PROPOSED WORK PROGRAMME FOR THE EUROPEAN UNION REFERENCE LABORATORY FOR FOOT-AND-MOUTH DISEASE

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Introduction

This document contains the 2015 proposed work programme for the European Union Reference Laboratory (EU-RL) for Foot-and-Mouth Disease. The work programme is based on the four Operational Objectives provided by DG Sanco. Activities, subdivided into tasks, are listed under each of these Operational Objectives. The overall work programme for the EU-RL has largely remained the same this year; however, slight adjustments have been made to specifically address the new structure of the objectives. The activity-based indicators have also been given for each activity. The proposed budget is attached as a separate document.

Our duty as the EU-RL is to provide services and advice to EU National Reference Laboratories, neighbouring EU countries and strategic countries. To achieve this goal ten activities have been listed as part of the 2015 proposed work programme:

- Distribution of high quality ELISA kits and reagents
- Communicate new analytical methods that have been developed
- Perform vaccine matching and European Phamacopeia potency tests on vaccine antigens held in the European Union FMD vaccine bank
- Maintain and continue to isolate FMDV strains to identify new emerging threats to Europe
- Carry out the 2015 Proficiency Testing Scheme (PTS) for the National Reference Laboratory
- EU-RL to carry out annual workshop for the National Reference Laboratory (NRLs)
- Train staff for emergency situations, missions and inspections
- Maintain of quality assurance schemes
- Share information between the EU-RLs and NRLs
- Administrative Activities to ensure sound and efficient management

Dr. Donald King
Head of the FMD EU-RL

Operational Objectives 1 – 4

Operational Objective 1: to ensure the development and use of high quality analytical methods across the EU-RL framework

Activity 1
Distribution of high quality ELISA kits and reagents

Task A	Maintain and update antigen and antibody detection ELISA kits for distribution to laboratories in member states *Sub-Task a* – produce specific guinea-pig and rabbit anti-sera against relevant FMDV serotypes *Sub-Task b* – obtain or produce antigens against relevant FMDV serotypes for use in routine ELISA tests *Sub-Task c* – maintain quality assurance and validation of these reagents
Task B	Validate next-generation ELISA kits for potential incorporation and/or replacement for current kits
Task C	Response to NRL queries and provide advice on best tests to use
Expected Results	Activity-based indicators – AH.PT.2, A.H.PT.3, AH.ANA.2 Provide quality antigen and antibody ELISA kits for use during surveillance or outbreak. Continual improvement of diagnostic kits

Activity 2
Review and evaluate new analytical methods that have been developed

Task A	EU-RL staff to attend international FAO/OIE missions to discuss the results of latest research for the evaluation of diagnostic methods and standards
Task B	Carry out an annual training course to provide training on OIE recommended tests to ISO/IEC 17025 standards
Task C	EU-RL staff to carry out tailored missions to individual NRLs that either request advice for diagnostic or had PTS results that require improvement
Task D	Present and discuss new analytical methods at the annual workshop
Task E	Assemble a resource of validated methods and supporting written procedures (including ISO 17025 accredited tests) that can be accessed by all NRLs
Expected Results	Activity-based indicators - AH.PT.3, AH.PT.5, AH.PT.6, AH.ANA.1, AH.NRL.4, AH.NRL.5, AH.COM.1, AH.OIE.1, AH.R&D.1 NRLs continue to improve and progress

Activity 3
Perform vaccine matching and European Pharmacopeia potency tests on vaccine antigens held in the European Union FMD vaccine bank

Task A	Carry out vaccine matching testing for FMDV field strains of potential threat to Europe using vaccines in the European Union FMD vaccine bank *Sub-Task a* – correlate data with other OIE/FAO reference laboratories
Task B	Produce new bovine vaccine sera for the EU FMD vaccines to be used for vaccine matching tests
Task C	Carry out heterologous potency tests for European Union FMD vaccines
Expected Results	Activity-based indicators - AH.PT.2 Provide advice to the EU on the suitability of vaccines held in the European Union FMD vaccine bank against contemporary viruses circulating in the field.

Activity 4
Identify new emerging threats to Europe

Task A	Receive and isolate FMDV strains from around the world *Sub-Task a* – undertake virus isolation and serotype characterisation *Sub-Task b* – generate sequence data for molecular characterization
Task B	To ensure reference and field strains are available to the NRL and the European Union FMD vaccine bank
Expected Results	Activity-based indicators - AH.PT.2 Maintain and increase the current FMD isolate bank and provide an ongoing assessment about the suitability of test methods to recognise and characterise FMD.

