ANNEX

EU reference laboratories and EU reference centres – Commission Work Programme for 2018, 2019 and 2020

1.1. Introduction

European Union reference laboratories (EURLs) and European Union reference centres (EURCs) are to perform activities in accordance with Article 32 of Regulation (EC) No 882/2004, Article 92-98 of Regulation (EU) 2017/625, Article 30 of Regulation (EU) No 652/2014 and Article 1 of Decision 463/96[1] and Article 29 of Regulation 1012/2016.

EURLs, EURCs, National Reference Laboratories (NRLs) and competent authorities (CAs) in the Member States form a network with the important role, both in the case of emergencies and in times of "business as usual". The network is thus a priority for the Commission.

In the framework of the Brexit procedure current British EURLs will be financed until 31.12.2018 and will be replaced as of 1.1.2019. Calls for selection have already been launched. As regards the EURL for crustacean diseases the mandate ends on 30 June 2018 as stipulated in Commission Implementing Regulation (EU) No 72/2013 of 25 January 2013.

The activities expected to be performed should support the related objectives of Union legislation. To ensure this the activities need to be specified in a work programme and priorities need to be identified. That said some flexibility needs to be provided for activities resulting from non-predictable events (e.g. food contamination, adulteration or fraud, re-emergence of diseases, introduction of new diseases and newly emerging plant pests).

1.2. Objectives – expected results

(a) General objective

- to contribute to health, safety and quality of animals and goods produced and traded in the agri-food chain by ensuring availability of harmonised, high quality and reliable methods of laboratory analysis, test or diagnosis and their correct implementation by National Reference Laboratories (NRLs) in official controls and investigations.

(b) Specific objectives

- to maintain and improve effectiveness, efficiency and reliability of official controls and thus support the enforcement of compliance with applicable legislation;
- to contribute to a timely detection and eradication of diseases and pests;
- to ensure the availability and uniform application of methods for performance testing and genetic evaluation for purebred breeding animals of the bovine species.

[1] OJ L 192, 2.8.1996, p. 19-20.

(c) Operational objectives, indicators and expected results

	OPERATIONAL OBJECTIVES	Indicators	Expected results
1	To ensure availability of harmonised, efficient and reliable methods of laboratory analysis, test or diagnosis and their correct implementation by Members States' National Reference Laboratories (NRLs) in official controls and investigations.	Availability of harmonised, efficient and reliable methods of laboratory analysis, test or diagnosis. Success rate of NRLs in proficiency tests and if necessary corrective action.	All NRLs implemented methods of laboratory analysis, test or diagnosis correctly and completed proficiency tests successfully.
2	To ensure the availability of scientific and technical assistance for NRLs.	Degree of satisfaction NRLs with technical assistance provided.	Timely and adequate response to technical assistance enquiries of NRLs.
3	To provide scientific and technical assistance within the scope of their mission to Commission and collaborate with laboratories in third countries and with European Food Safety Authority (EFSA), European Medicine Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC).	Satisfaction degree of the Commission	Timely and adequate response to scientific and technical enquiries of the Commission and other organisations.
4	To provide scientific and technical expertise within the scope of their mission in the form of coordinated assistance to relevant national support networks and bodies in the area of welfare requirements for animals.	Availability of updated, reliable and consistent technical data, research findings, new techniques and expertise necessary for the correct application of EU legislation in the field of animal welfare.	Efficient contribution to the performance of official controls and other official activities which are aimed at identifying possible violations to the rules perpetrated in the field of animal welfare.
5	To ensure a sound and efficient management of the EURL/EURC funding cycle.	Timelines and level of completion of necessary steps of EURL programmes' funding cycle.	Timely and completed funding cycle.

(d) Measures and activities for the implementation of the operational objectives

OPERATIONAL OBJECTIVE 1:
(a) provide national reference laboratories with details and guidance on the methods of laboratory analysis, testing or diagnosis, including reference methods; (b) provide reference materials to national reference laboratories; (c) coordinate practical arrangements (incl. validation) necessary to apply new methods of laboratory analysis, testing or diagnosis and informing the national reference laboratories of advances in this field; (d) organise regular proficiency tests and ensure appropriate follow-up in accordance, where available, with internationally accepted protocols. Inform the Commission and the Member States of the results and follow-up to the inter-laboratory comparative testing or proficiency tests; (e) ensure the cooperation among EURLs/EURCs, with national reference laboratories and with the Commission, as appropriate, to develop and/or validate methods of analysis, testing or diagnosis of high standards.

