6. Selection of chapters for update in 2019/2020 review cycle
   3.7. New taxonomy for contagious bovine pleuropneumonia
   3.8. Feedback from the OIE \textit{ad hoc} Group on Animal African Trypanosomes

4. OIE Reference Centres
   4.1. Annual reports of Reference Centre activities in 2018
   4.2. Applications for OIE Reference Centre status
   4.3. Changes of experts at OIE Reference Centres
   4.4. Review of new and pending applications for laboratory twinning
       \textit{Reference Laboratories}
   4.5. Development of procedures for the establishment and maintenance of OIE Reference Laboratory networks
       \textit{Collaborating Centres}
   4.6. Implementation of the new procedures for designation of OIE Collaborating Centres: mapping the existing Centres against the list of main focus areas and specialties

5. \textit{Ad hoc} Groups
   \textbf{Update on activities of past \textit{ad hoc} Groups}
   5.1. \textit{Ad hoc} Group on MERS-CoV (Middle East respiratory syndrome – coronavirus)
   5.2. \textit{Ad hoc} Group on Replacement of the International Standard Bovine Tuberculin (ISBT)
   5.3. \textit{Ad hoc} Group on Veterinary Biobanking
   5.4. \textit{Ad hoc} Group on High Throughput Sequencing and Bioinformatics and Computational Genomics (HTS-BCG)
   5.5. \textit{Ad hoc} Group Biological Threat Reduction in Relation to Identification, Assessment and Management of Dual Use in the Context of Responsible Conduct in Research

6. International Standardisation/Harmonisation
   6.1. OIE Register of diagnostic kits
       6.1.1. Update and review of new applications or applications

\textsuperscript{13} PCR: polymerase chain reaction
6.2. Standardisation programme
6.2.1. Update on project to extend the list of OIE approved reference reagents

7. Resolutions for the General Session
7.1. Resolutions that will be presented in May 2019

8. Conferences, Workshops, Meetings
Past Conferences, Workshops, Meetings
8.1. 7th meeting of the International Expert Group of Biosafety and Biosecurity Regulators in Ottawa, Canada 18–20 September 2018
8.2. Update on laboratory focal points and engagement from the Commission members
Future Conferences, Workshops, Meetings
8.3. 19th WAVLD Symposium, 19–22 June 2019, Chiang Mai, Thailand: 1-day OIE Seminar (Friday 21 June): finalising the programme

9. Liaison with other Commissions
9.1. Horizontal issues among the Specialist Commissions
9.1.1. Proposal of the ad hoc Group on Animal African Trypanosomoses
9.1.2. Feedback from September: proposed definition of “new strain” for the purpose of disease notification
9.2. Scientific Commission for Animal Diseases
9.3. Terrestrial Animal Health Standards Commission
9.3.1. Advice on Member Country questions on Chapter 1.4 Animal health surveillance
9.3.2. Proposal from a Member Country to develop a chapter on laboratory diagnosis
9.4. Aquatic Animal Health Standards Commission
9.4.1. Joint meeting between the two Specialist Commissions

10. Matters of Interest for Consideration or Information
10.1. Update on OFFLU
10.2. Sustainable laboratories project
10.3. Open innovation competition for sustainable labs
10.4. Network of Collaborating Centres for Emergency response
10.5. Update on VICH activities: 6th VICH Public Conference, 27–28 February 2019, Cape Town, South Africa
10.7. Validation of reference lists for OIE-WAHIS: Diagnostic tests
10.8. Update on activities on biological threat reduction
10.9. Update on rinderpest
10.10. Follow up from the OIE Consultation on Sustainable Laboratory Biosafety and Biosecurity: ad hoc Group on Veterinary Paraprofessionals

11 Any Other Business
11.1. Work plan
11.2. Dates of the next Biological Standards Commission meeting: 17–20 September 2019
MEETING OF THE OIE BIOLOGICAL STANDARDS COMMISSION
Paris, 12–15 February 2019

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REPORT OF THE MEETING OF THE OIE AD HOC GROUP
ON MIDDLE EAST RESPIRATORY SYNDROME CORONAVIRUS (MERS-CoV)

Paris, 22-24 January 2019

The meeting of the OIE ad hoc Group on Middle East Respiratory Syndrome Coronavirus (hereafter referred to as the Group) was held at the OIE Headquarters in Paris from 22 to 24 January 2019.

1. Opening, adoption of agenda and appointment of chairperson and rapporteur

Dr Matthew Stone, Deputy Director General of the OIE for International Standards and Science, welcomed the Group and thanked them for their participation in this meeting. He noted that the Group had been convened following a recommendation from Biological Standards Commission to draft a chapter in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals on MERS-CoV and emphasised that the purpose of the Terrestrial Manual chapter is to provide internationally agreed diagnostic laboratory methods to contribute to the improvement of animal health services world-wide.

Dr Stone explained that the OIE 6th Strategic Plan 2016-2020 emphasises the importance of scientific excellence as a basis for the development of OIE international standards, and the One Health approach through the Tripartite collaborations with FAO and WHO for controlling the risks at the human-animal-environment interface. He referred to the WHO Eastern Mediterranean Regional Office publication of MERS-CoV situation update (December 2018) which reported that 12 countries in the Middle Eastern Region have reported laboratory-confirmed MERS-CoV cases in humans.

In concluding, Dr Stone emphasised that the members of the Group were nominated by the Director General of the OIE according to their internationally recognised expertise and geographically balanced representation, but they were not representing their own countries or institutions in the meeting. He noted that all members of the Group were asked to declare any actual or potential conflict of interest and to respect the confidentiality of the process.

Dr Mehdi El Harrak was appointed as the Chairperson and Dr William Karesh as Rapporteur of the meeting. The draft agenda was adopted by the Group.

The Terms of Reference and agenda and list of participants are presented as Appendices I, II and III, respectively of this report.

