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ANNEX 1

ANNEX

to the

COMMISSION IMPLEMENTING DECISION

on the adoption of the work programmes of the Commission for the years 2015 and 2016 and on the financing of the Union contribution to the European Union reference laboratories

ANNEX

EU Reference Laboratories – Commission Work Programmes for 2015 and 2016

1.1. Introduction

On the basis of the objectives given in Regulation (EU) 652/2014, this work programme contains the actions to be financed for grants and to be implemented by the European reference laboratories (EU-RLs) in 2016 and 2017. These actions will be financed through the Union financial contribution to the implementation of functions and duties in the field of food and feed safety and animal health, animal welfare and plant health, in accordance with Article 32 of Regulation (EC) No 882/2004.

The Union co-finances the EU-RLs with the aim to ensure uniform high quality testing across the EU to support the Commission's activities in relation to risk management and risk assessment. EU-RLs are, in general, embedded in (national) public institutions with long-standing high level expertise, like national reference laboratories (NRLs) or regional reference laboratories of the World Organisation for Animal Health. They are designated by the Commission in accordance with sectoral legislation. Annex VII to Regulation (EC) No 882/2004 provides a list of the 43 EU-RLs.

The Commission works in close collaboration with the EU-RLs, which, together with the NRLs, play an essential role in the scientific and technical support for the establishment of uniform practices of official feed and food controls, as required by Regulation (EC) No 882/2004.

The implementation of this work programme will be subject to prior approval by the Commission of the EU-RL work programmes, which are to be in conformity with the objectives and priorities laid down in the present work programme. Once approved, the EU-RLs are to implement their work programmes and provide the Commission with a report on such implementation.

1.2. Legal basis

– Article 32(7) of Regulation (EC) No 882/2004 of the European 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 (OJ L 165, 30.4.2004, p. 1);

– Article 36(1) of Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material (OJ L 189, 27.6.2014, p. 1);

– Article 190(1)(d) of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union (OJ L 362, 31.12.2012, p. 1).

1.3. Budget line

– 17.0403 for both years

1.4. Objectives – expected results - measures

(a) General objective

– to contribute to a high level of health for humans, animals and plants, ensuring a high level of protection for consumers and the environment, while favouring competitiveness and creation of jobs.

(b) Specific objectives

– to contribute to a high level of safety of food/feed and food/feed production and a higher animal health status;

– to contribute to a timely detection and eradication of pests;

– to improve effectiveness, efficiency and reliability of official controls.

(c) Operational objectives, indicators and expected results

OPERATIONAL OBJECTIVES		*Indicator*	*Expected result*
1	To ensure the development and use of high quality analytical methods across the EU-RL framework	Number of available state-of-the-art analytical methods	Maintain or increase number
2	To maintain an appropriate level of inter-laboratory comparative testing ensuring efficiency of control analysis methods	Level of participation and successful completion of comparative testing	All NRLs completed comparative testing successfully
3	To ensure the availability of scientific and technical assistance provided by the EU-RLs	Satisfaction degree of support provided by the EU-RLs	Timely and adequate answer to all the assistance requests
4	To ensure a sound and efficient management of the EU-RL funding cycle	Timelines and level of completion of necessary steps of EU-RL programmes' funding cycle	Timely and completed funding cycle

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

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-RLs to NRLs;
– monitoring of publication by EU-RLs of new developed methods and corresponding validation studies;
– coordination of EU-RL activities on practical arrangements for the application of new analytical methods;
– EU-RLs, NRLs and Member States' coordination for the preparation of the 2016 and 2017 work programmes regarding new or improved methods, and/or dissemination of information on methods and reference materials;
– planning of trainings, meetings and workshops organised by the EU-RLs for the harmonization of diagnostic techniques and of methods of analysis;
– promotion of EU-RLs collaboration with laboratories in third countries.

OPERATIONAL OBJECTIVE 2: To maintain appropriate level of inter-laboratory proficiency testing ensuring efficiency of control analysis methods
– ensuring planning and initiation of comparative testing by EU-RLs in accordance with internationally accepted protocols; – addressing underperforming related issues within the EU-RL network; – coordination of EU-RLs, NRLs and the Member States for the planning of comparative testing in the work programmes.
OPERATIONAL OBJECTIVE 3: To ensure the availability of scientific and technical assistance provided by the EU-RLs
– queries to EU-RLs for policy making and enforcement; – promoting EU-RLs' collaboration with EFSA and international organisations; – organisation of meetings for scientific and technical assistance from the EU-RLs; – guidance initiation regarding analytical methods; – networking activities for appropriate assistance by the EU-RLs.
OPERATIONAL OBJECTIVE 4: To ensure a sound and efficient management of EU-RL funding cycle
– collection, verification and validation of EU-RL work programmes; – control and verification of financial expenditure; – communication with EU-RLs for the execution of their work programmes; – evaluation of the EU-RLs' annual technical and financial report; – support to the EU-RLs for the preparation of their annual work programmes; – evaluation of the EU-RLs' reported performance indicator ex-ante and ex-post.

