Call for Applications for the Designation of an EU Reference Laboratory for Public Health

Guide for applicants

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1.0	03.10.2023	▪ Initial version.
1.1	27.10.2023	▪ Additions and updates made to reflect outcome of information and Q&A webinar on 20 October.
1.2	29.11.2023	▪ Additions and updates made to reflect extension of application deadline. ▪ Additions and updates made to reflect questions received and answered which previously were published directly on the webpage (https://health.ec.europa.eu/health-security-and-infectious-diseases/surveillance-and-early-warning/eu-reference-laboratories-public-health-calls-application_en)
1.3	07.12.2023	▪ Additions and updates made to reflect questions received
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DISCLAIMER

Please note that this document is complementing the information provided in the call for applications, and that it is provided for guidance purposes only.

Applicants are required to carefully read all of the documents provided. In case of conflicts between information in the call for applications and the information provided in this document or in the Q&A provided on this page, information in the call for applications takes precedence.

This document is only applicable to the six EURL for public health calls for applications published by the European Commission on 2 October 2023. The content is therefore not applicable to calls for applications for EURLs in other sectors, nor to calls for applications for EURLs for public health published at a later date.

LIST OF ACRONYMS

CCB	Coordinating Competent Body
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EU	European Union
EURL	EU Reference Laboratory
HaDEA	European Health and Digital Executive Agency
IVD	In Vitro diagnostics
NFP	National Focal Point
NRL	National Reference Laboratory
OCP	Operational Contact Point
SRM	ECDC's Stakeholder Relationship Management system

GENERAL QUESTIONS

WHAT IS A EUROPEAN REFERENCE LABORATORY (EURL) FOR PUBLIC HEALTH?

Regulation 2022/2371 on serious cross-border threats to health provides the legal mandate for the European Commission to designate EU reference laboratories in the field of public health. The overall objective of an EURL is to provide support to national reference laboratories to promote good practice and alignment by Member States on a voluntary basis on diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States.

WHAT ARE THE DIFFERENCES BETWEEN A NATIONAL REFERENCE LABORATORY (NRL) AND AN EURL FOR PUBLIC HEALTH?

A National Reference Laboratory, formally designated or de facto performing this role, normally provides reference functions to an underlying network of laboratories within their country. The role of the EURL is to provide support to the NRLs to ensure data comparability and capacity strengthening to laboratory methods agreed to be important for EU level surveillance.

The nomination of network members is done by the Coordinating Competent Bodies (CCBs) through the ECDC Stakeholder Relationship Management (SRM) system as part of ECDC's agreed process for managing the disease networks and Member State contacts. (1) Please note that there is no requirement that a national laboratory must be formally named as an NRL in order to participate in the ECDC disease / laboratory networks.

WILL THE INTRODUCTION OF EURLS FOR PUBLIC HEALTH CHANGE THE NRL'S ROLE AND/OR MANDATE?

No. The mandate of laboratories at the national level, including NRLs, are set by each country. They do not change with the introduction of EURLs for public health.

HOW WILL THE EURLS FOR PUBLIC HEALTH BE GOVERNED?

The six EURLs for public health listed will be governed by the European Commission and ECDC, in accordance with Article 15 of Regulation 2022/2371. (2)

WHAT ARE THE DIFFERENCES BETWEEN THE EURLS FOR PUBLIC HEALTH AND THE EURLS FOR FOOD, FEED AND ANIMAL HEALTH, OR THE EURLS FOR *IN VITRO* DIAGNOSTICS?

The EU has the mandate to appoint European reference laboratories in a number of different sectors, with each set of EURLs providing support and reference functions for laboratories / organisations within their particular sector.

The EURLs for food, feed and animal health provide reference functions for laboratories in the food, feed and animal health sector, whereas the EURLs for *in vitro* diagnostics will have tasks related to conformity assessment of medical devices. The EURLs for public health will provide support to the public health laboratories to strengthen capacity and data comparability within the EU. The six EURLs must support the EU-level public health microbiology system.

HOW WILL THE LABORATORY SUPPORT PROVIDED BY AN EURL DIFFER FROM WHAT HAS BEEN PROVIDED TO THE MEMBERS OF THE DISEASE / LABORATORY NETWORKS TO DATE?

Disease and laboratory network members are nominated by Member States and effected through the ECDC SRM system, and this will not change (see also question "What are the differences between a National Reference Laboratory (NRL) and an EURL for public health?").