2. Update on the MERS-CoV situation in humans and dromedary camels

The representative from the WHO Eastern Mediterranean Regional Office, Egypt gave an overview of the current situation of MERS-CoV in humans. At the end of December 2018, a total of 2279 laboratory-confirmed cases of MERS-CoV in humans were reported globally. Dr Malik noted that dromedary camels are considered to be the natural host of MERS-CoV with repeated sporadic introductions into the human populations in the Arabian Peninsula. He showed the current geographic range of countries that have reported MERS-CoV in dromedary camels, countries with documented spill-over of camel-to-human transmission with subsequent human-to-human transmission and countries with reported human-to-human transmission.
The expert from the Abu Dhabi Food Control Authority, Abu Dhabi, UAE gave a presentation on MERS-CoV situation in dromedary camels. MERS-CoV remains primarily an infection of dromedary camels and the viral RNA have been detected in respiratory specimens, feces and milk collected from camels. He noted that there were at least eight occasions in which scientific evidence of zoonotic transmission of MERS-CoV from dromedary camels to humans occurred. He highlighted several challenges faced by veterinary diagnostic laboratories, including the lack of a standard testing algorithm for animal MERS-CoV testing, lack of standard diagnostic materials and quality assurance procedures, lack of a clear understanding of viral kinetics in animals, and lack of available MERS-CoV diagnostic kits that are validated for use in camels.

The expert from Saudi Arabia presented data from two field studies on MERS-CoV surveillance in camels in Saudi Arabia. The study indicated the prevalence of MERS-CoV infection among dromedary camels in livestock markets and slaughterhouses, especially in young age animals and during winter months. Genomic analysis indicated genetic similarity between viruses isolated from dromedary camels and humans.

The expert from the Erasmus Medical Centre reported the work with recombinant protein vaccine and modified vaccinia virus Ankara (MVA) vaccine in Llamas and dromedary camels respectively. He mentioned that these platform technologies can be used to prepare vaccines for humans and camels.

3. **Update of case definition for reporting MERS-CoV infection in dromedary camels to OIE**

The Group reviewed and amended the case definition for reporting MERS-CoV infection in dromedary camels to OIE drafted in May 2017. The Group agreed that only RT-PCR or antigen positive laboratory confirmed cases should be notifiable to the OIE as an emerging disease and “suspected cases” do not need to be reported to the OIE. Nevertheless, the Group asked to highlight the critical importance of investigating the suspected cases in the case definition for the purpose of surveillance within a country.

Since the virus is widely circulating in some populations of dromedary camels resulting in high antibody prevalence, serological evidence is not useful for determination of active infection or for purpose of definition of case confirmation.

The Group also discussed whether MERS-CoV is still an “emerging disease” as it has become established since 2012 in many camel-raising countries. Nevertheless, it was concluded that MERS-CoV would still be considered an emerging disease for the reason that MERS-CoV detection is expanding geographically and remaining uncertainty regarding the epidemiological factors involved in the transmission from dromedary camels to humans.

The amended case definition is presented as Appendix IV.

4. **Proposal to develop a preliminary draft chapter in the OIE Terrestrial Animal Health Code**

The Group offered to develop a draft chapter of the Terrestrial Animal Health Code (Terrestrial Code) for consideration if a decision is made for MERS-CoV to be included in the OIE listed diseases. The objective of preparing a concise Terrestrial Code chapter for Infection with MERS-CoV would be to provide Member Countries with recommendations on surveillance and guidance for facilitating safe trade of dromedary camels and their products. This guidance could serve the interests of Veterinary Services and camel owners whose animals are assembled for sales, shows, races and milk production. It was noted the chapter should highlight that the surveillance in camels is essential for prevention and control of human disease.

The Group recommended that the case definition for MERS-CoV in dromedary camels (Appendix IV) be presented to the Scientific Commission on Animal Diseases providing the scientific rationale for listing “Infection with MERS-CoV in dromedary camels” as a notifiable disease. The Group noted that the purpose of timely and consistent notification to the OIE is to support Member Countries by providing information needed to take appropriate action to prevent the transboundary spread of animal diseases, including zoonoses.
The Group expressed their concern that Member Countries may implement unjustified trade barriers as a consequence of notification and highlighted that Member Countries should not impose bans on the trade of dromedary camels or their products in response to such a notification, or other information shared on the presence of MERS-CoV, unless supported by an import risk assessment.

5. Assessment of whether MERS-CoV infection in dromedary camels should be included in the OIE listed diseases.

The Acting Head of the Science Department explained the criteria for inclusion of diseases, infections and infestations on the OIE list and the rationale for doing so. The Group assessed the MERS-CoV infection in dromedary camels according to the criteria provided in the Article 1.2.2 of the Terrestrial Code based on the recent published scientific data.

1) **International spread of the agent (via live animals or their products, vectors or fomites) has been proven**

The Group concluded that based on currently available field studies and genetic analyses, there is strong scientific evidence for international spread of MERS-CoV through live dromedary camels1,2.

AND

2) **At least one country has demonstrated freedom or impending freedom from the disease, infection or infestation in populations of susceptible animals, based on the animal health surveillance provisions of the Terrestrial Code, in particular those contained in Chapter 1.4**

The Group noted that currently MERS-CoV is not included in the OIE listed diseases and therefore no country has yet self-declared freedom from MERS-CoV from animal populations according to Chapter 1.6 of the Terrestrial Code. However, it was recognised that some countries are able to demonstrate freedom from their camel populations. The Group noted the demonstration of absence of MERS-CoV antibodies in feral dromedary camels in Australia3 and lack of published evidence of natural infections of camels in the Americas.

AND

3) **A reliable means of detection and diagnosis exists and a precise case definition is available to clearly identify cases and allow them to be distinguished from other diseases, infections and infestations**

The Group observed that although there are no specific clinical signs in camels, accurate molecular and serological diagnostic techniques are available to detect past and current infections of MERS-CoV in camels.

AND

4a) **Natural transmission to human has been proven, and human infection is associated with severe consequences**

The Group agreed that evidence from published epidemiologic studies and outbreak investigations has shown that natural transmission of MERS-CoV from dromedary camels to humans has occurred, and that MERS-CoV has been demonstrated to cause severe disease in humans4.

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OR

4b) *The disease has been shown to cause significant morbidity or mortality in domestic animals at the level of a country or zone*

The Group agreed that significant morbidity or mortality in domestic animals had not been attributed to MERS-CoV infection.

OR

4c) *The disease has been shown to, or scientific evidence indicates that it would, cause significant morbidity or mortality in wild animal populations*

The Group noted that significant morbidity and mortality in wild animals had not been attributed to MERS-CoV infection.

In conclusion, the Group arrived at the consensus that infection with MERS-CoV in dromedary camels meets criteria 1,2,3 and 4a and therefore it should be considered for inclusion as an OIE listed disease. An important consideration is that, although MERS-CoV infection in dromedary camels poses a relatively minimal threat to the health of infected animals, MERS-CoV presents a significant public health impact, especially for people in close direct and indirect contact with dromedary camels. The significant public health impact and the role of dromedary camels as a potential source of primary infections in people, necessitates rigorous control measures to minimise the risk of this route of transmission.