OPERATIONAL OBJECTIVE 2:
(a) provide Member States' national reference laboratories with details and guidance on developments in their field and in particular on new methods of laboratory analysis, testing or diagnosis, including the practical arrangements necessary to apply these methods; (b) provide information to national reference laboratories on research activities in their area of competence; (c) conduct training courses for staff of national reference laboratories and, if appropriate, staff of other official laboratories and experts from third countries.
OPERATIONAL OBJECTIVE 3:
(a) provide scientific and technical assistance to the Commission within the area of competence; (b) ensure the collaboration of EURLs/EURCs in within the area of competence and in view of the general and specific objectives of their work programme with laboratories in Member States, third countries, the European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC); (c) assist actively in the investigation of outbreaks of diseases in animals by carrying out epizootic studies on pathogen isolates or pest specimens and in the case of pests of plants performing confirmatory diagnosis characterisation and where necessary, wider taxonomic studies.
OPERATIONAL OBJECTIVE 4:
(a) provide scientific and technical assistance to relevant national support networks and bodies in the area of animal welfare, development and application of the animal welfare indicators, development of methods for the assessment of animal welfare and its improvement; (b) carry out scientific and technical studies on animal welfare of animals; (c) conduct training courses in the area of animal welfare for staff of the national support networks or bodies, of staff of the competent authorities and of experts from third countries; (d) disseminate research findings and technical innovations and collaborate with Union research bodies in the in the area of animal welfare within the framework of the general and specific objectives of their work programme.
OPERATIONAL OBJECTIVE 5:
(a) to collect, verify, and validate EURL work programmes; (b) to control and verify financial expenditure; (c) to communicate with EURLs for the execution of their work programmes; (d) to evaluate the EURLs technical and financial report; (e) to support the EURLs for the preparation of their work programmes.

1.3. Priorities

The priorities for the years 2018-2020 will follow a common logic of operational objectives as presented in Regulation (EU) No 652/2014. For the period of application of this Annex the following general priority areas are specified:

- The provision of certified reference material and methods of laboratory analysis
  - to detect and quantify chemical and microbiological hazards (chemicals, contaminants, pesticides, pathogens),
  - to detect the presence of unauthorised GMOs in food and feed and to detect and quantify authorised GMOs in view of enabling the verification of compliance with the GMO legislation,
  - to detect unauthorised substances or the unauthorised use of authorised substances,
  - to develop and validate methods of diagnosis for regulated and where considered necessary, un-regulated plant pests and diseases;

– The development of methods to detect fraudulent practices;

– Through timely communication of relevant information ensure the use of adequate methods of laboratory analysis when tolerances (maximum levels/ maximum limits, migration limit) are modified or new reference methods are introduced in legislation;

– To advise on improved official control requirements on animal welfare rules (e.g. on transport, slaughter and farming) to better meet the specific needs of animals guarantying their welfare.

1.4. Description of the activities to be funded

Pesticides	–	development, validation and dissemination of new and improved methods for analysing pesticide residues in food of animal origin, cereals and fruits and vegetables;
	–	provision of scientific and technical assistance to the Commission, especially concerning limits of quantification and residue definitions in the framework of the review of all existing MRLs laid down in Article 12 of Regulation (EC) 396/2005[2], the setting of MRLs for new active substances on the basis of Art. 6 and the deletion of MRLs following the revocation of authorisations for PPPs on the basis of Art. 17 of this Regulation.
Contaminants	–	ensuring reliability of analysis of dioxins and dioxin-like polychlorinated biphenyls (PCBs) and other persistent organic pollutants in complex feed and food matrices (such as feed additives, food supplements);
	–	ensuring reliability of analysis of metals, nitrogenous compounds, processing contaminants, mycotoxins and plant toxins in feed and food;
	–	specification of metals in feed and food by multi-analytical methods;
	–	screening methods for the presence of processing contaminants;
	–	ensuring reliability of analytical results for the control of mycotoxins with the use of screening methods;
	–	development of a multi-analytical method to analyse reliably the presence of regulated mycotoxins and their modified forms in feed and food.
Residues	–	method development and dissemination for analysis of residues of veterinary medicinal products (including prohibited substances and banned uses) in food of animal origin;
	–	technical assistance related to analytical aspects of residue monitoring.
Biological Risks	–	evaluation of new high quality analytical methods for biological hazards;
	–	improvement of existing methods for biological hazards;
	–	molecular characterisation of isolates from outbreaks investigation;
	–	delivery of training, information, updates to NRLs and third countries;
	–	cooperation among EURLs on biological risks to develop harmonized procedure for the application of molecular typing methods and to organize trainings on molecular typing analyses. A transition from traditional analytical methods to whole genome sequencing is expected in the coming years making this cooperation and support a priority;
	–	development, validation and dissemination of new and improved methods for biological hazards.