1.5. Priorities

Risk containment and enforcement needs in the areas covered by Regulation (EC) 882/2004 evolve constantly. In recent years, new challenges have emerged resulting from the increased trade in animals, food and feed and animal substances used for their production, and from progress in science and technology and, as a consequence, in diagnostic techniques.

A coordinated approach is needed to ensure:

– protection against the re-emergence of new/greater risks;

– prevention and early detection of diseases and threats through food and feed;

– effective implementation of enforcement and official controls.

EU-RLs, NRLs and competent authorities in the Member States form a network with a very important role, both in the case of emergencies and in times of "business as usual". The maintenance of the robustness of the network and its role will be a constant priority for the Commission's work programmes, not only for the years 2016-2017, but also in the future.

The priorities for the years 2016 and 2017 will follow a common logic over the operational objectives presented in Regulation (EU) No 652/2014, and will be developed in detail together with EU-RLs in their work programmes. In general terms, focus will be on:

– the development of certified reference material and standardised and validated methods for measurement and identification of hazards (chemicals,

contaminants, pesticides, pathogens), for the presence of unauthorised GMOs in food and feed, and the detection of unauthorised substances or the unauthorised use of authorised substances;

– the analysis of substances and authorised GMOs to enable the verification of compliance with the food and feed and animal health legislation;

– the use and communication of information on the adequate analytical methods (methods for new maximum levels of residues, methods for quantifying migration of substances in food and feed);

– the development of sound analytical capability to detect fraudulent practices (testing for DNA, pesticides, additives).

While core activities and priorities laid down in this work programme will be covered in collaboration with the EU-RLs when establishing their work programmes, a room for manoeuvre is necessary for activities resulting from non-predictable factors (e.g. factors related to the re-emergence of priority diseases, the potential introduction of new diseases, the increasing complexity of supply chains).

1.6. 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[1]
Contaminants	–	ensuring reliability of analysis of dioxins and dioxin-like polychlorinated biphenyls (PCBs) in complex feed and food matrices (such as feed additives, food supplements)
	–	specification of metals in feed and food by multi-analytical methods
	–	screening methods for the presence of polycyclic aromatic hydrocarbons
	–	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
Food Contact materials, GMOs, feed additives	–	continuing of development and validation of new and improved methods for testing metals migration from ceramic materials in the context of the revision of Council Directive 84/500/EEC[2]
	–	preparation for accelerated collection of new methods for substances

[1] 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.

[2] Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs (OJ L 277, 20.10.1984, p. 12).

		regulated under Commission Regulation (EU) No 10/2011[3] including the continuing development of an online database for dissemination purposes with a special focus on methods for quantifying the migration of oligomers and multianalyte methods
	–	development of high-throughput analytical methods for GMO detection and dissemination to NRLs
	–	delivery of training, information, updates to NRLs and third countries
	–	analysis and testing of fat-soluble vitamins (Vitamin A), and cobalt in feedingstuffs
Animal Health	–	development and implementation of high quality analytical methods specific to the diagnosis and differential diagnosis 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 from outbreaks, sequence data banks and vaccine matching results

1.7. Essential criteria

1. ELIGIBILITY CRITERIA

   status of a EU-RL in accordance with Regulation (EC) 882/2004, excluding EU-RLs within the Joint Research Centre.

2. EXCLUSION CRITERIA

   the applicants are not in any of the situations of exclusion listed in Articles 106 and 107 of Regulation (EU, Euratom) No 966/2012.

3. AWARD CRITERIA

   – conformity with objectives and priorities of the present Commission's work programme for the years 2016 and 2017.

   – The consistency of the programme with the objectives and expected results listed in point 1.4.

   – The overall quality of the programme, namely, the relevance of the planned activities (type of actions proposed and the quantities of actions) taking into account the specific activity field of the EU reference laboratories.

1.8. Implementation

The work programme will be implemented directly by the Commission.

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

January 2016

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

100%

[3] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1).

