OIE Reference Centres: role, rights and commitments

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Director General of the OIE
OIE Mandate and OIE Reference Centres

- The World Organisation for Animal Health is responsible for improving animal health and welfare worldwide.

- OIE provides disease control methods through standards, guidelines and scientific publications.
The OIE standards are all *science based* and democratically adopted by its 180 Member Countries.

The OIE fulfils this mandate with support from its experts and the Network of designated Reference Laboratories and Collaborating Centres.
OIE Mandate and OIE Reference Centres

- The integrity and credibility of the OIE is intimately tied to the quality of the science to which it has access.
- The OIE depends very heavily on its designated Reference Centres and disease experts for scientific advice and support.
- This need for scientific expertise and advice will continue to increase and our reliance on your expertise will continue to grow into the future.
Reference Laboratories: Beginnings

- Discussions begin in 1981
- Norms Commission (now the Biological Standards Commission) proposed that:
  - Reference Laboratories should be Government institutions recognised in their own countries as having the highest standards and with reference functions for tests and reagents
1985: Norms Commission finalised a set of criteria for designation, functions and responsibilities of OIE Reference Laboratories, these were adopted by the International Committee (now the World Assembly) in 1986.
Reference Laboratories: Beginnings

- **Purposes:**
  - diagnosis and immunoprophylaxis of the most important infectious diseases of animals

- **Selection criteria to become a Reference Laboratory:**
  - national and international scientific standing of the laboratory, the staff and facilities
  - stability of staffing and funding
  - capacity to fulfil a role in support of OIE activities
Reference Laboratories: Beginnings

Functions listed under **nine** headings (1):

- Provision of expertise on the subject and standardisation of methodology
- Supply of standard strains, diagnostic standards, antisera, antigens and other reagents
- Development of new methods
- Collection and analysis of epizootiological data
Reference Laboratories: Beginnings

Functions listed under nine headings (2):

- Consultancy for the OIE
- Training
- Organisation of scientific meetings for the OIE
- Coordination of collaborative studies
- Publication and dissemination of information
1989, the Commission also considered broader topics rather than the disease-specific focus of an Reference Laboratory. This presaged the development of the concept of OIE Collaborating Centres.
1993: a Network is launched

- In response to a questionnaire, the Norms Commission selected 75 laboratories to be proposed for designation by the International Committee as OIE Reference Laboratories and one to be proposed as OIE Collaborating Centre.

- In 1993 official mandates and rules were formally adopted.

- In 2006 the first Global conference of RL and CC is organised in Florianopolis with the support of Brazil.
The present

FROM THE SECOND GLOBAL CONFERENCE OF OIE REFERENCE CENTRES HELD AT THE OIE HEADQUARTERS IN PARIS IN 2010 TO TODAY
World Distribution of OIE Ref. Labs

In 2014, the OIE has a global network of **247** Reference Laboratories covering 117 diseases in 38 countries…
World Distribution of OIE Collab. Centres

…and **49** Collaborating Centres covering 46 topics in 26 countries
OIE Reference Centres: Roles

- **OIE Reference Laboratory**: principal mandate to function as a world reference centre of expertise on designated pathogens or diseases

- **OIE Collaborating Centre**: principal mandate to function as a world centre of research, expertise, standardisation of techniques and dissemination of knowledge on a specialty
Reference Centres: Rights

- Use of the title ‘OIE Reference Laboratory’ or ‘OIE Collaborating Centre’ as appropriate and the OIE emblem on all documents issued by the Reference Centre in its official capacity
- For the Reference Laboratory, the designated specialist can use the title of OIE Expert
- Use of the emblem for conferences (upon request)
- Win win mechanism
Reference Centres: Rights

Guidelines on the Use of the OIE Emblem by OIE Reference Centres

Sent to all new Reference Centres following their official adoption by the World Assembly at the General Session in May of each year.

