



MINISTERIO
DE AGRICULTURA, ALIMENTACIÓN
Y MEDIO AMBIENTE

DIRECCIÓN GENERAL DE SANIDAD DE LA
PRODUCCIÓN AGRARIA

SUBDIRECCIÓN GENERAL DE SANIDAD E HIGIENE
ANIMAL Y TRAZABILIDAD

LABORATORIO CENTRAL DE VETERINARIA

Proposal on a Working Program for the Period January-December 2015

from the

European Union Reference Laboratory for African Horse Sickness



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1. INTRODUCTION

The EURL for African Sickness proposed the following Work Program for the period January-December 2015 under the provisions defining their functions and duties of Annex III to the *Council Directive 92/35/EEC* of 29 April 1992 laying down control rules and measures to combat African Horse Sickness, and the article 32 of the *Regulation (EC) 882/2004* of the Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

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 EURL to be funded. ***The activities of EURL for AHS are proposed under the framework of the Commission Operational Objectives defined in the epigraph 1.4. of the Annex to this Decision.***

The European Commission launched in 2012 the Performance Indicator Exercise for EURLs, as a new management tool for the evaluation of activities based on activity based-performance indicators, and a better and best practice approach for their evaluation. ***For establishing the expected results of the activities proposed, the EURL for AHS has used the ex-ante indicator format that has been incorporated as an annex to this proposal.***

Algete, Madrid, 14th August 2014

Dr. Montserrat Agüero-García
Director of the EU-RL for African Horse Sickness





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 the EU-RL accredited reference methods:

- Blocking ELISA Assay
- RT-PCR Assay (Gel-based PCR)
- RRT-PCR Assay (Real Time)
- RRT-PCR Assay Serotype-Specific (Real Time)

Objective: Revision of SOPs, distribution and technical support to the NRLs to ensure the harmonization of the analytical methods used in the Community.

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

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

- Panel of sera
- Working serum
- Viral AHS suspension
- Viral AHS heat inactivated suspension as source of Nucleic Acid for the Quality Assurance of PCR method

Objective: to assure the quality control of the methods implemented by the NRLs in the Community

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

Activity 3: Maintenance of AHSV strain and sera collections, and sensitive cell culture lines.

Objectives:

- to keep a viral isolates collection available that includes prototype strains (serotypes 1-9), isolates from the Spanish outbreak 1987-90 and other isolates from recent outbreaks
- to ensure the availability of reference material to be used in RT-PCR
- to keep sera collection as reference material to be used in the validation and quality control of serological tests



- to maintain sensitive cell lines for the AHS diagnosis such as BHK-1 and VERO

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

Activity 4: Molecular characterization of recent circulating AHSV strains through total or partial sequencing of the VP2 and VP7 coding regions.

Objectives:

- To characterize isolates of AHSV by the most up-to-date methods available to allow greater understanding of the epizootiology of African horse sickness
- To keep updated molecular diagnostic tools (PCR) to detect and type the AHSV

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

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

Activity 5: Annual Meeting and exchange of information within EURL-NRL network

Sub-activity 5.1. Organization of an annual meeting of NRLs. Presentation and discussion of proficiency test results and update on technical issues

Objectives:

- To harmonize and update the laboratory diagnosis ensuring the highest quality performance
- To coordinate the AHS diagnostic methods used by the Members States
- To ensure a close relationship among the NRL Network

Expected results: the annual meeting will take place in November-December of 2015. Elaboration of a report of the meeting that will be sent to all the participants. See Performance Indicator **AH.NRL.1**

Sub-activity 5.2. Launching of a satisfaction survey : EURL stakeholder survey for NRLs

Objectives:

- To know the opinion of the NRLs regarding the performance fo EURLs
- To evaluate the survey outcome and take measures to address relevant negative feed-back

Expected results: See Performance Indicators **AH.NRL.2, AH.NRL.3**



▪ **Initiation of EURL collaboration with laboratories in third countries**

Activity 6: Collaboration of EURL with Laboratories of Third Countries

Objectives:

- To exchange information and technical criteria
- To promote the participation of these Laboratories in the Proficiency Test organized by the EURL
- To provide with SOPs and reference material to ensure the performance of high quality analytical method
- To get a better knowledge of the disease in those countries in terms of analytical methods used, epidemiology, use of vaccines, etc.