Currently, EU-level laboratory support is provided to members of the disease / laboratory networks through service contracts with ECDC, but in accordance with Article 15 of Regulation 2022/2371 laboratory support to the Member State laboratories shall in the future primarily be provided through EURLs for public health. With the introduction of the EURLs for public health, it is expected that the ECDC service contracts will gradually be phased out as EURLs in the same fields are designated.

To ensure continuity for the network members, the EURLs for public health will be required to continue to support the ECDC's laboratory (sub-)networks, and to provide them with certain essential laboratory support activities. These essential activities are included in the calls for applications as mandatory tasks.

WHAT LABORATORIES WILL BENEFIT FROM THE SUPPORT OF THE EURLS FOR PUBLIC HEALTH?

The EURLs for public health will support the members of the relevant ECDC laboratory (sub-)network(s) that consist of the National Focal Points (NFPs) and the Operational Contact Points (OCPs) for Microbiology for the pathogens / health issues covered by the EURL.

The nomination of network members is done by the CCBs through the ECDC SRM system as part of ECDC's agreed process for managing the disease networks and Member State contacts. (1)

WILL THE SERVICES OF THE EURL FOR PUBLIC HEALTH BE BENEFICIAL TO LOCAL AND/OR REGIONAL LABORATORIES?

Mainly indirectly, as most of the ECDC laboratory (sub-)network(s) do not include local laboratories. It is however expected that the national laboratories collect and analyse needs of the local and/or regional laboratories, and they may consider asking the EURL for support on specific issues that cannot be solved at the national level.

ARE ALL LABORATORIES REQUIRED TO SUBMIT AN APPLICATION TO BECOME AN EURL FOR PUBLIC HEALTH?

No. Only laboratories that want to be designated as an EURL for public health, and have the knowledge and capacity to carry out the EURL work, should apply.

Network member laboratories that do not apply to be an EURL for public health will remain members of the network, and will at a later date receive laboratory support from the EURL for public health designated for their particular pathogen / health issue.

HOW MANY EURLS WILL BE DESIGNATED PER PATHOGEN / HEALTH AREA?

Only one applicant (either a single laboratory or a consortium of up to five laboratories) will be designated for each topic of the call. In total, this will result in six EURLs for public health, one per topic.

WHERE CAN I FIND THE CALL ID?

In the document with the terms of the call for applications, the call ID can be found in the header, at the top of the page.

OVERALL PROCESS

WHY WILL THE EURLS BE DESIGNATED FOR 7 YEARS?

The EURLs for public health will be designated for seven (7) years to give the designated EURLs more long-term security in terms of appointment and planning. However, the performance of the EURLs for public health will be regularly reviewed and evaluated. Should the designated EURL fail to meet their obligations the European Commission may proceed to de-designate the EURL before the end of the designation period, and re-launch an application procedure to designate another applicant instead.

WHAT WOULD HAPPEN IF A DESIGNATED EURL DOES NOT PERFORM ITS AGREED TASKS?

The performance of the EURLs for public health will be regularly reviewed and evaluated. Should the designated EURL fail to meet their obligations the European Commission may proceed to de-designate the EURL before the end of the designation period.

WHICH ARE THE EURLS FOR PUBLIC HEALTH TO BE IMPLEMENTED IN THIS FIRST ROUND?

In 2023, the European Commission has published calls for applications for the designation of EURLs for public health in the following fields:

EURL call ID	EURL topic
EURL-PH-2023-01	Antimicrobial Resistance (AMR) in bacteria
EURL-PH-2023-02	Vector-borne viral pathogens
EURL-PH-2023-03	Emerging, rodent-borne and zoonotic viral pathogens
EURL-PH-2023-04	High risk, emerging and zoonotic bacterial pathogens
EURL-PH-2023-05	Legionella
EURL-PH-2023-06	Diphtheria and Pertussis

WHAT IS THE TIMELINE FOR THE DESIGNATION OF EURLS FOR PUBLIC HEALTH UNDER THESE CALLS?

The indicative timetable for the designation of the EURLs for public health under these calls is:

Timetable and deadlines (indicative)	
Call publication:	2 October 2023
Deadline for submission of applications:	5 January 2024 17:00 CET
Evaluation:	January 2024

Timetable and deadlines (indicative)	
Information on evaluation results:	January – February 2024

WHAT ARE THE STEPS AND OVERALL TIMELINE BEFORE THE EURLS FOR PUBLIC HEALTH UNDER THESE CALLS BECOME OPERATIONAL?

