EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Director-General

Brussels, 23. 01. 2017
SANTE/E2/FV/md (2017) 129000
Ares(2017) 354557

Your Excellency,

Subject: Call for selection and designation of European Reference Laboratories

I am pleased to inform you that, with this letter, the Directorate General for Health and Food Safety is formally launching a call for selection of three European Union Reference Laboratories (EURLs).

I would be grateful if you could forward the attached documentation to all relevant authorities in your country. I would like to draw your attention to the fact that applications must be submitted by the national competent authorities.

Let me stress that the requirements in the support documentation must be strictly complied with, including the deadlines for submission of applications.

I look forward to the possible submission of candidate EURLs by your country.

Please contact the following e-mail address: SANTE-CONSULT-E2@ec.europa.eu for further information (subject: Call of interest for selection and designation of EURLs).

Yours faithfully,

Xavier Prats Monné

Enclosures: Practical instructions
Call for selection and designation of EURLs - support document

By email to: Permanent Representations of all EU Member States
Heads of delegation Standing Committee on Plants, Animals, Food and Feed, sections Toxicological Safety of the Food Chain and Animal Nutrition.

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

CALL FOR

SELECTION AND DESIGNATION OF EUROPEAN UNION REFERENCE LABORATORIES

SUPPORT DOCUMENT

1. INTRODUCTION

1.1. Purpose

The purpose of this call for proposals is to select potential candidates for designation as European Union Reference Laboratories (EURLs) operating in the areas of

1) metals and nitrogenous compounds in feed and food

2) processing contaminants

3) mycotoxins and plant toxins in feed and food

The intention is to designate three EURLs, each dealing with one of the above mentioned areas, that shall become operational by January 2018.

EURLs support the activities of the Commission in relation to risk management, and as appropriate risk assessment, mainly in the area of laboratory analyses, and coordinate activities of National Reference Laboratories (NRLs) in the Member States.

The networks of EURLs and NRLs are essential tools in the framework of official feed and food control as well as animal health. Their role has been recognised by 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[1].

Experience has shown that reference laboratories play an important role as a scientific and technical support in the area of feed and food safety and animal health. This assistance has also been necessary for emerging risks. Input of EURLs in the international arena, such as standardisation of analytical methods, is present and should be further developed.

1.2. The principles of the call for selection of EURLs:

Considering the responsibilities of the EURLs in the framework of the official feed and food controls, as well as the support required by the National Competent Authorities (NCA) for any EURL located in their country, the NCAs are responsible for submitting the dossiers of the respective applicant laboratories to the Commission, after they have performed a preliminary check that the eligibility, exclusion and selection criteria are fulfilled by the candidate laboratories.

A selection panel will be set up within Directorate-General for Health and Food Safety, with possible external support as appropriate (e.g. EFSA, other Directorates General) in order to evaluate the respective merits of the

[1] OJ L 165, 30.4.2004 (corrigendum in OJ L 191, 28.5.2004, p.1)

applicant laboratories on the basis of the dossiers submitted through the national authorities.

The applicant laboratories may be subject to visits by delegates of the selection panel at any time after applications have been received, in order to support the selection process.

The procedure can be summarised as follows:

- Directorate General for Health and Food Safety (DG SANTE) to send to the NCAs in the Member States an invitation to submit applications for candidate laboratories in their country, together with the terms of reference.
- The NCAs shall organise a preselection of candidate laboratories, on the basis of the eligibility and selection criteria set under chapters 4 and 5 below, and submit relevant applications. NCAs shall not submit more than one candidate laboratory by topic on which a EURL is to be selected. One laboratory may apply for more than one topic.
- A Commission selection panel will evaluate the applications by following the eligibility, selection and preference criteria.
- The NCAs will be informed about the outcome of the call.

Thereafter, the relevant EURLs will be designated by Commission Decision, in accordance with comitology procedure (Standing Committee on Plants, Animals, Food and Feed)

1.3. Legal framework

Requirements and missions of EURLs

Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, includes provisions for the management of EURLs in the whole sector, including EURLs for animal health.

Article 32 of the Regulation lays down the general missions/duties and requirements for EURLs for food and feed and for animal health. General missions/duties of NRLs are established in Article 33 of the Regulation and additional responsibilities and tasks of EURLs/NRLs may be laid down by comitology procedure. According to Article 32 (9), the provisions for EURLs shall apply without prejudice to more specific rules laid down in other specific legislation.