6. Drafting a chapter in the OIE *Terrestrial Manual* on infection with MERS-CoV in dromedary camels.

The Group was provided the standardised template to draft a new chapter in the OIE *Terrestrial Manual*. The chapter will set laboratory standards and provide validated procedures that reflect international consensus to be used for MERS-CoV confirmatory diagnosis in animals.

As a first step, the Group worked on and finalised the critical table that provides test methods available and their purpose for MERS-CoV.

*Test methods available for the diagnosis of MERS and their purpose*

<table>
<thead>
<tr>
<th>Method</th>
<th>Population freedom from infection</th>
<th>Individual animal freedom from infection prior to movement</th>
<th>Contribute to eradication policies</th>
<th>Confirmation of clinical cases</th>
<th>Prevalence of infection -- surveillance</th>
<th>Immune status in individual animals or populations post-vaccination</th>
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<td>Antigen detection</td>
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<td>Virus isolation and identification</td>
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<td><strong>Detection of immune response</strong></td>
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<td>IgG indirect and competitive ELISAs</td>
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<td>Pseudo-particle neutralisation assay</td>
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The Group could not finalise the full draft *Terrestrial Manual* chapter elaborating all the above diagnostic tests during the 3-day meeting and agreed to share the responsibility to write it after the meeting. The Group descriptions of the various diagnostic tests listed in the table will be sent to the OIE Secretariat. The OIE Secretariat will collate all the sections and circulate the full draft chapter to the experts for their further review and comments.

For the section on requirements for vaccines in the *Terrestrial Manual*, the Group noted that to reduce primary cases of MERS-CoV in humans, vaccination of dromedary camels may be considered. However, yet there are currently no vaccines commercially available. So, the Group agreed to add a paragraph in the *Terrestrial Manual* about MERS-CoV vaccines under development for animal use and discuss the vaccination strategies, ideally in combination with other antigens such as camel pox.

7. **Update of the Question and Answer document on MERS-CoV**

The Group reviewed and amended the OIE Question and Answer document on MERS-CoV (August 2014 version) reflecting the latest scientific knowledge. The recent update included scientific evidence to prove dromedary camels are the natural host of MERS-CoV and that dromedary viruses are similar to those infecting humans. Countries like Qatar, Oman, Jordan, Saudi Arabia, Iran and Kuwait have met their obligations to OIE by reporting that MERS-CoV has been identified in dromedary camels. A precise case definition was developed by OIE for reporting confirmed cases of MERS-CoV in dromedary camels. Positive PCR findings in dromedary camels should trigger joint animal-human investigations and initiate public health risk mitigation measures. Isolation of infected camel(s) should be done until RT-PCR testing is negative. An updated version of the Question and Answer document can be found in Appendix V.

8. **Review of guidance for managing MERS-CoV at the human-animal interface**

The Group reviewed a recommendation document that was drafted in MERS-CoV regional workshops, Muscat (2014) and Doha (2015) and subsequently updated following the Tripartite FAO/OIE/WHO MERS-CoV meeting for managing the MERS-CoV at the human animal interface in September 2017, Geneva, Switzerland. The Group proposed comments to update various sections of the document on MERS-CoV surveillance, management of PCR positive animals, joint outbreak investigation, case control studies, testing of animals at quarantine and entry points, food safety and environment, risk communication and awareness raising, inter-sectoral collaboration and coordination, addressing knowledge gaps.

The Group considered this document as a good source of best practices and recommendations that could be followed by Member Countries for managing the MERS-CoV at the human-animal interface. However, the Group noted that the document lacks detailed protocols and guidelines for managing cases in specific situations like sales, shows, races, movement etc. and these need to be established in future.

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<tr>
<th>Method</th>
<th>Population freedom from infection</th>
<th>Individual animal freedom from infection prior to movement</th>
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Key: +++ = recommended for this purpose; ++ = recommended but has limitations; + = suitable in very limited circumstances; – = not appropriate for this purpose; RT-PCR = reverse-transcription polymerase chain reaction; ELISA = enzyme-linked immunosorbent assay; VN = virus neutralisation.

### Table 2: Methods of detecting MERS-CoV

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<tr>
<th>Method</th>
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9. Any other issues

OIE Reference Laboratories for MERS-CoV

The Group noted that currently there are no OIE Reference Laboratories for MERS-CoV and recommended that animal health and public health laboratories with necessary expertise in MERS-CoV should consider applying as per the standard procedures to be recognised as an OIE Reference Laboratory. This would be useful in supporting disease surveillance and research, as well as providing technical advice to Member Countries.

10. Adoption of the report

The Group reviewed the draft report provided by the rapporteur and agreed to circulate it electronically for comments before the final adoption.

…/Appendices
OVER THE PAST FEW YEARS, NATIONAL ANIMAL HEALTH AND PUBLIC HEALTH LABORATORIES ARE USING A VARIETY OF SENSITIVE AND SPECIFIC DIAGNOSTIC ASSAYS FOR DETECTING MERS-CoV IN ANIMALS. THE BIOLOGICAL STANDARDS COMMISSION, IN ITS FEBRUARY 2017 MEETING, NOTED THAT THERE IS NOT A CHAPTER FOR MERS-CoV IN THE TERRITORIAL MANUAL THAT WOULD HELP MEMBER COUNTRIES’ LABORATORY CONFIRMATION OF POSITIVE CASES BY VALIDATED TESTING METHODS. THE COMMISSION RECOMMENDED THAT THE PRESIDENT OF THE OIE AD HOC GROUP ON MERS-CoV DEVELOP A CHAPTER IN CONSULTATION WITH OTHER MERS-CoV EXPERTS.

Also in September 2017, at a tripartite global technical meeting on MERS-CoV at WHO headquarters in Geneva, experts recognized the need for international organizations to update technical standards for compliance by the countries in the areas of harmonization of testing methods, management of PCR positive animals and procedures for testing of imported animals and quarantine measures to be adopted.

In view of this, the OIE Director General agreed to convene the OIE ad hoc group on MERS-CoV with the following terms of reference.

Terms of Reference

1. Review the current case definition for reporting positive MERS-CoV cases to OIE for any updates if needed.

2. To evaluate whether MERS-CoV infection in camels should be an OIE Listed Disease based on the criteria for inclusion of the disease.