The indicative timetable for the establishment of the EURLs for public health under these calls is:

- Designation of EURLs: Q1 2024
- Publication of EU4Health call for proposals: Q2 2024
- Signature of grant agreements for EURLs: before end Q4 2024
- Start of EURL activities: Q1 2025

Please note that this timetable may change, and may also vary for the EURLs for public health in different fields.

WHICH OTHER EURLS FOR PUBLIC HEALTH ARE CURRENTLY ENVISAGED TO BE IMPLEMENTED IN THE FUTURE?

It is envisioned that other EURLs covering additional topics will be funded in the coming years. Public health needs, budget availability within EU4Health annual work programme will steer the implementation of EURLs in other fields. Based on the needs and the available funding, ECDC will make an annual proposal on diseases / health issues within communicable diseases that it recommends for implementation as an EURL. The decisions on which EURLs to implement in which year will be made by the European Commission.

WILL GEOGRAPHIC SPREAD OF THE EURLS ACROSS THE EU/EEA BE A CONSIDERATION IN THE DESIGNATION OF THESE EURLS?

No, not for these six EURLs. However, the overall distribution of EURLs across the EU/EEA countries is an issue that will continue to be discussed with the countries over the coming years as more EURL calls for application are set to be issued.

ELIGIBILITY OF APPLICANTS, AND ENDORSEMENTS BY NATIONAL COMPETENT AUTHORITIES

WHO CAN SUBMIT AN APPLICATION?

The call for applications is aimed at laboratories in the EU Member States and EEA countries that play an active role in a national and/or EU-level public health microbiology system.

An applicant to the call may be a single laboratory or a consortium of up to five laboratories. Please note that a laboratory may only apply to each topic once, i.e. either as a single laboratory or as a member of a consortium.

All laboratories applying to the call, whether as a single laboratory or as a member of a consortium, must be endorsed by a national competent authority that will confirm that each laboratory meet the eligibility criteria.

A laboratory already nominated as a WHO Coordination Centre or as a EURL in a different area (e.g. a veterinary laboratory that is already EURL for an animal

disease) may still apply, provided that they meet the eligibility criteria and are endorsed by a national competent authority.

CAN A NATIONAL COMPETENT AUTHORITY SELF-NOMINATE AS A CANDIDATE FOR AN EURL FOR PUBLIC HEALTH?

In principle, yes. However, a national competent authority may endorse more than one applicant per topic. In their role as national competent authorities, they are therefore expected to, in a fair and transparent manner, also endorse other national laboratories that are interested in applying and that meet the eligibility criteria.

CAN ONE LABORATORY APPLY TO MORE THAN ONE EURL TOPIC?

Yes, one laboratory may apply to one or more EURL topics if they have the capacity and expertise. However, please note the following:

- A separate endorsement is needed for each of the EURL topics that a laboratory submits an application for. This is because the staff qualifications, equipment, infrastructure required for each topic is different, and separate confirmations of eligibility are therefore needed from the national competent authority.
- Applicants those applications are successful for more than one topic may be requested to demonstrate that they have the capacity to carry out all their activities across all EURL fields for which their applications have been successful.

ENDORSEMENT BY NATIONAL COMPETENT AUTHORITIES

Are there defined criteria for the national competent authorities to assess the suitability of laboratories to be endorsed before their application?

Yes – they are the eligibility criteria listed in section 2.7 of the calls for applications.

Each national competent authority is required to confirm that laboratories applying to the call meet the eligibility criteria of the call. It is up to each national competent authority to determine if, and if so what, supporting documentation they may require from the laboratories in this process.

Which are the national competent authorities able to endorse applicants?

There is a recommendation that the ECDC Coordinating Competent Bodies (https://www.ecdc.europa.eu/en/about-ecdc/who-we-are/governance/competent-bodies) be used, but endorsements by other relevant public health national authorities (Ministries of Health, health authorities, national institutes or agencies for public health, etc.) will also be accepted.

Is there a template for the endorsement letter?

Yes – it's Annex I of the call for applications. It's also available as a Word file here.