[2] Regulation (EC) NO 396/2005 of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.

Food Contact materials	–	development, validation, deployment and ILC of multi-analyte methods and methods for oligomers and mineral oils. In addition the EURL shall support the establishment of the new measure on printed FCM with respect to methods and rules for testing
GMOs	–	Development of analytical methods for GMO detection (with particular reference to high-throughput analytical methods and dissemination to NRLs;
	–	Delivery of guidance, training, information, updates to NRLs and non-EU countries;
	–	Bioinformatic support to the Commission for the implementation of the GMO legislation.
Feed additives	–	2018 Training program to address underperforming of proficiency tests in carotenoids (canthaxanthin and astaxanthin);
	–	2019 Developing a method of analysis for p-phenetidine and an inter laboratory study for the determination of the chelate degree of trace elements (e.g. copper) containing feed additives;
	–	2020 Proficiency tests for vitamin D3 and antioxidants.
Plant Health	–	development, validation and dissemination of new and improved diagnostic methods for pests and disease of plants and plant products;
	–	provision of scientific and technical assistance to the Commission;
	–	activities related to Standard Operation Procedures (SOPs) preparation and distribution, reference material and agents for the diagnostic methods;
	–	molecular and biological characterisation of isolates of pests of plants;
	–	where relevant for the area of competence, establishing and maintaining reference collections of pests of plants and/or reference strains of pathogenic agents.
Animal Health	–	development and implementation of high quality analytical methods specific to the diagnosis and differential diagnosis of notifiable and regulated diseases regarding outbreaks, epidemiological investigations and control measures (e.g. characterization of the pathogen, vaccine matching);
	–	activities related to SOPs preparation and distribution, reference standards and other biological reagents for serological and agent identification tests;
	–	molecular and biological characterisation of isolates of pathogens from outbreaks, sequence data banks and vaccine matching results.
Animal welfare	–	development of animal welfare indicators and of methods for the assessment of the level of welfare of animals and of methods for the improvement of the welfare of animals;
	–	carrying out studies on the welfare of animals used for commercial or scientific purposes;
	–	conducting training courses for experts of national scientific support networks, experts of the competent authorities and third countries;
	–	disseminating research findings and collaborating with Union research bodies in the field of animal welfare.
Zootechnics	–	working with breed societies and third parties designated by breed societies to facilitate the uniform application of methods for performance testing and genetic evaluation for purebred breeding animals of the bovine species and informing them on methods of performance testing and genetic evaluation of purebred breeding animals of the bovine species;
	–	regular revision of the results of performance testing and genetic evaluations of purebred breeding animals of the bovine species carried out by breed societies or third parties designated by those breed societies and of the data on which they are based;
	–	comparing methods of performance testing and genetic evaluation of purebred breeding animals of the bovine species;

– providing data on the genetic evaluation of purebred breeding animals of the bovine species and training to support breed societies or third parties designated by those breed societies which are participating in international comparisons of the results of genetic evaluations; – facilitating the resolution of emerging problems in Member States linked to the genetic evaluation of purebred breeding animals of the bovine species.

1.5. Essential criteria

1. ELIGIBILITY CRITERIA Status of a EURL/EURC in accordance with Regulation (EC) 882/2004, Regulation (EC) 2017/625 is maintained (exception EURLs established within the COM Joint Research Centre). 2. EXCLUSION CRITERIA Any of the situations of exclusion listed in Articles 106 and 107 of Regulation (EU, Euratom) No 966/2012. 3. AWARD CRITERIA – Conformity to the Commission's work programme for the respective period; – Consistency of the programme with the objectives and expected results listed in point 1.2; – The overall quality of the programme, i.e. the relevance of the planned activities (type and impact of actions proposed) taking into account the specific activity field of the EURL/EURC.

1.6. Implementation

The work programme will be implemented directly by the Commission.

1.7. Indicative timetable of the grants awarded without a call for proposals

January 2018

1.8. Maximum possible rate of co-financing of the total costs

100%