Designation of EURLs

As it is established in Article 32.5 of Regulation (EC) No 882/2004, the comitology procedure is required for adding EURLs to the list or amending the list of EURLs.

Designation can be withdrawn at any time, if an EURL does not comply with the relevant EU requirements or does not fulfil its missions/duties.

EU financial assistance to EURLs

The EU provides financial assistance to EURLs. Currently, this assistance is in the form of a grant which allows the amount deemed necessary to cover eligible costs. The eligible expenditures of EURLs are laid down in article 30[2] of Commission Regulation (EC) No 652/2014 of 15 May 2014[3]. The eligible costs correspond to eligible activities defined in the work-programmes of the EURLs.

The EU funding may cover up to 100% of the eligible expenditures.

2. THE NEED FOR THESE EURLS

The Joint Research Centre (JRC) of the European Commission currently hosting the EURL for heavy metals in feed and food, the EURL for polycyclic aromatic hydrocarbons (PAHs) and the EURL for mycotoxins in feed and food since 2006, has informed the Directorate General for Health and Food Safety no longer to continue to host these EURLs as from 1 January 2018.

As it is necessary and important to maintain an EURL in these areas, new EURLs have to be designated for these areas. However as since 2006, new priorities have been identified, it is necessary to widen the scope of the new EURLs to be designated.

The scope of the current EURL for heavy metals in feed and food is therefore extended to all metals (including besides heavy metals, compounds such as nickel, aluminium,...) and nitrogenous compounds (e.g. nitrates, nitrites, melamine) in feed and food.

The scope of the current EURL for PAHs is therefore extended to all processing contaminants (including besides PAHs, compounds such as acrylamide, furan, MCPD and their esters, glycidyl esters). While for the time being the main activity for processing contaminants is related to food, it cannot be excluded that certain processing contaminants shall be of relevance for feed also.

The scope of the current EURL for mycotoxins in feed and food is therefore extended to mycotoxins and plant toxins (e.g. pyrrolizidine alkaloids,

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[2] 1. Grants may be awarded to the European Union reference laboratories referred to in Article 32 of Regulation (EC) No 882/2004 and to the European Union reference centres referred to in Article 29 of Regulation (EU) 2016/1012 of the European Parliament and of the Council for the costs that they incur in implementing the work programmes approved by the Commission.

2. The following costs may be eligible for grants under paragraph 1:

(a) costs of personnel, regardless of their status, directly involved in activities of the laboratories or centres which are carried out in their capacity as European Union reference laboratory or centre;
(b) costs of capital equipment;
(c) cost of consumables;
(d) costs of shipment of samples, missions, meetings, training activities.

[3] OJ L 189, 27.6.2014, p. 1

gossypol, tropane alkaloids, tetrahydrocannabinol, opium alkaloids, hydrocyanic acid) in feed and food.

2.1. Metals and nitrogenous compounds in feed and food

Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs[4] sets maximum levels for several metals and nitrogenous compounds in many different foods.
Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[5] sets maximum levels for several metals and nitrogenous compounds.

Besides the establishment of maximum levels, monitoring recommendations are taken in this area of metals and nitrogenous compounds in view of a possible setting of maximum levels for which the support of EURL on the analytical aspects is requested.

The EURL is needed to take initiatives and co-ordinate activities on the development, improvement and application of sample preparation and methods of analysis for the control of the presence of metals and nitrogenous compounds in feed and food.

2.2. Processing contaminants

Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs sets maximum levels for certain processing contaminants.

Besides the establishment of maximum levels, monitoring recommendations are taken in this area of processing contaminants in view of a possible setting of maximum levels for which the support of EURL on the analytical aspects is requested.

The EURL is needed to take initiatives and co-ordinate activities on the development, improvement and application of sample preparation and methods of analysis for the control of the presence of processing contaminants mainly in food for the time being but possibly also in feed in the future.

2.3. Mycotoxins and plant toxins in feed and food

Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs[6] sets maximum levels for several mycotoxins and plant toxins in food.

[4] OJ L 364, 20.12.2006, p. 5
[5] OJ L 140, 30.5.2002, p. 10
[6] OJ L 364, 20.12.2006, p. 5

Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed[7] sets maximum levels for mycotoxins and plant toxins in feed.

Commission Recommendation of 17 August 2006 on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in products intended for animal feeding[8] establishes guidance levels for certain mycotoxins in feed.

Besides the establishment of maximum levels and guidance levels, monitoring recommendations are taken in this area of mycotoxins and plant toxins in view of a possible setting of maximum levels for which the support of EURL on the analytical aspects is requested.