Does a declaration of one or more potential conflict(s) of interest mean that the candidate laboratory cannot be endorsed by a national competent authority?

No. A national competent authority may endorse a candidate laboratory that has identified one or more potential conflict(s) of interest that they will declare as part of their application form.

However, the competent authority should only endorse this candidate laboratory if the competent authority's assessment is that none of these potential conflict(s) of interest are of such significance that they would affect the impartiality of the candidate laboratory's professional conduct or commitment as regards the exercise of their tasks as EURL.

Should something be unclear about any declared potential conflicts of interest, the European Commission may at the evaluation stage contact the applicant and/or the endorsing national competent authority for more information.

Can a national competent authority be held responsible regarding its examination of the potential applicants, especially if the designated EURL ends up being unfit?

The European Commission and ECDC want to ensure that the laboratories that are endorsed have the right skills and competencies to perform the work, and that they are appropriately positioned as part of national public health activities. Clearly, national competent authorities are better placed to assess this for laboratories based in their respective countries. As such, there is a level of responsibility on the national competent authorities to carefully consider that the endorsed laboratories meet the eligibility criteria, and they are free to consider what information to request from the applicants in the endorsement process. Should something be unclear about any endorsement, the European Commission may at the evaluation stage contact the applicant and/or the endorsing national competent authority for more information.

If the designated EURL does not perform its agreed tasks or fails to meet its obligations, a procedure will be in place to de-designate an EURL (see question "What would happen if a designated EURL does not perform its agreed tasks?"). Should this happen, the European Commission would not hold the endorsing national competent authority legally liable for any failings.

Can a consortium apply if the national competent authority does not endorse one participating laboratory?

No - all participants in a consortium are required to be endorsed; the consortium would have to rethink their composition.

Do national competent authorities have a role working alongside the EURLs after nomination?

For the EURL designation process, the national competent authorities are not expected to be actively involved once the application has been submitted, as they only have a formal role in the endorsement process. The work that the designated laboratories perform in their role as EURL will be governed by the European Commission and ECDC (see also question "How will the EURLs for public health be governed? ").

CONFLICTS OF INTEREST

How will the applicant declare their potential conflicts of interest?

As part of the application form in EUSurvey, all applicants will be required to reply to the following question(s) before they can submit their applications:

- We confirm that to our best knowledge no relevant conflicts of interest exist that may affect the impartiality of our professional conduct or commitment as regards the exercise of tasks as the EURL for public health in the field of XXX", with response options:

- Yes (No potential conflicts of interest to declare)
- No (Potential conflicts of interest listed below)

- (If No) Explain the nature(s) of the potential conflict(s) of interest and provide details

Please note that for a consortium application, the coordinator must collect information about potential conflicts of interest from all of the consortium members and enter information covering the entire consortium into the application form.

What could be relevant potential conflicts of interest?

Relevant potential conflict of interests should be declared if an association exists that either is or may be a perceived as a conflict of interest by an outside observer. For example, an applicant that is already under contract to provide a group of reference laboratories with laboratory support within a similar field (e.g. as a WHO Collaborating Centre or similar) would be required to explain how they would manage the existing contract and their role as an EURL to ensure that the two are not mixed up. External funding for related activities should always be declared.

In general, applicants are obliged to show that they have considered potential conflicts of interest. Disclosing a potential conflict of interest does not prevent an applicant from applying or being designated as an EURL, as long as a fair and transparent process of managing the source of the potential conflict of interest is ensured, and the potential conflict of interest is not deemed to affect the applicant's performance or conduct as an EURL.

CONSORTIUM-RELATED QUESTIONS

How many organisations can be part of the consortium?

Between two (2) and five (5) laboratories can form a consortium applying to be designated as EURL.

Why do we need to appoint one organisation as the "Coordinator"?

All consortium-based EU projects are required to have one coordinator that has the mandate to represent the consortium on specific, often administrative, issues.

At a later stage, for successful applicants the coordinator will have certain mandatory responsibilities from a grant management perspective, primarily related to communications with the funding body (i.e. the European Commission and the European Health and Digital Executive Agency [HaDEA]) and the distribution of the EU contribution to the other consortium members in accordance with the agreed budget.

What are the rights and responsibilities of a consortium coordinator with regards to the other members of the consortium?