3. To draft a chapter in the OIE Territorial Manual to provide validated diagnostic tests available for MERS-CoV as fit for purpose for surveillance and detection of infections in animal populations for the Member Countries.

4. Appropriate guidance on control measures and action, if any, to be taken on positive surveillance findings in dromedary camels.

5. Appropriate science-based animal health management measures for management of animals to limit potential for further human infections.

6. Guidance on quarantine measures to be adopted when importing animals.

7. Recommendations on research priorities arising from the discussions related to 1-6 above.

8. Update on the MERS-CoV Question and Answer document on the OIE website.

9. Review of animal vaccines and vaccination strategies as intervention measures based on recent research findings.

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Appendix II

MEETING OF THE OIE AD HOC GROUP ON MERS-CoV

Paris, 22 – 24 January 2019

Agenda

1. Welcome and introductions
2. Appointment of chair and rapporteur
3. Adoption of the agenda
4. Brief update of MERS-CoV situation in humans and camels
5. To evaluate whether MERS-CoV infection in camels should be an OIE Listed Disease based on the criteria for inclusion of the disease
6. Review the current case definition for reporting positive MERS-CoV cases to OIE for any updates if needed
7. To draft a chapter in the OIE Terrestrial Manual to provide validated diagnostic tests available for MERS-CoV as fit for purpose for surveillance and detection of infections in animal populations for the Member Countries. The chapter will be drafted using a standardised template with the following headings:
   - Introduction with a brief description of the disease
   - Table providing test methods available for diagnosis of MERS-CoV in animals and their purpose
   - Identification of the agent – description of methods applied
   - Serological diagnosis
   - Requirements for vaccines and diagnostic biologicals when applicable
8. Review and update the MERS-CoV Question and Answer document on OIE website
9. Review and comment on the MERS-CoV at the human-animal interface document drafted in regional workshops and updated in other meetings.
10. Any other issues
11. Adoption of the report
### MEETING OF THE OIE AD HOC GROUP ON MERS-CoV
Paris, 22 – 24 January 2019

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#### List of Participants

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Appendix IV

Case Definition for reporting MERS-CoV in dromedary camels to OIE
(Update January 2019)

Introduction

Middle East respiratory syndrome (MERS) is a viral respiratory infection of humans and dromedary camels which is caused by a coronavirus called Middle East Respiratory Syndrome Coronavirus (MERS-CoV).

Dromedary camels (Camelus dromedarius) have been confirmed by several studies to be the natural host and zoonotic source of the MERS-CoV infection in humans. Other species may be susceptible to infection with MERS-CoV. However, their epidemiological significance has not been proven.

MERS-CoV has been associated with mild upper respiratory signs in some camels. While the impact of MERS-CoV on animal health is very low, human infections has a significant public health impact.

Positive RT-PCR results for MERS-CoV or isolation of the virus from camels is notifiable to the OIE because MERS is an emerging disease with a significant public health impact to human. The aims of reporting to the OIE are to mitigate the human health risk of MERS-CoV and to prevent international spread, while ensuring safe international trade.

Confirmed case

The following defines a laboratory confirmed case of MERS-CoV infection (with or without clinical signs):

1) MERS-CoV has been isolated from a dromedary camel; OR
2) Viral nucleic acid has been identified in a sample from a dromedary camel on:
   a. at least two specific genomic targets; OR
   b. a single positive target with sequencing of a secondary target; OR
   c. a single positive target and tested positive to rapid MERS-CoV antigen test

Additional notes

A case can be suspected based on a direct epidemiological link with a confirmed human case, living or traveling together in close proximity to a MERS-CoV infected dromedary camel or sharing the same environment with an individual dromedary infected with MERS-CoV. If testing for MERS-CoV is unavailable, negative or inconclusive on a single inadequate specimen, the case should also be suspected. Inconclusive tests may include a positive screening test on a single real time RT-PCR target without further confirmation. Animals with an inconclusive initial test should undergo additional sampling and testing to determine if the animal can be classified as a confirmed MERS-CoV case. Preference should be a repeat nasopharyngeal specimen. Other types of clinical specimens could also be considered for molecular testing if necessary, including blood/serum, and stool/rectal swab. These generally have lower titres of virus than respiratory tract specimens but have been used to confirm cases when other specimens were inadequate or unobtainable.
What is MERS-CoV?

MERS-CoV is a coronavirus (CoV) which causes Middle East Respiratory Syndrome (MERS), a severe respiratory disease, in humans. It was identified in humans in April 2012.

Sporadic human cases of MERS have occurred and continue to occur over a wide geographical distribution with the majority of cases reported from the Arabian Peninsula. Infections in dromedary camels also have been detected in a wide geographic distribution and widespread in some countries. Some human MERS cases could be linked to zoonotic transmission (transmission from animals to humans). In other cases, human infections are either linked to health care settings or remain unexplained. There is no evidence of sustained human to human transmission in the community but the clusters that have occurred in health care settings and households demonstrate that human to human transmission is possible.

The patterns of infection in humans include:

1. community acquired cases and reported links to dromedary camels
2. infections acquired through close human to human contact mostly in health care settings.

What are coronaviruses?

Coronaviruses are a family of RNA (ribonucleic acid) viruses. They are called coronaviruses because under an electron microscope the virus particle exhibits a characteristic ‘corona’ (crown) of spike proteins around its lipid envelope. Coronavirus infections are common in animals and humans, and there is a history of coronaviruses crossing species and adapting to new hosts. There are many species and strains of coronavirus which have different characteristics, causing a range of clinical signs– from very mild to severe disease – in humans and in different animal species.

MERS-CoV is genetically and biologically distinct from other known coronaviruses, e.g. the coronavirus causing Severe Acute Respiratory Syndrome (SARS) in humans.

Why the concern?

MERS-CoV is considered to be a serious public health threat to humans, because:

1. the infection can cause severe disease in humans
2. infection is confirmed to be widespread in dromedary camels in the Middle East and Africa
3. coronaviruses may adapt to new hosts, and then become more easily transmittable between humans

For these reasons, it is important to prevent spillover of these viruses into the human population.

What is the source of MERS-CoV?