The EURL is needed to take initiatives and co-ordinate activities on the development, improvement and application of sample preparation and methods of analysis for the control of the presence of mycotoxins and plant toxins in feed and food.

3. FUNCTIONS AND DUTIES OF A EURL

Pursuant to Article 32 (1) of Regulation (EC) No 882/2004, the general functions and duties applicable to EURLs for feed and food are the following:

(a) providing national reference laboratories with details of analytical methods, including reference methods;
(b) coordinating application by the national reference laboratories of the methods referred to in (a), in particular by organising comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols, when available;
(c) coordinating, within their area of competence, practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field;
(d) conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries;
(e) providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses;
(f) collaborating with laboratories responsible for analysing feed and food in third countries.

Additional tasks for each specific EURL are the following

[7] OJ L 140, 30.5.2002, p. 10
[8] OJ L 229, 23.8.2006, p. 7

- FOR METALS AND NITROGENOUS COMPOUNDS IN FEED AND FOOD

The EURL shall also have the following functions:

- Drafting and keeping up to date the quality control procedures for metals and nitrogenous compounds.
- Preparation of common guidelines for validation of analytical methods, distribution to the Member States and provide assistance to the laboratories in their implementation.
- Investigating and validating analytical methods for metals and nitrogenous compounds.
- Organising workshops on annual basis to the benefit of national reference laboratories in the Member States as agreed in the work programme, including training of experts from the Member States and, as appropriate, non-member countries, in new analytical methodologies.
- To provide technical assistance to the Commission and, upon its request, to participate in international fora relating to the area of competence, concerning in particular the standardisation of analytical methods and their implementation.

- FOR PROCESSING CONTAMINANTS

The EURL shall also have the following functions:

- Drafting and keeping up to date the quality control procedures for processing contaminants.
- Preparation of common guidelines for validation of analytical methods, distribution to the Member States and providing assistance to the laboratories in their implementation.
- Investigating and validating analytical methods for processing contaminants.
- Organising workshops on annual basis to the benefit of national reference laboratories in the Member States as agreed in the work programme, including training of experts from the Member States and, as appropriate, non-member countries, in new analytical methodologies.
- To provide technical assistance to the Commission and, upon its request, to participate in international fora relating to the area of competence, concerning in particular the standardisation of analytical methods and their implementation.

- FOR MYCOTOXINS AND PLANT TOXINS IN FEED AND FOOD

The EURL shall also have the following functions:

- Drafting and keeping up to date the quality control procedures for mycotoxins and plant toxins.
- Preparation of common guidelines for validation of analytical methods, distribution to the Member States and provide assistance to the laboratories in their implementation.
- Investigating and validating analytical methods for mycotoxins and plant toxins.
- Organising workshops on annual basis to the benefit of national reference laboratories in the Member States as agreed in the work programme, including training of experts from the Member States and, as appropriate, non-member countries, in new analytical methodologies.
- To provide technical assistance to the Commission and, upon its request, to participate in international fora relating to the area of competence, concerning in particular the standardisation of analytical methods and their implementation.

In the framework of Comitology, additional responsibilities and tasks for EU Reference Laboratories may be laid down on request and agreement of Member States and the Commission.

4. ELIGIBILITY AND EXCLUSION CRITERIA

4.A. ELIGIBILITY CRITERIA

In order for the applicant laboratories to be eligible:

- The applicant laboratories shall be viable without EU financial assistance.

Means of proof: NCAs shall provide a certificate stating that they will ensure that the required support in relation to human and financial resources necessary for the satisfactory operation of the EURL will be provided by the NCAs, or an appropriate body. This certificate must be dated and signed by an authorized representative of the NCAs

- The applicant laboratories shall be accredited in accordance with standard EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories' for the areas of competence of the EURL for which the application is made
Means of proof: Description and certification to be provided with the application.

- The applicant laboratories shall have been entrusted to perform tasks of public interest in the area of competence of the call, under the supervision of the competent authorities
Means of proof: Description and certification to be provided with the application.

4.B. EXCLUSION CRITERIA

Applicant laboratories shall be excluded if:

- They have been excluded by the national authorities from the laboratories involved in official controls pursuant to relevant EU legislation.

- They have conflicting interests with private or public companies or organisations that could restrict the ability of the laboratory to receive isolates from throughout the EU, restrict the dissemination of information derived during the execution of EURL activities, or that could prevent it from acting in an unbiased manner when assisting the Commission, especially in case where Member States contest the results of analyses.

