Work Program Proposal for the Period January-December 2015

European Union Reference Laboratory for Bluetongue

1. INTRODUCTION

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 network
2.2. ACTIVITIES UNDER THE COMMISSION OPERATIONAL OBJECTIVE 2: To maintain appropriate level of proficiency testing ensuring efficiency of control analysis methods
2.3. ACTIVITIES UNDER THE COMMISSION OPERATIONAL OBJECTIVE 3: To ensure the availability of scientific and technical assistance provided by EU-RLs
2.4. ACTIVITIES UNDER THE COMMISSION OPERATIONAL OBJECTIVE 4: To ensure sound and efficient management of EU-RL funding cycle

1. INTRODUCTION

The EU-RL for Bluetongue virus proposes the following Work Program for the period January-December 2015.

The *Commission Implementing Decision* establishing the work program for the year 2015 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.***

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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 network.

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

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 meeting will take place in November-December of 2015. 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 appropriate level of proficiency 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 a 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 meeting in late 2015.
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 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 sound and efficient management of EU-RL funding cycle

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

Sub-activity 10.1. 2015 Funding Cycle

Objectives:

- To prepare the annual EU-RL work program in line with the Commission Work Program
  To prepare an estimated financial budget
- To prepare ex-ante Performance Indicator report
- To prepare annual EU-RL technical and financial reports
- To prepare ex-post Performance Indicator report
- 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**