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

JANUARY 2016 TO DECEMBER 2017

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Introduction

This document contains the 2016 to 2017 proposed work programme for the European Union Reference Laboratory (EU-RL) for Foot-and-Mouth Disease. The work programme is arranged according to the four Operational Objectives provided by DG Sante. Activities, subdivided into tasks, are listed under each of these Operational Objectives. The overall proposed work programme for the EU-RL during 2016-17 has largely remained the same as 2015. However, to address recent discussions with Drs Alf Fuessel and Francisco Reviriego-Gordejo at the EU Commission, we have expanded the scope of the proficiency testing scheme to include Swine Vesicular Disease Virus, which remains a reportable livestock disease in the EU. This work was previously covered by our work as the EU-RL for SVD, and in order to accommodate these activities within the EU-RL for FMD, we have requested a modest increase to the budget to cover the extra staff time needed to prepare the SVDV samples (serological and viral specimens), and analyse NRLs' capability to diagnose SVDV. 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, nine activities have been listed as part of the 2016 and 2017 proposed work programme:

Activity 1 Distribution of high quality ELISA kits and reagents
Activity 2 Review and evaluate new analytical methods that have been developed
Activity 3 Promotion of EU-RLs collaboration with laboratories in third countries
Activity 4 Perform vaccine matching and European Pharmacopeia potency tests on vaccine antigens held in the European Union FMD vaccine bank
Activity 5 Identify new emerging threats to Europe
Activity 6 Carry out Proficiency Testing Scheme (PTS) for the National Reference Laboratories in EU member states in 2016 and 2017
Activity 7 EU-RL to carry out an annual workshop for the National Reference Laboratories
Activity 8 Share information between the EU-RL and NRLs
Activity 9 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	Respond to NRL queries and provide advice on best tests to use for different diagnostic scenarios
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. These documents will describe those tests that are recommended for diagnostic use and are listed in the OIE diagnostic manual. We

	anticipate that this information will be available on our EU-RL website. In addition to information about the specific tests we will also provide guidance on sampling and transport of samples.
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
Promotion of EU-RLs collaboration with laboratories in third countries

Task A	EU-RL staff to attend missions of the FAO/OIE FMD Laboratory Network (2016/17) to build collaborations with third countries
Task B	Annual training course opened to delegates from NRLs representing third countries to encourage harmonisation of laboratory methods
Task C	EU-RL staff to carry out tailored missions to third countries that either request advice for diagnostic or had PTS results that require improvement
Task D	Invite speakers to the annual Workshop of the EU-RL for FMD from third countries currently experiencing outbreaks of FMD that threaten the EU
Expected Results	Activity-based indicators - AH.NRL.5, AH.COM.1, AH.OIE.1, AH.R&D.1 Building of network between NRLs, EU-RLs and third countries to improve surveillance and diagnostics of FMD.

Activity 4
Perform vaccine matching and European Pharmacopeia potency tests on vaccine antigens held in the European Union FMD vaccine bank*

Task A	Carry out routine 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 vaccine matching on order to determine use in EU bank.
Task C	Carry out at least one heterologous potency tests for European Union FMD vaccines (to address a priority FMDV strain that threatens Europe)
Expected	Activity-based indicators - AH.PT.2

Results	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. Quarterly report summarising vaccine matching work to be provided to Alf-Eckbert.Fuessel@ec.europa.eu and Ewa.Camara@ec.europa.eu.

* NB: The funds to support the in-vivo work are allocated to the *consumables* component of the budget: in 2015 this work was subsequently allocated to *sub-contracting* in order to complete this work at CVI-Lelystad.

Activity 5
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 representative contemporary viruses are available for future use in the European Union FMD vaccine bank (via supply to commercial manufactures). In addition, (if requested) we will also supply these viruses to other NRLs within the EU so that they can ensure that their diagnostic approaches are able to detect new lineages.
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 inter-laboratory comparative testing ensuring efficiency of control analysis methods

Activity 6
Carry out Proficiency Testing Scheme (PTS) for the National Reference Laboratories in EU member states in 2016 and 2017

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) *Panel 4* – Serology non-infectious panel for SVDV (n=6) *Note – Each of the panels will describe a specific scenario (outbreak in EU and/or import-export of livestock). Laboratories are expected to use the appropriate tests to identify if the samples contain FMDV and SVDV. This proposed workplan includes samples to evaluate SVDV diagnostic tests and we request a modest increase to the budget to cover this additional activity.*
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
Task D	We anticipate that we will adopt the UKAS ISO 17043 standard by the end of 2017.
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 FMD and/or SVD outbreaks.

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

Activity 7
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 FMD Laboratory Network
Task B	Organize an annual workshop in 2016 and 2017 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
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

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

Activity 8
Share information between the EU-RL and NRLs

Task A	Develop new content and maintain the EU-RL 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 9
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 reports
Task C	Control, verification and evaluation of financial expenditure
Task D	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