



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

CALL FOR
SELECTION AND DESIGNATION OF A EU REFERENCE LABORATORY FOR FOODBORNE
VIRUSES

TERMS OF REFERENCE

1. INTRODUCTION

1.1. Purpose

The purpose of this call for proposals is to select potential candidates for designation as EU Reference Laboratory (EURL) operating in the area of foodborne viruses.

The intention is to designate a EURL dealing with foodborne viruses in food (including food of non-animal origin and water).

EURLs support the activities of the Commission in relation to risk management and, as appropriate, risk assessment, mainly in the area of laboratory diagnosis and 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 is described in 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 rules¹ and before by vertical Directives on EU measures for the control of certain animal diseases.

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 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, in order to evaluate the respective merits of the applicant laboratories on the basis of the dossiers submitted through the national authorities.

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.
- 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 - PAFF).

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

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.

Although designation is due to be made for an undetermined duration, it might be withdrawn if, for example, 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 30² of Commission Regulation (EC) No 652/2014 of 15 May 2014³. 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 AN ADDITIONAL EURL

Viruses are the main cause of food-borne outbreaks in Europe (20% of all outbreaks in 2014, thus as many as Salmonella for that year). Furthermore foodborne viral infections are very common in many parts of the world.

Foodborne viruses originate from the human intestine and contamination of food occurs either by contamination from an infected food handler during preparation or by contact with sewage,

² 1. Grants may be awarded to the European Union reference laboratories referred to in Article 32 of Regulation (EC) No 882/2004 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 which are carried out in their capacity of Union reference laboratory;

(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

sewage sludge or polluted water. Control measures mainly depend on good hygiene. Food items such as salads and dessert dishes that receive considerable handling during preparation and are not given any further heat treatment before consumption are often implicated in foodborne viral outbreaks. Consumption of contaminated water and ice, or their use in food preparation, can also cause viral illness.

The effectiveness of official controls depends on the availability of validated and reliable methods of analysis to be used by accredited official laboratories across the EU. Although well-established methods to detect viruses in foods exist, the effectiveness of controls is hampered by the lack of uniformity in the use of the tests, the fact that no proficiency tests are being performed to assess the methods and the laboratories' capability to use them, and the resulting difficulties by some official laboratories in getting the accreditation necessary to work in accordance to Regulation 882/2004. Hence the current lack of a EURL on foodborne viruses negatively affects the ability to perform official controls in this area.

Taking into account the current epidemiological situation regarding foodborne viral infections in humans it is necessary to designate a EURL for foodborne viruses both for food of animal origin and food of non-animal origin (including water).

3. FUNCTIONS AND DUTIES OF THE EURL

Pursuant to Article 32 (1) of Regulation (EC) No 882/2004, the general functions and duties applicable to EURLs in the food sector 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.

The laboratory must ensure liaison between the national laboratories of the Member States and relevant stakeholders (EU Commission and agencies, Member States and third countries) and provide optimal methods for Hepatitis A virus, Norovirus and other relevant foodborne viruses, where necessary, for each Member State specifically by:

- 1) Organising proficiency tests to provide National Reference Laboratories with details of relevant analytical methods for performing proficiency tests that mimic realistic food samples to be analysed for foodborne viruses, in particular for Hepatitis A virus and Norovirus, in the Member States. To assess the performance of the National Reference Laboratories and to identify potential analytical problems that could be solved by assistance from the EURL in order to improve performance.

- 2) Supporting the National Reference Laboratories for the accreditation of methods for the determination of Hepatitis A virus and Norovirus (CEN ISO/TS 15216)
- 3) Producing and validating analytical methods to provide information about new or modified methods for analysis of foodborne viruses (including new and/or emerging foodborne viruses) in different types of food sample and validating and/or participating in validation studies of methods.
- 4) Producing and validating analytical methods to test and modify molecular typing methods for detection, species identification and strain characterization (“typing”) of foodborne viruses in order to provide the National Reference Laboratories with details about the methods and advances in the field.
- 5) Providing reference materials and advice on specific issues to National Reference Laboratories.
- 6) Providing training and support to National Reference Laboratories and other relevant stakeholders about ongoing activities in the area of foodborne viruses at EU level.
- 7) Assisting National Reference Laboratories with scientific and technical advice and training their staff in conventional and molecular techniques for foodborne viruses analyses
- 8) Ensuring that the EURL staff is well trained, up-dated and knowledgeable about the area of foodborne viruses so that appropriate expertise can be provided to stakeholders (EU Commission and agencies, Member States and third countries), notably in case of emergency situations so that the latter can be handled in a proper and efficient way.
- 9) Providing scientific and technical assistance to the Commission and other EU structures related with food safety and actively participating in CEN/ISO standardization activities.
- 10) Communicating relevant information with the Commission and its agencies, with National Reference Laboratories, Official Laboratories and other relevant stakeholders and providing rapid assistance whenever required.