- They are bankrupt, subject to insolvency or winding up procedures, their assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, their business activities are suspended or they are in any analogous situation arising from a similar procedure provided for under national legislation or regulations.

- They have been convicted of an offence concerning their professional conduct by a judgement, which has the force of *res judicata*;

- It has been established by a final judgement that applicant laboratory/ responsible person for applicant laboratory is guilty of any of the following:

  (i) fraud, within the meaning of Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995;

  (ii) corruption, as defined in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of EU Member States, drawn up by the Council Act of 26 May 1997, and in Article 2(1) of Council Framework Decision 2003/568/JHA, as well as corruption as defined in the legal provisions of the country where the contracting authority is located, the country in which the person is established or the country of the performance of the contract;

  (iii) participation in a criminal organisation, as defined in Article 2 of Council Framework Decision 2008/841/JHA;

  iv) money laundering or terrorist financing, as defined in Article 1 of Directive 2005/60/EC of the European Parliament and of the Council;

  (v) terrorist-related offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA, respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;

  (vi) child labour or other forms of trafficking in human beings as defined in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council;

- It has been established by a final judgement or a final administrative decision that applicant laboratory/ responsible person is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the law of the country in which it is established, with those of the country in which the contracting authority is located or those of the country of the performance of the contract.

- It has been established by a final judgement or a final administrative decision that applicant laboratory/ responsible person is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the person belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:

  (i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of selection criteria or in the performance of a contract;

  (ii) entering into agreement with other persons with the aim of distorting competition;

  (iii) violating intellectual property rights;

  (iv) attempting to influence the decision-making process of the contracting authority during the award procedure;

  (v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure;

- Applicant laboratory/ responsible person has shown significant deficiencies in complying with the main obligations in the performance of a contract financed by the Union's budget, which has led to its early termination or to the application of liquidated damages or other contractual penalties, or which has been discovered following checks, audits or investigations by an Authorising Officer, OLAF or the Court of Auditors;

- It has been established by a final judgment or final administrative decision that the applicant laboratory/ responsible person has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95;

- For the situations of grave professional misconduct, fraud, corruption, other criminal offences, significant deficiencies in the performance of the contract or irregularity, the applicant is subject to:

  i. facts established in the context of audits or investigations carried out by the Court of Auditors, OLAF or internal audit, or any other check, audit or control performed under the responsibility of an authorising officer of an EU institution, of a European office or of an EU agency or body;

  ii. non-final administrative decisions which may include disciplinary measures taken by the competent supervisory body responsible for the verification of the application of standards of professional ethics;

iii. decisions of the ECB, the EIB, the European Investment Fund or international organisations;

iv. decisions of the Commission relating to the infringement of the Union's competition rules or of a national competent authority relating to the infringement of Union or national competition law; or

v. decisions of exclusion by an authorising officer of an EU institution, of a European office or of an EU agency or body.

Means of proof: Applicant laboratory/responsible person must declare on honour that they are not in one of the situations listed above. The declaration must be dated and signed by an authorized representative.

5. SELECTION CRITERIA

5.A. ECONOMIC AND FINANCIAL CAPACITY

The laboratories shall provide evidence of financial and economic standing based on the following documents: balance sheets, profit and loss accounts or annual reports for the last three financial years balance. Where available, audits reports of the last 3 years should be provided as well.

5.B. TECHNICAL CAPACITY

The selection criteria below are extracted from the requirements laid down in Article 32.4 and Article 12(2) and 12(3) of Regulation (EC) No 882/2004.

(a) The laboratory has suitably qualified staff with adequate training in diagnostic and analytical techniques applied in their area of competence.

Requirement: the Director of the EURL shall have a post-graduate degree and 5 years professional experience (from which 3 years experience in the area of competence of the EURL); the scientific staff shall have a post-graduate degree and 2 years experience (from which 1 in the area of competence of the EURL); the technical staff shall have a technical degree and 1 year experience;
The Director of the laboratory has satisfactory knowledge of English
In addition to the Director, the laboratory shall have at least 1 scientist, one technician staff and one administrative staff at its disposal

- Means of proof: CVs and copies of degrees of all staff involved in EURL tasks.

(b) The laboratory possesses the equipment and products needed to carry out the tasks assigned to them.

Requirement: the laboratory shall possess the equipment necessary to fulfil the missions/duties in the area of competence of the EURL, according to the specifications for the EURL

- Means of proof: statement accompanied by description of technical equipment and informatics

(c) The laboratory has an appropriate administrative infrastructure.