Evidence suggests that MERS-CoV has adapted to dromedary camels which are a natural host for the virus. However, not all community acquired cases of MERS-CoV had reported prior animal contact and it is unclear how these persons were infected. Therefore, investigations of human cases of MERS-CoV infection should continue to include gathering information about potential sources of exposure, including other humans, camels (including certain raw products, such as raw milk and meat and secretions/excretions), other domestic and wild animals, as well as the environment, food and water.
The OIE together with its partner organisations, the World Health Organisation (WHO), the Food and Agriculture Organization of the United Nations (FAO) and national animal health authorities of affected countries is closely following investigations which aim to better understand the epidemiological aspects of the disease, including its transmission between animals and from animals to humans.

**Are animals responsible for MERS-CoV infections in people?**

MERS-CoV has been isolated from humans and dromedary camels and studies suggest that dromedary camels can be a source for human infections. MERS-CoV strains isolated from dromedary camels are genetically and phenotypically similar to those infecting humans. Joint human health and animal health investigations are needed to establish the mechanism of transmission and source for human infections with MERS-CoV when not acquired from another human.

There remains the possibility that other animal species may be involved in the maintenance and transmission of MERS-CoV, but evidence gathered so far does not point towards their epidemiological importance.

**What is known about MERS-CoV in dromedary camels?**

Between November 2013 and January 2019, Qatar, Oman, Jordan, Saudi Arabia, Iran and Kuwait have met their obligations to OIE by reporting that MERS-CoV has been identified in dromedary camels.

Other published studies have indicated that MERS-CoV or viral RNA from MERS-CoV have been identified in camels in countries in the Middle East and North Africa; antibodies to MERS-CoV have been identified in samples taken from camels in the Middle East and Africa. Similar strains of MERS-CoV have been identified in samples taken from camels and humans in the same locality and in some cases there has been an association between infections in humans and camels. So far, all human index cases outside the Arabian Peninsula have been epidemiologically linked to Middle East countries. However, zoonotic transmissions of MERS-CoV from camel to human outside the Arabian Peninsula cannot be excluded at this stage.

Serological studies suggest that antibodies to MERS-CoV have been detected with a prevalence range of 0-100% (varying within countries and between countries) in populations of camels in Middle East and African countries. This range of prevalence indicates the need to assess risk factors for infection between and within herds.

Infections with MERS-CoV have sometimes been associated with mild respiratory signs in camels, but this needs further investigation. Significant morbidity or mortality of unknown aetiology should be investigated.

Evidence from MERS-CoV infections in camels suggests that infection has resulted in virus shedding for a limited period. Reinfection has been shown to occur and immunity to infection is poorly understood. MERS-CoV has been identified in camels which have antibodies against the virus. The implications of these findings for management and control recommendations need further investigation.

OIE together with WHO and FAO reiterate the importance of the public health sector and the animal health sector working together to share data and design studies to develop a better understanding of the overall epidemiology of MERS.

**Are other animal species involved?**

Although genetically related viruses have already been detected in bat species, more evidence is needed to directly link the MERS-CoV to bats or other animal species.

According to published literature other species of animals (including sheep, goats, cattle, water buffalo and wild birds) have tested negative for the presence of antibodies to MERS-CoV. However, owing to the relatively small sample sizes the results of these studies cannot exclude infection in other animal species.
Recently there is a single report from Africa following surveillance of other domestic mammalian species like sheep, goat, cow and donkeys that are in contact with infected camels showed positive for MERS-CoV infection informing that domestic livestock in contact with MERS-CoV infected camels may be at risk of infection.

In countries where MERS-CoV is present, studies to assess the presence of MERS-CoV in wild and other domestic species should be conducted to detect possible infection in other hosts.

**How can camels and other animals be tested for MERS-CoV infection or previous exposure?**

Serological tests detect antibodies produced by the host against the virus but do not detect the virus itself. Depending on the test that is used, the presence of antibodies may indicate previous exposure to MERS-CoV or a similar virus. Virus neutralisation is the most specific assay.

RT-PCR (molecular) tests detect genetic material of the virus. Genome sequencing of the virus (parts of, or full genome) is the best way to confirm that the genetic material belongs to a MERS-CoV. Genetic data also provide important information about the evolution of the virus and how closely related MERS-CoV isolates are.

Specific confirmatory molecular and serology diagnostic tests are now available for MERS-CoV. Positive results from screening tests should be confirmed using a confirmatory test. Processing of samples and laboratory testing should be conducted under appropriate biorisk management conditions.

**What action should be taken when an animal is confirmed to be positive for MERS-CoV?**

Infection by MERS-CoV in animals is confirmed by a positive detection of the virus or genetic material belonging to the virus in a sample taken from an animal.

OIE Member Countries are obliged to report a confirmed case of MERS-CoV in animals to the OIE, as an “emerging disease” with zoonotic potential in accordance with article 1.1.4 of the OIE Terrestrial Animal Health Code.

Positive findings should trigger joint animal-human investigations and initiate public health risk mitigation measures. Isolation of infected camel(s) should be done until RT-PCR testing is negative. Precautionary public health measures should be implemented to reduce the risk of human infection in accordance with WHO’s guidance on the WHO website (https://www.who.int/csr/disease/coronavirus_infections/transmission-and-recommendations/en/).

**Is a vaccine or treatment currently available for MERS-CoV in animals?**

There are no treatments available for MERS-CoV in animals. However, research for commercially licensed vaccines is underway to develop and assess potential intervention measures targeted at camels to prevent transmission of MERS-CoV among camels, and from camels to humans.

**What is OIE doing?**

OIE is working closely with its partner organisations FAO and WHO to collate and share data to gain a better understanding about the disease situation in animals and to assess implications for animal and human health.

OIE has consulted its *Ad Hoc* Group on MERS-CoV Infections in Animals and the *Ad hoc* Group on Camelid diseases to provide recommendations and guidance, including on priority research activities for the animal health sector, based on latest scientific information.

The OIE is also working closely with its Member Countries to provide technical support and to encourage reporting of MERS-CoV detections in animals. The OIE has updated the case definition for reporting confirmed MERS-CoV cases in dromedary camels.
OIE develops and publishes international standards and guidelines on the prevention, control and surveillance of animal diseases including zoonoses (animal diseases transmissible to humans). These science-based standards provide guidance on the best control measures which should be applied, where appropriate, to allow control of infection in the identified animal source and prevent geographic spread.

The OIE is the reference organisation for international standards relating to animal health and zoonoses under the World Trade Organization Sanitary and Phytosanitary Agreement (SPS Agreement). Decisions related to safe trade in terrestrial animals and animal products must respect the standards, recommendations and guidelines found in the OIE Terrestrial Animal Health Code.