For any questions regarding the use of the OIE emblem, please contact the OIE Scientific and Technical Dept: scientific.dept@oie.int
OIE Basic Texts: adopted in 2011

- The “mandates” for Reference Laboratories and Collaborating Centres (now “Reference Centres”) were updated and called “Terms of Reference (ToRs)”; the Internal Rules were also updated.
- Some of the ToRs are common to both Reference Laboratories and Collaborating Centres, some are specific to each entity.

http://www.oie.int/en/about-us/key-texts/basic-texts/
Reference Centres: New commitments

Basic Texts adopted in 2011:

- Sign Confidentiality Undertaking and Declaration of Interest forms
- Respect the legitimate confidentiality of information
- Respect the intellectual property rights on samples received
- Establish and maintain specific networks
Reference Centres: New commitments

Regarding commitment to “establish and maintain networks”

Guidance for the Management of OIE Reference Centre Networks

Reference Laboratories: New commitments
Basic Texts adopted in 2011

- No more than one Reference Laboratory shall be designated for the same pathogen or disease in the same country
Reference Laboratories: New commitments

To highlight the importance of the obligation to report positive diagnostic results, this text was integrated into the Basic Texts in 2011.

In the case of positive results for diseases that are reportable to OIE, the Reference Laboratory should immediately inform the Delegate of the OIE Member Country from which the samples originated, as well as the OIE Headquarters at the same time.
Reference Laboratories: New commitments

Basic Texts adopted in 2011

- Validate diagnostic methods according to OIE Standards
- Maintain a system of quality assurance, biosafety and biosecurity
- Organise inter-laboratory proficiency testing to ensure comparability and equivalence of results
- Develop reference material in accordance with OIE requirements
Reference Laboratories: New commitments

Regarding commitment to “Organise inter-laboratory proficiency tests”

Reference Laboratories: New commitments
Regarding commitment to “Develop reference materials”

Our scientific expertise

OIE-approved International Standard Sera

The OIE Biological Standards Commission (Laboratories Commission) coordinates a programme for the preparation, validation and distribution of OIE-approved International Reference Standards for antibody assays for infectious diseases of animals. The standards are prepared by an OIE Reference Laboratory in accordance with Guidelines drawn-up by the Laboratories Commission and in collaboration with other laboratories. Such standard preparations are designated by the OIE as primary reference standards for use in conjunction with tests described in the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (mammals, birds and bees). The aim of the programme is to harmonise diagnostic testing and encourage the mutual recognition of test results for international trade.

Currently available OIE-approved International Standard Sera

<table>
<thead>
<tr>
<th>Disease</th>
<th>Test</th>
<th>Available from</th>
</tr>
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<tbody>
<tr>
<td>African horse sickness</td>
<td>Enzyme-linked immunosorbent assay</td>
<td>Marisa Arias, Centro de Investigación en Sanidad Animal, Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (CISA-INIA), 28130 Valdeolmos, Madrid, Spain Tel: (34-91) 623.23.00 Fax: (34-91) 623.22.47 <a href="mailto:arias@inia.es">arias@inia.es</a> / <a href="mailto:diagnosi@inia.es">diagnosi@inia.es</a></td>
</tr>
<tr>
<td>Aujeszky’s disease</td>
<td>Enzyme-linked immunosorbent assay</td>
<td>Dr André Jeslin, Laboratoire de Laboratoire d’études et de recherches porcines et piscicoles, B.P. 53 22440 Ploufragan, France Tel: +33 (0)2 96 01 62 22 Fax: +33 (0)2 96 01 62 53</td>
</tr>
</tbody>
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Collaborating Centres: New commitments
Basic Texts adopted in 2011

- No more than one Collaborating Centre shall be designated for the same category of specialty in the same region or, exceptionally, in a sub-region
Collaborating Centres: New commitments

Led to new rules for applicants: formation of Consortium:

- Delegates of the countries involved approve
- The Institutions need to work out how they will operate as a consortium: e.g. sign a Memorandum of Understanding
- Define separate responsibilities
- Define operating procedures
- Usually a ‘lead’ Centre, which is the main point of entry for Member Country enquiries designated on a rotating basis (change every 3 years)
The criteria to be applied in the selection of institutions for designation as an OIE Reference Centre were also included in the *Basic Texts* in 2011.
Reference Centres: Selection criteria (2)