Expected results: see Performance Indicator **AH.OIE.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 imitation of comparative testing by EURL in accordance with internationally accepted protocols

Activity 7: Organization of a Proficiency Test (PT) within the European Union framework for African horse sickness virus antibody and nucleic acid detection test. In the second semester of the year

Sub-activity 7.1 Preparation and shipping of the sample panels

Sub-activity 7.2 Evaluation of the results obtained by the NRLs and elaboration of general and personalized reports to each of the participant laboratories.

Objectives:

- To ensure the use of high quality analytical methods recommended by EURL as fit for purpose.
- To harmonize the methods used by the Member States for the African horse sickness diagnosis.
- To collect and collate data and information on methods of diagnosis used and the results of test carried out in the Community.

Expected results: See Performance Indicators **AH.PT.1, AH. PT2, AH PT 3, AH PT.4**

- Address underperforming related issues within EURL network

Activity 8: Collaboration with underperforming NRLs in the PT framework in order to identify critical points and proposal of corrective measures. Organization of a second PT round with all underperforming NRLs

Objectives:

- To ensure follow up of poor results in PTs.
- To ensure the use of high quality analytical methods
- To harmonized the methods used
- To inform EU-Commission following the *Protocol for management of underperformance in comparative testing and/or lack of collaboration of NRLs with EURL activities*

Expected results: See Performance Indicator **AH.PT.5, AHPT 6**



Activity 9: Organization of training stays at the EURL of technicians from underperforming NRLs.

Objective:

- To train/retrain technicians
- To approximate criteria on analytical methods
- To improve the performance of those NRLs.

Expected results: See Performance Indicator **AH.PT.5**



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

- Initiation of EURLs collaboration with EFSA and international organization

Activity 10: Maintenance of close and fluent relationships with the world Laboratories for AHS designed by the World Organization Animal Health (OIE), and with the NRLs

Objectives:

- To maintain a mutual and reciprocal information exchange
- To get a better knowledge of the disease epidemiology
- To harmonize analytical method within the world organization network

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

Activity 11: Evaluation of the inter-laboratory collaborative trial organized in 2014 by the OIE Reference Laboratory Network and other expert Laboratories to assess the diagnostic performance of available PCR methods

Objectives:

- To acquire a general overview of PCR methods used worldwide
- To advise the EU Commission about the best PCR methods available to monitor the disease
- To propose amendments of the OIE Manual AHS chapter, if appropriate

Expected results: See Performance Indicator **AH.OIE.1**



- **Networking activities for appropriate assistance by the EURLs**

Activity 12: Update of trained staff available for emergency situation occurring within the EU and to assist the Commission, EFSA, ECDC and the Veterinary Service of EU-MSs in case of specific request

Objectives:

- To cooperate with NRLs in the rapid diagnosis of AHS outbreaks in EU territories
- To have qualified staff with relevant completed training able to travel
- To assist during outbreaks/crisis situation and/or to engage on-site

Expected results: See Performance Indicator **AH.COM.1, AH COM2**

Activity 13: Participation in the EURL Directors' Working group on relationships with NRLs chaired by DG SANCO Unit E

Objectives:

- To facilitate a shared understanding of training needs and to develop consistency across the EURLs' implementation of training program
- To identify, discuss and address issues of common concern
- To exchange ideas, strengthen skills and share example of good practices

Expected results: See Performance Indicator **AH.COM.1**



2.4. OTHER ACTIVITIES

Activity 14: Maintenance of Quality Assurance schemes

Objectives:

- To maintain the accreditation scheme according to ISO 17,025: 2005 "General requirements for the competence of testing and calibration laboratories"
- To maintain the accreditation scheme according to ISO 14,001:2004 "Environmental Management System "

Expected results: See Performance Indicator **AH.ANA.QI**

Activity 15: Administrative activities to ensure a sound and efficient management of the EURL

Objectives:

- To elaborate the annual EURL work program in line with the Commission Work Program and the financial estimated budget
- To elaborate ex-ante Performance Indicator report
- To elaborate the annual EURL technical and financial reports
- To elaborate ex-post Performance Indicator report
- To provide/elaborate reports for EU Commission under request

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

Activity 16: Redesign of EURL–AHS Website and content update

Objectives:

- To disseminate relevant scientific information regarding the monitoring of relevant publication
- To disseminate analytical and reference methods
- To disseminate information concerning previous annual meetings, proficiency test and other relevant issues about the EURL

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

3. ANNEX: Ex-ante Performance Indicators for EURL in the Field of Animal Health. Year 2015