For further information about public health implications visit the WHO website.
REPORT OF THE MEETING OF THE OIE AD HOC GROUP 
ON BIOLOGICAL THREAT REDUCTION IN RELATION TO IDENTIFICATION, ASSESSMENT AND MANAGEMENT OF DUAL USE IN THE CONTEXT OF RESPONSIBLE CONDUCT IN RESEARCH

Paris, 27 – 29 November 2018

The meeting of the ad hoc Group on Biological Threat Reduction in Relation to Identification, Assessment and Management of Dual Use in the Context of Responsible Conduct in Research (hereafter the Group) was held at the OIE Headquarters from 27 to 29 November 2018.

1. Opening

On behalf of Dr Monique Eloit, Director General of the OIE, Dr Matthew Stone, the OIE Deputy Director General for International Standards and Science, welcomed the Group and gave thanks for their commitment and support to the OIE mandate. Dr Stone provided context on the OIE Strategic Plan, the biological threat reduction work programme and the methodology for establishment of expert groups. Dr Stone explained how the establishment of this ad hoc group relates to the recommendations that stemmed from the 2nd OIE Global Conference on Biological Threat Reduction, which encouraged OIE to include dual use in its biological threat reduction work programme and to collaborate with international organizations that work in the domain of law enforcement and health security. Dr Stone expressed his trust in the Group to create a set of guidelines that is in line with the OIE mandate and complements the guidance already available from other sources. Finally, Dr Stone acknowledged the presence of Emmanuel Couacy-Hymann, the President of the OIE Biological Standards Commission (BSC) and emphasized BSC’s role in curating the OIE Manual of Diagnostic Tests and Vaccines and overseeing the network of OIE Reference Centres, which will be a vital part of the audience for the guidelines that would stem out of the ad hoc group meeting.

The meeting was opened by the Chair of the ad hoc Group, Dr David Ulaeto, who led the Group through a roundtable introduction.

2. Adoption of the agenda and Terms of Reference (ToR)

The agenda and ToR for the Group were reviewed and agreed on without modifications.

The ToR, agenda and the list of participants are provided as Appendices I, II and III respectively.

The Discussion Paper that provided background for the preliminary discussions of the Group is provided as Appendix IV; for this purpose, some internal information was removed without changing the subject matter.

3. Discussion

First day

In accordance with its terms of reference, the Group was entrusted with developing a set of guidelines on the identification of research with dual use implications, including related risk-benefit analysis and implementation of risk mitigation strategies. These guidelines will be complementary to the OIE Guidelines on Investigation of Suspicious Biological Events, already published on the OIE website. Although guidance on dual use has been

1 Available at: http://www.oie.int/en/scientific-expertise/biological-threat-reduction/
published by national governments and other international organizations, it mostly relates to public (human) health. There is a gap on guidance related to dual-use in the context of veterinary research. Therefore, these guidelines aim to be specific to the scope of OIE’s mission and strategic plan. The Members of the Group had reviewed examples of relevant existing guidance as well as publications of research with dual use implications prior to the meeting.

The Group discussed how the guidelines should be structured and the ideal length of the document. It was deemed that the goal was to develop six to eight pages of structured guidance for its users to identify dual use implications, assess, and mitigate foreseen as well as unintended consequences of research. It was decided that the guidelines would have an introduction followed by identification of the target audience, introduction of risk management and indication of how to use these guidelines. Further sections would include an overview of responsibilities of stakeholders, guidance on risk assessment and on implementation at institutional and national level, and references to external publications.

When discussing the target audience, it was deemed that the guidelines would aim to raise awareness and spark critical thinking on dual-use potential amongst the research community, academia, donors, funders and publishers. National Veterinary Services, including regulators and policy makers should also be considered. These guidelines would not attempt to redefine well established concepts, but rather fill in the gap left for considerations on dual use in relation to veterinary research and laboratories and cover research with impact on cross border trade in animals and animal products, food security, working animals and animal welfare. It was deemed that the guidelines would not refer to specific technologies, due to the ever-changing nature of science and the fact that any technology can be misused.

During the afternoon of the first day, the meeting participants were split into breakout groups assigned to developing sections of the guidelines. These sections were subsequently merged into a single draft file, the draft guidelines, which the Group reviewed together, identifying gaps and areas for improvement.

Second day

The draft guidelines were revised overnight by a member of the Group, who provided meaningful considerations on ethics, regulations and public health. The Group started the second day by doing a thorough review of the draft text, considering both new additions and planned discussions on points flagged for improvement. The highlights of the discussion were:

- The importance of ethics in the dual use risk assessment of research projects. The Group was of the opinion that the main responsibility should be borne by institutions and researchers who, besides doing the ethics and risk assessment evaluation of projects, should also be aware of the potential for misuse of research carried out in their facility. The guidelines will not prescribe or recommend the existence of a separate committee for assessment of dual use purposes.

- The overall benefits of the research, risk–benefit evaluation and risk mitigation processes should be clear to the public. The Group highlighted the value of transparency and openness in establishing trust with the community. The guidelines would encourage institutions and researchers to liaise with the rest of society in a responsible manner.

- In relation to risk assessment, the guidelines should prompt researchers and institutions to integrate dual-use assessment into their existing/standard risk assessment procedures.

- The Group is aware that OIE Member Countries have different levels of and mechanisms for regulatory oversight of research. The guidelines aim to inspire critical thinking in researchers and institutions from countries where these regulations are already in place, as well as to fill the gap in relation to dual use implications of veterinary science. In countries where an appropriate regulatory framework does not yet exist, the guidelines could work as a foundation on which to build future policies. Considering its work within the scope of the Veterinary Legislation Support Programme, the OIE may be in a position to assist countries to develop legislation addressing dual use implications in veterinary science.
The Group finished the review of the draft document and proceeded to discussing existing lists of criteria for identification of dual use implications, including the dual use list of Robert Koch Institute and the list of experiments of concern of the Fink Report, as a basis for a list to be included in the guidelines. This list of considerations would be broad ranging and intend to give examples of what researchers and institutions need to look at in relation to dual use implications of research in animal health; however, the list included in the Guidelines would not attempt to be exhaustive.