Operational Objective 2: To maintain appropriate level of proficiency testing ensuring efficiency of control analysis methods

Activity 5
Carry out the 2015 Proficiency Testing Scheme (PTS) for the National Reference Laboratories in EU member states

Task A	Preparation, testing and distribution of virological and serological samples for annual proficiency testing scheme *Panel 1* – Virology infectious panel for FMDV/SVDV (n=6) *Panel 2* – Virology non-infectious panel for FMDV/SVDV (n=8) *Panel 3* – Serology non-infectious panel for FMDV (n=8)
Task B	Collate and gather data and information on the methods used by the NRLs and insure that they are appropriate (i.e. outlined in OIE manual etc.)
Task C	Analyse PTS results and give individual results to each laboratory to review overall and individual test performance (against agreed criteria) and highlight the areas where improvement may be required
Expected Results	Activity-based indicators - AH.PT.1, AH.PT.2, AH.PT.3, AH.PT.4, AH.PT.5, AH.PT.6 Improve harmonisation of diagnostic tests amongst NRLs and insure NRLs are able to diagnose both virological and serological samples during or after an FMD outbreak.

Operational Objective 3: To ensure the availability of scientific and technical assistance provided by the EU-RLs

Activity 6
EU-RL to carry out an annual workshop for the National Reference Laboratories

Task A	Communicate the latest FMD epidemiology regionally and globally including information from OIE/FAO world reference laboratories
Task B	Organize an annual workshop to present the results from the PTS for all NRLs *Sub-Task a* – Present results of annual PTS and the harmonisation amongst the labs *Sub-Task b* – Review diagnostic techniques and share newest diagnostic research *Sub-Task c* – Participate in the EURL Directors' Working group on relationships with NRLs chaired by DG SANCO Unit E and report back to NRLs
Task C	Discuss with NRLs any questions, concerns they have about their current diagnostic abilities *Sub-Task a* – set-up additional telephone, meetings or training to insure NRLs are able to be successful carry out future PTS
Task D	Receive feedback *Sub-Task a* – set time aside in agenda for discussion *Sub-Task b* – Activity seek feedback throughout the workshop *Sub-Task c* – follow up with online feedback survey
Expected Results	Activity-based indicators - AH.PT.3, AH.PT.4, AH.PT.5, AH.PT.6, AH.ANA.1, AH.NRL.1, AH.NRL.2, AH.NRL.3 , AH.NRL.6, AH.R&D.1, AH.OIE.1, AH.COM.1 Successful annual NRL workshop

Activity 7
Train staff within the EU-RL to respond to emergency situations, missions and inspections

Task A	Provide training to staff to work at ISO/IEC 17025 accreditation
Task B	Have a contingency plan in place that provides information to the staff regarding the flow of work during an outbreak
Task C	Train staff to be qualified to assist with veterinary/epidemiological investigations into outbreaks of FMDV in field member states and/or neighbouring countries
Expected Results	Activity-based indicators – AH.COM.1, AH.COM.2, AH.OIE.1 Provide assistance to outbreaks in Europe in a timely and efficient manner

Operational Objective 4: To ensure a sound and efficiency management of the EU-RL funding cycle

Activity 8
Maintenance of quality assurance schemes

Task A	Maintain UKAS ISO 17025 accredited tests *Sub-Task a* – External training on UKAS ISO 17025 accreditation *Sub-Task b* – Quality assurance training for all new starters *Sub-Task c* – External and Internal QA audits
Task B	The Pirbright Laboratory is working towards ISO 14001 accreditation
Expected Results	Activity-based indicators – AH.PT.QI, AH.ANA.QI, AH.NRL.QI, AH.COM.QI, AH.OIE.QI, AH.R&D.QI Maintain the UKAS ISO 17025 accreditation

Activity 9
Share information between the EURL and NRLs

Task A	Maintenance of the EURL website *Sub-Task a* – links to FAO/OIE reference FMD laboratory *Sub-Task b* – update on the annual PTS and workshop *Sub-Task c* – latest information on FMD situation around the world *Sub-Task d* – current relevant manuscripts and research
Task B	Communicate and ask for feedback on updated website
Expected Results	Activity-based indicators – AH.R&D.1 Maintain an Activity EURL website

Activity 10
Administrative Activities to ensure sound and efficient management

Task A	Prepare annual EU-RL work program and performance indicator reports in line with the commission work program
Task B	Prepare annual EU-RL technical and financial reports
Task C	Provide reports for the EU commission upon request
Expected Results	Activity-based indicators – AH.COM.2 To disseminate information in a timely and efficient manner