Work Program Proposal for the Period January 2016 - December 2017

European Union Reference Laboratory for Bluetongue

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1. INTRODUCTION

The EU-RL for Bluetongue virus proposes the following Work Program for the period January 2016 -December 2017.

The *Commission Implementing Decision* establishing the work program for the year 2016/17 on financial contribution to the European Union reference laboratories lays down the general, specific and operational objectives of the European Commission within this aspect and describes the range of activities EU-RL to be funded. ***The activities of EU-RL for BTV are proposed under the framework of the Commission Operational Objectives defined in section 1.4. of the Annex to this Decision.***

Dr. Carrie Batten
Head of the EU-RL for Bluetongue

2. PROPOSED ACTIVITIES

2.1 ACTIVITIES UNDER THE COMMISSION OPERATIONAL OBJECTIVE 1: To ensure the development and use of high quality analytical methods across the EU-RL framework.

Ensuring dissemination of analytical and reference methods from EU-RL to NRLs.

Activity 1: Distribution of Standard Operating Procedures (SOPs) to the NRLs of EU-RL ISO/IEC17025 accredited methods:

- ELISA
- Virus Isolation for BTV
- Real Time RT-PCR Assay (Hofmann *et al*)
- Real Time RT-PCR Assay (Shaw *et al*)

And non-accredited methods

- Real Time RT-PCR Assays (Serotype-Specific)
- SNT
- VP2 sequencing

Sub-activity 1.1: Maintenance of Quality Assurance schemes

Objectives:

- Distribution and technical support to the NRLs on request and through upload onto EU-RL website to ensure/encourage the harmonization of the analytical methods.
- To maintain the test accreditation according to ISO/IEC 17025: 2005 "General requirements for the competence of testing and calibration laboratories
- Quality assurance training for all new starters
- External and Internal QA audits

Expected results: see Performance Indicator **AH.ANA.1, AH.ANA.QI**

Activity 2: Production and supply of reference materials to the NRLs

- Non-infectious serum panel
- Infectious EDTA blood panel
- Reference antiserum
- Reference viruses
- Nucleic Acid on request when other control material cannot be used
- Preparation of EU-RL project license in line with UK home office guidelines
- *In vivo* experiment to generate reference reagents to novel BTV isolates
- Development and production of a nucleic acid standard for use in BTV real time RT-PCR assays to act as a synthetic control

Objectives:

- To assure the quality control of methods implemented by the NRLs.
- To create new reference antisera to novel BTV isolates
- To create a bank of biologicals for use in future PT schemes

Expected results: see Performance Indicator **AH.PT.2, AH.ANA.QI**

Activity 3: Maintenance of BT virus and sera collections, and sensitive cell culture lines.

Objectives:

- Keep a comprehensive virus collection available, that includes reference viruses (serotypes 1-24 and 26), isolates from historical outbreaks and novel isolates from recent outbreaks.
- Ensure the availability of reference materials for diagnostic tests.
- Maintain a sera collection as reference material to be used in the validation and quality control of serological tests.
- Maintain sensitive cell lines for the isolation of BTV to include BHK-21, VEROs and KC cells.

Expected results: see Performance Indicator **AH.PT.2**

Activity 4: Seek and receive virus isolates and related information from Member States and from any other country, as part of the diagnostic or confirmatory service of the EU-RL for BT.

Objectives:

- Grow and antigenically characterise virus isolates using serogroup specific polyclonal antisera and/or molecular techniques, as required **(Contributing to Activity 3)**.
- Examination of new isolates, field and vaccine derived, for significant differences to current reference strains, by serological and molecular techniques.
- Sequence (through total or partial sequencing of VP2 and where necessary whole genome sequencing) virus isolates to add to the Pirbright Institute database for topo-typing virus isolates and determination of their phylogenetic and functional relationships, for the purposes of identifying the geographical and biological origins of BT virus isolates.
- To keep updated molecular diagnostic tools (RT-PCR) to detect and serotype isolates of BTV

Expected results: see Performance Indicator **AH.ANA.1**

- **Planning of trainings, meetings and workshop organized by the EU-RL for the harmonization of diagnostic techniques and of methods of analysis**

Activity 5: Organise and deliver annual BTV diagnostic Training course and annual meeting.

Sub-activity 5.1. Annual BTV training course to be held at the EU-RL for member states and third party participants

Objectives:

- To harmonize and update laboratory diagnosis.
- To coordinate BTV diagnostic methods used by members states and third parties.
- To ensure close relationships within the NRL network

Expected results: see Performance Indicator **AH.NRL.5**, **AH.NRL.6, AH.ANA.1**

Sub-activity 5.2. Organization of an annual meeting with NRLs. Presentation and discussion of proficiency test results and update on technical issues

Objectives:

- To harmonize and update laboratory diagnosis
- To coordinate BTV diagnostic methods used by Members States
- To ensure close relationships within the NRL Network

Expected results: The annual joint meeting/workshop of the BTV and AHSV NRLs will take place in November-December of 2016 (AHSV EU-RL budget) and November-December of 2017 (BTV EU-RL budget). Collate and edit material for a report of the meeting that will be sent to all the participants. See Performance Indicator **AH.NRL.1**

Sub-activity 5.3. EU-RL stakeholder survey for NRLs

Objectives:

- To establish the opinion of the NRLs regarding the performance of the EU-RL
- To evaluate the survey outcome and take measures to address relevant negative feed-back

Expected results: see Performance Indicator **AH.NRL.2, AH.NRL.3**

- **Initiation of EU-RL collaboration with laboratories in third countries**

Activity 6: Collaboration of EU-RL with Laboratories of Third Countries through ongoing research projects, replying to requests for information, participation on EC led projects/initiatives

Objectives:

- To exchange information and technical data
- To promote the participation of third country Laboratories in the Proficiency Test organized by the EU-RL
- To provide SOPs and reference material to ensure the performance of high quality analytical methods
- To gain knowledge of the disease status, epidemiology, use of vaccines, analytical methods etc.

