OIE Reference Centres: role, rights and commitments

Dr Peter Daniels
Member of the Biological Standards Commission
OIE Mandate and OIE Reference Centres

- 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
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
In 2015, the OIE has a global network of **252** Reference Laboratories covering 118 diseases in 39 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
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”

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

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<thead>
<tr>
<th>Disease</th>
<th>Test</th>
<th>Available from</th>
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<tbody>
<tr>
<td>African horse sickness</td>
<td>Enzyme-linked immunosorbent assay</td>
<td>Marisa Arias&lt;br&gt;Centro de Investigación en Sanidad Animal&lt;br&gt;Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (CISA-INIA), 28130&lt;br&gt;Valdemossos, Madrid, Spain&lt;br&gt;Tel: (34-91) 626.23.00&lt;br&gt;Fax: (34-91) 620.22.47&lt;br&gt;<a href="mailto:arias@inia.es">arias@inia.es</a> / <a href="mailto:diagnostic@inia.es">diagnostic@inia.es</a></td>
</tr>
<tr>
<td>Aféjeszky’s disease</td>
<td>Enzyme-linked immunosorbent assay; Virus neutralisation</td>
<td>Dr André Justin&lt;br&gt;Laboratoire de Recherche&lt;br&gt;22440 Ploufragan, France&lt;br&gt;Tel +33 (0)2 96 01 62 22&lt;br&gt;Fax: +33 (0)2 96 01 62 53</td>
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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)
Reference Centres: Selection criteria
Basic Texts adopted in 2011

- 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
Application for Reference Centre status received by DG from Delegate

Dossier number assigned and logged (Scientific and Technical Department oversees the whole process)

Opinion sought from the most relevant Specialist Commission (and Working Group, if needed)* (specialty listing below, not exhaustive)

- Terrestrial animal disease diagnostics
- Biotechnology
- Veterinary products
- Veterinary laboratory capacity
  - Biological Standards Commission

- Aquatic animal disease control
- Aquatic animal disease diagnosis
  - Aquatic Animal Health Commission

- Food and feed safety
- Animal welfare
  - Terrestrial Animal Health Commission

- Legislation
- Veterinary education and training
  - WG Animal Welfare
  - WG Animal Production Food Safety

- Terrestrial animal disease control
- Epidemiology
- Risk analysis
  - Scientific Commission for Animal Diseases

- Wildlife
- Animal-human-ecosystems interface
  - WG Wildlife Diseases

Application referred to corresponding Regional Commission (only for Collaborating Centres)*

Order depends on the meeting calendar

OIE Council*

World Assembly
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
Thank you for your attention

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