In the afternoon of the second day, the Group drafted the introduction to the guidelines, making sure to include a definition for dual use, the purpose of the guidelines and their rationale within OIE’s mandate. Later, the Group discussed the concluding remarks to the guidelines, and recommended including statements on:

- Consideration and application of the guidelines to all scientific activities, irrespective of where the research is being conducted and, where possible, inclusion of the guidelines in national legislation. This aims to reflect the fact that citizen scientists as well as traditional researchers are expected to follow these principles.

- The role of researchers’ culture on shaping the moral compass of young scientists. The Group recommended that “responsible conduct in research” should be part of the education curricula of scientific disciplines at all levels.

**Third day**

During the third day, the Group worked on the comments made on the guidelines overnight by all members. The Group discussed the role of non-scientific communication channels (e.g. social media, online media, word of mouth…) in disseminating scientific content. The Group deemed that all parties involved, whether individuals or institutions, bear responsibility for both the context and the information that they disseminate, whether it is sourced from scientific publications or directly from individuals and institutions.

Finally, the Group did a last review of the full text in order to agree on the structure and terminology.

4. **Recommendations**

In accordance with the Terms of Reference, the Group developed several recommendations:

1. Training and education:
   - It is recommended to include dual use as a topic in the curricula of all life scientists. While it is acknowledged that the curricula are already densely packed, the added benefits have the potential to be substantial and also of great value in planning and executing their work responsibly, applying critical thinking and sound risk mitigation while pursuing even the most challenging research tasks.
   - Dual use issues should be an integral part of continuing education in all relevant stakeholder institutions and organisations.
   - While the group refrained from listing current technologies that are considered especially relevant for dual use, it is understood that there is great interest in this discussion and in understanding the issues better. Therefore, it is recommended that OIE considers “horizon scanning”, providing basic information (that can be understood by non-experts) on emerging or changing technologies and putting these developments into context, i.e. describing potential benefits and potential risks for the veterinary community.
   - Consider providing online learning tools or a collection of materials for self-study on OIE’s Biological Threat Reduction page.
2. Legislation & regulation:
   - Legislation and regulation that govern fundamental dual use issues are vital. It is recommended to consider adding support in the context of the Veterinary Legislation Support Programme for Member Countries that ask for this support.
   - It is recommended to distinguish between laws and regulations. The reason for this is that it can take years for new legislation to pass; regulation can be issued much faster and thus can provide guidance and legal certainty much faster as well, which in turn helps to keep up with the pace of technological advancements.

3. Pathway of Veterinary Services (PVS):
   - Consider adding dual use provisions in the long-term to the PVS.

4. Risk management guidelines
   - Develop OIE guidelines for laboratory and veterinary health research risk management, including risk identification, assessment and risk mitigation options.

5. Further guideline development
   - It is recommended to continue developing guidelines related to biological threat reduction, disaster and emergency management. The existing guidance on disaster management and risk reduction and for investigation of suspicious biological events has been well received, the format and content are deemed appropriate to inform stakeholders. Future Guidelines in this area should consider the existing Guidelines and build on it. In time it should also be considered to review and update these Guidelines.

5. Adoption of the draft guidelines

The draft guidelines were adopted by the group, acknowledging that the text would be revised internally by the OIE, including its Specialist Commissions, before being considered as final.

6. Adoption of the draft report

The Group reviewed and amended the draft report provided by the rapporteur. The Group agreed that the report reflected the discussions.

.../Appendices
Background:
The OIE supports its Member Countries and helps them strengthen and improve the structure of their national animal health systems through international standards and guidelines. Veterinary laboratories pursue research priorities that are important for ensuring and improving animal health in this respect. The OIE provides guidance for Veterinary Laboratories in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals and Aquatic Animals. However, in accordance with its mandate, this guidance focuses on diagnostic methods and vaccine production but not on veterinary research. The issue of dual use, the possibility that animal pathogens, other material, knowledge or technology can be used for beneficial purposes (e.g. vaccine production) or malicious purposes (e.g. biological weapons) is relevant for all functions carried out in the context of veterinary laboratories, this includes handling dangerous pathogens for diagnostic purposes but also developing or manufacturing vaccines and of course research involving these pathogens.

It important to understand the potential impact of misuse, while at the same time understanding the potential benefits from research. In other words, it is crucial to balance risks and benefits, and consequently to develop and implement sound risk mitigations strategies. There are publically available guidance documents – institutional, national, and international – but these are focused almost exclusively on human health. This ad hoc group will be tasked with a review of existing guidance in respect to any gaps that might exist in relation to veterinary laboratories and if so, to suggest ways to address these gaps. In the end, a concise document that can be used by Veterinary Services and laboratories, including Collaborating Centres and Reference Laboratories, for awareness raising and guidance should be developed.

I. Terms of Reference

The ad hoc Group will be asked to:

Review existing guidance documents which pertain to this topic, among these are WHO’s Guidance Document\(^2\) ‘Responsible life science research for global health security’ (2010) and the National Academies of Sciences Report\(^3\) ‘Globalization, Biosecurity, and the Future of Life Sciences’ (2006). In addition, several relevant studies with significant dual use potential will be considered, including ‘Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox’\(^4\), ‘Poxvirus interleukin-4 expression overcomes inherent resistance and vaccine-induced immunity: Pathogenesis, prophylaxis and antiviral therapy’\(^5\), ‘Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template’\(^6\), ‘Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome’\(^7\), ‘Construction of an infectious horsepox virus vaccine from chemically synthesized DNA fragments’\(^8\), ‘Airborne

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\(^2\) http://www.who.int/csr/resources/publications/HSE_GAR_BDP_2010_2/en/
\(^3\) https://www.nap.edu/download/11567
\(^4\) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC114026/pdf/jv001205.pdf
\(^5\) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3008208/pdf/nihms252658.pdf
\(^6\) http://science.sciencemag.org/content/297/5583/1016
\(^7\) http://science.sciencemag.org/content/329/5987/52.long
\(^8\) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5774680/pdf/pone.0188453.pdf
Transmission of Influenza A/H5N1 Virus Between Ferrets\(^9\), ‘Experimental adaptation of an influenza H5 haemagglutinin (HA) confers respiratory droplet transmission to a reassortant H5 HA/H1N1 virus in ferrets\(^{10}\), and ‘Experimental adaptation of Wild-Type Canine Distemper Virus (CDV) to the Human Entry Receptor CD150\(^{11}\), as well as relevant commentaries on these publications.