- Institution’s ability, capacity and readiness to provide services
- Scientific and technical standing of the institution at the national and international levels
- Presence of veterinary experts within scientific teams
- Place the institution occupies in the Member Country’s animal health, scientific or educational structures
Reference Centres: Selection criteria (3)

- Quality of its scientific and technical leadership including internationally recognised expertise in the field of its competence
- Institution’s prospective stability in terms of personnel, activity and funding
- Working relationship with other institutions in the territory, as well as at the regional and global levels
- Technical and geographical relevance of the institution and its activities to OIE’s programme priorities
New rules for applications for Reference Centre status

Guidelines for applicants

Revised to include updated ToRs covering applications for OIE Reference Centre status

The main difference:

- Relevant legal and budgetary provisions: provide assurance on the sustainability and functioning of the laboratory

- Capability for timely international shipment and receipt of samples (Reference Laboratories only)
New rules for applications for Reference Centre status

Collaborating Centres: updated review process

- Under the updated ToRs for the four OIE Specialist Commissions, new applications for OIE Collaborating Centre status are assigned to one of the four Commissions for approval according to the proposed specialty and the competence of the respective Commissions.
Official listing of Reference Laboratories

- Application from the candidate structure
- Agreement of the national Delegate
- Assessment by the Biological Standards or Aquatic Animals Commission
- Agreement from the Council
- Vote from the World Assembly of National OIE Delegates
Official listing of Collaborating Centres or Consortium

- Application from the candidate structure
- Agreement of the national Delegate
- Assessment by the relevant Specialist Commission
- Agreement by the relevant OIE Regional Commission
- Agreement from the Council
- Vote from the World Assembly of National OIE Delegates
Delisting of Reference Centres

- Request received by the Director General (from different potential sources: Specialist Commission, Council, Member Country …)
- Assessment by the relevant Specialist Commission
- Assessment by the Council
- Vote from the World Assembly of National OIE Delegates
New rules for changes of expert at Reference Laboratories

- Nomination of replacement expert with documented proof of his/her work in the disease to be sent officially to OIE from the OIE Delegate
- Reviewed by Specialist Commission
- Referred to the OIE Council for final approval (Resolution No. 34 adopted in May 2013)
- If approved, the nomination is immediately official
The future

NEW PROJECTS AND DIRECTIONS
New Project: OIE Genomic Sequence Platform (1)

Background

- Growing reliance on generating and using sequence information
- Concurrent ever-increasing trend toward global open information systems
- Crucial and far-reaching implications for veterinary laboratories and the traditional notification and management of infectious diseases and food-borne infections
- The OIE considers that sequence and sequence analysis data should be an integral and necessary part of the analysis and the reporting of diagnostics at the international level.
Creation of an OIE platform for the collection and management of genomic sequences in animal health

- The OIE intends to make full use of the unique worldwide Reference Centre network’s competence and expertise as the key to developing policies and practices for the management and use of sequence information in the framework of WAHIS with direct access for Reference Centres
New Project: Creation of a biobank

- The OIE aims to create a veterinary biobank network to optimise the occasions for cooperation in sharing biological resources, including reference reagents, within the OIE Reference Centre network.

- This network will be fully connected and open to other biobanks when relevant.
New Project: Laboratory visits

Member Countries approved the undertaking of periodic evaluations of OIE Reference Centres to ensure their on-going compliance with expected quality management systems, standards and ToRs.

Biological Standards Commission has developed a structured approach to monitoring Reference Centres through the annual reports; visits to laboratories will be proposed.
New activities

- PVS Pathway component for laboratories
- National Focal Points for Veterinary Laboratories
- Reference Centres commitment to disseminate quickly new relevant scientific information to the OIE, and support OIE publications through contributions or peer reviews to ensure the scientific accuracy and robustness of its information
New activities

- These and other projects mentioned here will be presented in detail in the following presentations during this Third Global Conference

- The final Recommendations from this Third Global Conference will reflect the projects and discussions
Thank you for your attention

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