International reference material - Challenges

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Overview

• Reminder of the requirements under Terms of Reference of Reference Laboratories

• Current availability of international reference standards

• Commission’s activities
  o Work in progress
  o Future work

• Challenges
Terms of Reference of OIE Reference Laboratories

Includes the requirements:

- “To develop reference material in accordance with OIE requirements, and implement and promote the application of OIE Standards”.

- “To store and distribute to national laboratories biological reference products and any other reagents used in the diagnosis and control of the designated pathogens or diseases.”
Requirements

• Standards are prepared by an OIE Reference Laboratory in accordance with Guidelines drawn-up by the Laboratories Commission and in collaboration with other laboratories.

• The Commission views the production of International Reference Standards as a key activity of Reference Laboratories and information on the availability and provision of such materials is requested through the annual reports of activities of the OIE Reference Laboratories.
Current availability of International Reference Standards

- List of currently available OIE-approved International Standard Sera on OIE website
- There are currently 22 International Reference Standards available for 19 of the 111 OIE-listed diseases.
- These materials are produced by 19 separately-listed Reference Laboratories.
- Nine of the 22 standards are produced in only two institutions.
Review of procedure and guidelines

Based on returns of annual questionnaires by Reference Laboratories

• Few are aware of current procedure and list despite being mandated to develop reference materials,

• **vast majority of Ref Labs produce materials but do not submit them for evaluation**

• In response the Commission agreed that its standardisation programme will be reviewed.
Work in progress

• Report of the OIE survey carried out by the Collaborating Centre “Veterinary Biologicals Biobank” in Brescia, Italy

• Commission’s Guide: International Reference Antibody Standards for Antibody Assays to be put on-line following expert review

• Other guidelines already exist under the OIE umbrella and could be cross referenced, e.g. OFFLU guidelines on molecular tests
Future work

• At present only OIE-approved International standard sera are available. A guide for antigen standards will be developed.

• The Commission will initiate work to identify priorities in terms of diseases and/or materials for which reference standards are required.
Challenges 1

Charging for reference materials

• The Commission understands and acknowledges that some Reference Laboratories may need to make a charge for the provision of International Standards.
• Any charges should be designed to cover the cost of production where this is necessary and not to return a profit for the laboratory.
• Where possible laboratories should consider providing standards free of charge.
Challenges 2

Non-provision

- At its meeting in September 2014, the Commission noted that in a number of cases Reference Laboratories had failed to respond to requests for materials.

- A subsequent amendment to the reference standards page now advises:

  “Should you contact one of these OIE Reference Laboratories to obtain reference materials and get no response, please inform the OIE Scientific and Technical Dept.”
Challenges 3

Other barriers to production and submission of International Reference Standards for OIE approval

- Meeting the requirement of the Terms of Reference
- “To develop reference material in accordance with OIE requirements, and implement and promote the application of OIE Standards”

- Understanding the barriers and providing further help and guidance for Ref Labs to meet this requirement
Summary

• The Commission has initiated work to review the provision of international reference standards by Reference Laboratories with the emphasis being on providing clarification and guidance on expectations and procedures.

• The Commission welcomes views of Reference Laboratories on this important topic and will set priorities based on the outcome of discussions from the conference and survey.