1. To develop a holistic and comprehensive guidance for laboratories of the Veterinary Services for the identification, assessment and management of dual use in the context of responsible conduct of research, which may include:
   a. Criteria for the identification of relevant dual use issues (DURC).
   b. Defining additional skills and capabilities required for the management of such issues.
   c. Developing recommendations for risk management in relation to dual use, including communication.
   d. To identify further issues that require in-depth review and propose, to the DG, the composition and terms of reference for groups of experts convened specifically to study such issues, and if necessary, to participate in the work of these groups.

2. To consider further recommendations for Veterinary Authorities, regulatory authorities or other stakeholders.

\(^9\) [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4810786/pdf/nihms764094.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4810786/pdf/nihms764094.pdf)
\(^10\) [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3388103/pdf/nihms348446.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3388103/pdf/nihms348446.pdf)
\(^11\) [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3595274/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3595274/)
MEETING OF THE OIE AD HOC GROUP
ON BIOLOGICAL THREAT REDUCTION IN RELATION TO IDENTIFICATION, ASSESSMENT AND MANAGEMENT OF DUAL USE IN THE CONTEXT OF RESPONSIBLE CONDUCT IN RESEARCH

Paris, 27 – 29 November 2018

Agenda

Tuesday, 27 November 2018
9:30 Welcome – Matthew Stone, OIE Deputy Director General
Introductions
Appointment of chairperson and rapporteur
Review Terms of Reference
Outline of guidelines
Work on the draft guidelines
17:00 Adjourn for the day

Wednesday, 28 November 2018
9:00 Reconvene and work on the draft guidelines
17:00 Adjourn for the day
19:00 Group Dinner

Thursday, 29 November 2018
9:00 Reconvene and review the draft guidelines
Any other business
Adoption of the report
15:00 Adjourn
Appendix III

MEETING OF THE OIE AD HOC GROUP
ON BIOLOGICAL THREAT REDUCTION IN RELATION TO IDENTIFICATION, ASSESSMENT AND MANAGEMENT OF DUAL USE IN THE CONTEXT OF RESPONSIBLE CONDUCT IN RESEARCH

Paris, 27 – 29 November 2018

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## Work Programme for the OIE Biological Standards Commission

<table>
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<tr>
<th>Subject</th>
<th>Issue</th>
<th>Status and Action</th>
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<tr>
<td>Updating the Terrestrial Manual</td>
<td>1) Circulate the chapters approved by the BSC to Member Countries for second-round comment</td>
<td>March 2019</td>
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<td></td>
<td>2) Remind authors of the chapters identified previously for update but not yet received. Inform the BSC of the date authors were first asked for their contribution</td>
<td>On-going</td>
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<td>Collaborating Centres</td>
<td>1) Implementation of the adopted SOPs:</td>
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<td>a) finish mapping of existing Collaborating Centres to identify their main focus areas and specialties, and overlapping specialties based on the annual reports</td>
<td>March 2019</td>
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<td>b) write to Centres to inform of outcome of discussions and propose a way forward: status quo or form a consortium.</td>
<td>March/April 2019</td>
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<td>c) review feedback from Centres. Where there is agreement, ask for a 5-year proposed activity plan. Where there are divergent views, continue the dialogue</td>
<td>September 2019</td>
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<td>2) In-depth review of all annual reports for activities in 2018 based on the performance criteria to identify any that are not complying</td>
<td>March–May 2019</td>
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<td>3) Feedback of review of annual reports for the Aquatic Commission on Centres that cover aquatic animal health issues</td>
<td>September 2019</td>
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<tr>
<td>Reference Laboratories</td>
<td>1) In-depth review of all annual reports based on the performance criteria to identify any that are not complying</td>
<td>March–May 2019</td>
</tr>
<tr>
<td>Reference Centres</td>
<td>1) Develop SOPs for networks: review existing guidance to see if it can form the basis for an SOP</td>
<td>For September 2019</td>
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<td></td>
<td>2) Contact three potential leading Reference Laboratories identified for ASF, PPR and rabies to see if willing to establish networks</td>
<td>March 2019</td>
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<tr>
<td>Standardisation/</td>
<td>1) Project to extend the list of OIE approved reference reagents</td>
<td>On-going</td>
</tr>
<tr>
<td>Harmonisation</td>
<td>2) Update the three existing guidelines to include a template as an annex for the data to be submitted with a request for approval to be added to the list of approved reagents</td>
<td>For September 2019</td>
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<td></td>
<td>3) Project to develop Replacement International Standard Bovine Tuberculin:</td>
<td>On-going, for 2020</td>
</tr>
<tr>
<td></td>
<td>a) Review final report</td>
<td>February 2020</td>
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<tr>
<td>Ad hoc Groups</td>
<td>1) Replacement of the International Standard Bovine Tuberculin</td>
<td>Virtual meetings</td>
</tr>
<tr>
<td></td>
<td>2) High Throughput Sequencing and Bioinformatics and Computational Genomics (HTS-BCG):</td>
<td>On hold awaiting funding</td>
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<td></td>
<td>3) Veterinary Biobanking</td>
<td>On hold awaiting funding</td>
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</tbody>
</table>
### Work Programme for the OIE Biological Standards Commission

#### Conferences, Workshops and Meetings with participation by BSC Members

<table>
<thead>
<tr>
<th>Subject</th>
<th>Issue</th>
<th>Status and Action</th>
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</thead>
<tbody>
<tr>
<td>Conferences, Workshops and Meetings with participation by BSC Members</td>
<td>1) WAVLD, June 2019: finalise programme and list of speakers</td>
<td>February 2019</td>
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<tr>
<td></td>
<td>2) Regional Seminars for OIE National Focal Points for Veterinary Laboratories</td>
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<td>a) Asia-Pacific: second cycle</td>
<td>17–18 June 2019, Thailand</td>
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<td></td>
<td>b) Americas: second cycle</td>
<td>Date TBD, Mexico</td>
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<td></td>
<td>c) Europe: third cycle</td>
<td>27–29 August 2019, Ukraine</td>
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<td>3) OIE ad hoc Group on PVS Sustainable Laboratories Tool</td>
<td>8–10 October 2019, OIE HQ</td>
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<tr>
<td>Develop laboratory standards for emerging diseases</td>
<td>1) Discuss the Terrestrial Code chapter once adopted in May 2019 with the aim of introducing a corresponding chapter for the Terrestrial Manual</td>
<td>After May 2020</td>
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</tbody>
</table>