Requirement: the laboratory shall have appropriate laboratory and administrative support

- Means of proof: description

(d) The laboratory has sufficient knowledge of international standards and practices.

Requirement: the laboratory shall have experience and implement ISO, CEN and possibly other international standards, as well as Good Laboratory Practices and other relevant practices applicable to the area of competence of the EURL.

- Means of proof: description standards and practices implemented

(e) The laboratory has available, if appropriate, an updated list of available reference substances and reagents and an updated list of manufacturers and suppliers of such substances and reagents.

Requirement: self-explanatory

- Means of proof: provide list(s)

(f) The laboratory has trained personnel available for emergency situations occurring within the EU.

Requirement: the laboratory shall state its availability for ad-hoc support upon request by the Commission, including during non standard working time (week ends in particular)

- Means of proof: description of mechanisms/arrangements in place, or that could be initiated

(g) The laboratory is accredited in accordance with standard EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories'. The accreditation may relate to individual tests or groups of tests.

- Means of proof: declaration and relevant certificate. In addition, the laboratory shall supply any evidence of having taken part successfully into ring tests in their area of competence within the previous 3 years, as appropriate, or justifications for not having taken part in such ring tests.

6. PREFERENCE CRITERIA

Means of proof: the applicant laboratories mentioned hereinafter shall provide adequately and detailed evidence to support their submission.

TEAM COMPOSITION AND EXCELLENCE: Rate: 40%

In the area of competence, level of experience of staff, knowledge of scientific background for the area of competence, including scientific publications; research activities in the area of competence; judicial expertise; availability of validated methods

INFRASTRUCTURE AND TECHNICAL COMPETENCE Rate: 20%

In the area of competence, the infrastructure, equipment and technical capability available to perform the EURL tasks

INTERNATIONAL Rate: 15%

Participation in international standardisation activities; participation in international networks, such as involvement in WHO, FAO and CODEX activities

COORDINATION: Rate: 25%

Organisation/interpretation of ring trials; activities as (national) reference laboratory; organisation of training activities; capacity/capability to organise workshops

7. SELECTION

The application selected will be the one with the highest score.

Practical instructions:

- The support document on the call for selection and designation of the three EURLs is intended to give detail information and help to structure the technical answer of the potential candidates.
- The document is available in English only. English will be the working language for this call: dossiers should as much as possible be completed in English, except where it would be inappropriate, e.g. for means of evidence such as certificates.
- The applicants shall answer to the call by following closely the instructions contained in the support document. In particular, the limit date for submission of applications is very strict.
- Only applications submitted via the national competent authorities (central level; NCA) will be considered by the Commission panel.

NCAs are requested to submit the applications, duly signed, not later than **17 March 2017** for the three topics: 'Metals and nitrogenous compounds in feed and food', 'Processing contaminants' and 'Mycotoxins and plant toxins in feed and food' (date as per postmark).

The application can be submitted:

- Either by registered mail, to be posted at the latest by **17 March 2017** (date as per postmark). The application must be sent to the following postal address:

  Directorate General for Health and Food Safety
  Maria Iglesia
  European Commission
  Office: B232 04/049
  B – 1049 Brussels

- Or by hand, to the above address not later than 17.00 (Brussels time) on the date indicated above.

The application must be submitted using the double envelope system as follows:

The outer envelope or parcel should be sealed with adhesive tape and signed across the seal and carry the following information:

- The title ("Call for selection and designation of European Union Reference Laboratories").
- The name of the NCA.
- The topic(s) covered by the application(s).
- The posting date (if applicable) should be legible on the outer envelope.

Different inner envelopes should be used for each topic for which an application is made. Each envelope should contain

- One original version of the application (clearly marked as "original")
- 3 copies of the application
- An electronic copy of the application

Only contacts between representatives of Directorate General Health and Food Safety and NCAs will take place. Applicant laboratories shall contact their NCAs for information.

The Commission may, on its own initiative, inform interested parties of any error, inaccuracy, omission or other clerical error in the text of the call.

Submission of an application following this call implies acceptance by the applicant and NCAs of all provisions and conditions stipulated in this call (contained in the support document of the call for selection and designation of European Union Reference Laboratories, as well as this document on practical instructions)

Directorate General Health and Food Safety will not reimburse any expenses incurred in preparing and submitting applications.

This call in no way constitutes an obligation on behalf of the Commission to designate, nor award a financial contribution. Designation as EURL will be done through the appropriate institutional procedure.