Expected results: see Performance Indicator **AH.OIE.1, AH.R&D.1**

2.2. ACTIVITIES UNDER THE COMMISSION OPERATIONAL OBJECTIVE 2: To maintain an appropriate level of inter-laboratory comparative testing ensuring efficiency of control analysis methods.

Ensuring planning and initiation of comparative testing by EU-RL in accordance with internationally accepted protocols/Address underperforming related issues within NRL network

Activity 7: Organization of an annual Proficiency Test (PT) within the European Union framework for Bluetongue virus antibody and nucleic acid detection test.
Sub-activity 7.1 Preparation of panels (A: Infectious – EDTA blood and B: non infectious serum). Including relevant innocuity testing.
Sub-activity 7.2 Shipment of samples to destination NRLs and third party participants
Sub-activity 7.3 Evaluation of the results obtained by the NRLs and preparation of data to be presented at annual meeting. Organise and facilitate the annual meetings/workshops.
Sub-activity 7.4 Preparation and dissemination of individual reports to NRLs and third party participants and final meeting report
Sub-activity 7.5: Collaboration with underperforming NRLs in the PT framework in order to identify root cause and proposal of corrective measures. Organization of a second PT round with all underperforming NRLs and/or Organization of training visits either at the NRL or at the EU-RL for technicians from underperforming NRLs (if applicable).
Objectives:

- To ensure the use of high quality analytical methods used in NRLs as fit for purpose.
- To encourage the harmonization of methods used by the Member States.
- To collect and collate data and information on methods of diagnosis used and the results of tests carried out in the Community.
- To ensure follow up of poor results in PTs.
- To inform EU-Commission following the *Protocol for management of underperformance in comparative testing and/or lack of collaboration of NRLs with EU-RL activities*
- To train/retrain technicians
- To improve the performance of the underperforming NRL.

Expected results: See Performance Indicators **AH.PT.1, AH. PT.2, AH.PT.3, AH.PT.4, AH.PT.5, AH.PT 6, AH.NRL.4**

2.3. ACTIVITIES UNDER THE COMMISSION OPERATIONAL OBJECTIVE 3: To ensure the availability of scientific and technical assistance provided by the EU-RLs

Initiation of EU-RLs collaboration with EFSA and international organization/Organization of meetings for scientific and technical assistance from the EU-RLs

Activity 8: Maintenance of relationships with the world Laboratories for BTV designated by the World Organization Animal Health (OIE), and with NRLs

Objectives:

- To maintain a mutual and reciprocal information exchange
- To get a better knowledge of disease epidemiology
- To harmonize analytical methods within the world organization network
- Participate on relevant conference organizing committees and EU led initiatives.
- Participation in the EU-RL Directors' Working group on development and evaluation of NRL workshops and training programs with NRLs chaired by DG SANCO

Expected result: See Performance Indicator **AH.OIE.1, AH.COM.1**

Queries to EU-RLs for policy making and enforcement/Networking activities for appropriate assistance by the EU-RLs

Activity 9: Availability of trained staff for emergency situations, missions and inspections occurring within the EU to assist the Commission on request.

Objectives:

- Maintain competence through the attendance of meetings and conferences related to BTV.
- Keep abreast of BTV related issues through reading, training and research programs.
- To co-operate with NRLs in the rapid diagnosis or confirmation of BTV outbreaks in member states and/or neighboring countries.
- To have qualified staff with relevant training able to travel to assist with veterinary/epidemiological investigations into outbreaks of BTV in the field in member states and/or neighboring countries.
- To provide training to EU personnel as required on BT diagnosis and/or clinical assessment and advice on vaccine use/control strategies.
- Respond to Commission requests for information effecting policy (or for general information) in a timely and efficient manner.

Expected results: See Performance Indicator **AH.COM.1, AH.COM.2, AH.OIE.1**

2.4. ACTIVITIES UNDER THE COMMISSION OPERATIONAL OBJECTIVE 4: To ensure a sound and efficient management of the EU-RL funding cycle

Activity 10: Administrative activities to ensure sound and efficient management of the EU-RL

Sub-activity 10.1. Funding Cycle

Objectives:

- To prepare the bi-annual EU-RL work program in line with the Commission Work Program
  To prepare an estimated financial budget
- To prepare ex-ante Performance Indicator reports
- To prepare annual EU-RL technical and financial reports
- To prepare ex-post Performance Indicator reports
- To provide reports for the EU Commission upon request

Expected results: See Performance Indicator **AH.COM.2**

Sub-activity 10.2: Redesign of EU-RL–BTV Website and content update

Objectives:

- To disseminate relevant scientific information including validation data where applicable/ relevant publications
- To disseminate analytical and reference methods
- To disseminate information concerning previous annual meetings, proficiency tests and other relevant issues

Expected results: see Performance Indicator **AH.ANA.2**