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 authorised representative of the NCA.

- 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.

- The applicant laboratories shall be accredited for the use of the most recent edition of the standard CEN ISO/TS 15216, for at least one type of matrix for food of non-animal origin and at least one type of matrix for food of animal origin.

Means of proof: Certificate to be provided with the application.

4.B EXCLUSION CRITERIA

Candidates 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 cases where Member States contest the results of analyses.
- it is bankrupt, subject to insolvency or winding up procedures, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended or it is 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 the person 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 the 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 the 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;
- the 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 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: Declare on honour that they are not in one of the situations listed above. The declaration must be dated and signed by an authorised representative of the NCA.

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 from 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 of Regulation (EC) No 882/2004.

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

Requirement: the Director of the EURL must have a post-graduate degree and 5 years professional experience (from which 2 years of experience in the area of competence of the EURL); the scientific staff shall have a post-graduate degree and 2 years of 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 the 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: statement and description

- (d) The laboratory ensures that their staff respect the confidential nature of certain subjects, results or communications;

Requirement: self-explanatory

- Means of proof: statement and description

- (e) 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, comparative testing and other relevant practices applicable to the area of competence of the EURL.

- Means of proof: description of standards and practices implemented

- (f) The laboratory has available an up-to-date list of available reference substances and reagents and an up-to-date list of manufacturers and suppliers of such substances and reagents.

Requirement: self-explanatory

- Means of proof: provide list(s)

- (g) The Laboratory takes account of research activities at national and Union level;

Requirement: self-explanatory

- Means of proof: statement and description

- (h) 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 (weekends in particular)

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

The requirements laid down in Article 12(2) and 12(3) of Regulation (EC) No 882/2004 selection criteria. In particular:

- (i) 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 supporting certificate(s)

6. PREFERENCE CRITERIA

The applicant laboratories mentioned hereinafter shall provide adequate and detailed evidence of the following issues to support their submission.

TEAM COMPOSITION and EXCELLENCE Rate: 25%

In the area of competence, level of experience, knowledge of scientific background for the area of competence, including scientific publications, references of research work and activities in the area of competence, both to support routine reference laboratory activities and to assist the Commission and Member States in emergency response, availability of validated methods.

INFRASTRUCTURE and TECHNICAL COMPETENCE Rate: 25%

In the area of competence, infrastructure and capability for, and experience in testing foodborne viruses in all types of food matrixes. Possession, or access to, reference collections of relevant viruses strains for appropriate analyses and if possible to have a sufficiently updated database on sequenced isolates for epidemiological investigations.

CAPACITY TO DEVELOP A WORK PROGRAM AS A EURL Rate: 10%

Evidence of understanding of the mission as a EURL through a presentation of a simulation Work Program⁴ (description of the activities, objectives, expected outputs) to be developed over three years (maximum ten pages, assuming a maximum budget of 250 000€ per year).

INTERNATIONAL Rate: 20%

Involvement and participation in international standardisation activities and networks (e.g. CEN, ISO), involvement and participation in other multinational activities/projects (e.g. research projects), reliable and proven system of procedures for the dispatch to and receipt from laboratories situated in the EU & third countries of samples, including infectious material, for diagnostic or research purposes,

COORDINATION Rate: 20%

Organisation/interpretation of comparative tests, organisation of workshops, training activities, capacity/capability to organise workshops, activities as reference laboratory, close working relations with other laboratories for foodborne viruses.

7. SELECTION

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

⁴ See Commission Implementing Decision C(2015)4993 final.