1.11. List of EU Reference Laboratories

1. European Union Reference Laboratory for: brucellosis	ANSES - France
2. European Union Reference Laboratory for: bovine tuberculosis	VISAVET - Spain
3. European Union Reference Laboratory for: fish diseases	DTU - Denmark
4. European Union Reference Laboratory for: bivalve mollusc diseases	IFREMER - France
5. European Union Reference Laboratory for: foot-and-mouth disease	The Pirbright Institute - United Kingdom
6. European Union Reference Laboratory for: crustacean diseases	CEFAS - United Kingdom
7. European Union Reference Laboratory for: Newcastle disease	APHA - United Kingdom
8. European Union Reference Laboratory for: bluetongue	The Pirbright Institute - United Kingdom
9. European Union Reference Laboratory for: zootechnics	INTERBULL - Sweden
10. European Union Reference Laboratory for: rabies	ANSES - France
11. European Union Reference Laboratory for: avian influenza	APHA - United Kingdom
12. European Union Reference Laboratory for: African horse sickness	LCV - Spain
13. European Union Reference Laboratory for: equine diseases other than African horse sickness	ANSES - France
14. European Union Reference Laboratory for: classical swine fever	Institut für Virologie - Germany
15. European Union Reference Laboratory for: African swine fever	Centro de Investigación en Sanidad Animal - Spain
16. European Union Reference Laboratory for: honeybee health	ANSES - France
17. European Union Reference Laboratory for: escherichia coli, including verotoxigenic E. coli (VTEC)	ISS - Italy
18. European Union Reference Laboratory for: campylobacter	SVA - Sweden
19. European Union Reference Laboratory for: residues of veterinary medicines and contaminants in food of animal origin (for the residues listed in Annex I, Group B 3(c) to Directive 96/23/EC)	ISS - Italy
20. European Union Reference Laboratory for: additives for use in animal nutrition	JRC - Belgium
21. European Union Reference Laboratory for: dioxins and PCBs in feed and food	CVUA - Germany
22. European Union Reference Laboratory for: residues of veterinary medicines and contaminants in food of animal origin (for the residues listed in Annex I, Group A 1, 2, 3, 4, Group B 2(d) and Group B 3(d) to Directive 96/23/EC)	RIKILT - Netherlands

23. European Union Reference Laboratory for: listeria monocytogenes	ANSES - France
24. European Union Reference Laboratory for: animal proteins in feedingstuffs	CRA-W - Belgium
25. European Union Reference Laboratory for: polycyclic aromatic hydrocarbons (PAH)	JRC - Belgium
26. European Union Reference Laboratory for: the monitoring of marine biotoxins	AECOSAN - Spain
27. European Union Reference Laboratory for: coagulase positive staphylococci, including staphylococcus aureus	ANSES - France
28. European Union Reference Laboratory for: residues of pesticides (cereals and feedingstuffs)	DTU - Denmark
29. European Union Reference Laboratory for: residues of pesticides (food of animal origin and commodities with high fat content)	CVUA - Germany
30. European Union Reference Laboratory for: residues of pesticides (single residue methods)	CVUA - Germany
31. European Union Reference Laboratory for: heavy metals in feed and food	JRC - Belgium
32. European Union Reference Laboratory for: milk and milk products	ANSES - France
33. European Union Reference Laboratory for: residues of veterinary medicines and contaminants in food of animal origin (for the residues listed in Annex I, Group B 1 and B 3(e) to Directive 96/23/EC and carbadox and olaquindox)	ANSES - France
34. European Union Reference Laboratory for: modified organisms (GMOs)	JRC - Italy
35. European Union Reference Laboratory for: mycotoxins	JRC - Belgium
36. European Union Reference Laboratory for: monitoring the viral and bacterio-logical contamination of bivalve molluscs	CEFAS - United Kingdom
37. European Union Reference Laboratory for: transmissible spongiform encephalopathies (TSEs)	APHA - United Kingdom
38. European Union Reference Laboratory for: material intended to come into contact with foodstuffs	JRC - Italy
39. European Union Reference Laboratory for: parasites (in particular trichinella, echinococcus and anisakis)	ISS - Italy
40. European Union Reference Laboratory for: the analysis and testing of zoonoses (salmonella)	RIVM - Netherlands
41. European Union Reference Laboratory for: antimicrobial resistance	DTU - Denmark
42. European Union Reference Laboratory for: residues of veterinary medicines and contaminants in food of animal origin (for the residues listed in Annex I, Group A 5 and Group B 2(a), (b), (e) to Directive 96/23/EC)	BVL - Germany
43. European Union Reference Laboratory for: residues of pesticides (fruits and vegetables, including commodities with high water and high acid content)	LAGV - Spain