At this stage, the only explicit responsibilities of the coordinator of a consortium are to submit the application on behalf of the consortium, and (if needed) to represent the consortium in contacts with the European Commission and/or ECDC on any application-related issues during the application and evaluation processes.

All consortium members that are not the coordinator are required to authorise the coordinator to submit the application on their behalf and to represent the consortium

during the application and evaluation phases of the selection procedure. The template for this authorisation forms part of Annex II of the call for applications.

Can a National Reference Centre composed of 3 laboratories, which is already considered as only one entity (the National Reference Centre for X) by the national health authorities, count only as one participant inside a consortium or will these 3 laboratories be considered as 3 distinct participants of the consortium (maximum 5 in the final consortium)?

With reference to section 4.1.4 in the Call for Application (Modalities relevant to EURL applications by a consortium), a "consortium" is defined as "between two and five eligible entities in one or more EU Member States and/or EEA countries working together to perform the tasks of the EURL".
Laboratories that are separate legal entities will be considered as separate laboratories within the consortium.

Is a consortium agreement needed at the application stage?

No, a consortium agreement is not needed at the application stage. Successful consortium applicants will however need to set up a consortium agreement as part of their funding process; more information on that will follow at a later date.

What does "joint and several liability" mean with regards to the consortium?

If their application is successful, the members of a consortium will be jointly and severally liable for carrying out the tasks of the EURL. This means that if one consortium member were to fail to implement its part of the tasks, the other members would become responsible for implementing that part.

To confirm the consortium member's understanding of this situation, all consortium applications must be accompanied by agreement letters on the joint and several liability from all consortium members, except the coordinator who will need to agree to this via the application procedure, before submitting the application in EUSurvey.

The template for the agreement letter on the joint and several liability forms part of Annex II of the call for applications.

Is there a way for laboratories potentially interested in forming a consortium for a specific EURL topic to get in contact with other interested laboratories?

Yes – ECDC is operating a service to put laboratories in contact with other laboratories interested in forming a consortium and submitting a joint EURL application in a specific field.

Eligible laboratories interested in this service should send an email to ECDC at EURL-PH@ecdc.europa.eu, indicating the following:

- The call ID and EURL field
- Laboratory name and contact details (name, email address and phone number) of the main contact person

ECDC will then place this information on a restricted access website (or similar) that is only accessible to the laboratories that have expressed an interest in finding partners for a consortium application in the same field. Those laboratories will receive separate emails informing them on how to access this information.

Do applicants have to use the ECDC-provided service to find consortium partners?

No, not at all – eligible laboratories are perfectly free to form their own consortia based on direct contacts with other eligible laboratories. There is no requirement to inform the European Commission or ECDC of the formation of a consortium prior to the submission of the application.

PREPARING THE APPLICATION

CONSIDERING THE EXTENSION OF THE DEADLINE FOR THE SUBMISSION OF THE APPLICATIONS, WILL APPLICANTS THAT HAVE ALREADY SUBMITTED THEIR APPLICATIONS BE ALLOWED TO EDIT AND UPDATE THEIR APPLICATIONS UNTIL THE EXTENDED DEADLINE IF THEY WISH TO DO SO?

Yes. To edit their submitted contribution, applicants should use the same link that they used to edit the draft application. Should they have any issues with this, please send an email explaining the issue to EURL-PH@ecdc.europa.eu. Draft applications that have not yet been submitted in EUSurvey remain open for editing and submission by the applicants.

WHERE DO I FILL IN THE ADMINISTRATIVE INFORMATION ABOUT THE APPLICATION AND THE APPLICANT?

The administrative information about the (single laboratory or consortium) applicant is filled out directly in EUSurvey.

HOW DO I FILL IN THE TECHNICAL INFORMATION ABOUT THE PROJECT?

The technical information, including scenario workplans, descriptions of applicant teams and staff, expected impact of the proposed activities etc, is entered into the different sections of the Technical Description template (Annex III of the call for application). The completed Technical Description file must then be uploaded in EUSurvey before the application form is submitted.

WHAT'S THE PASSWORD FOR ACCESSING THE APPLICATION FORMS IN EUSURVEY?

The password for accessing the application forms is "EURL2023".

FOR EURLS COVERING MORE THAN ONE PATHOGEN / HEALTH ISSUE, IS IT POSSIBLE TO APPLY TO BE AN EURL FOR ONLY ONE OF THEM?

No, at least not as a single laboratory applicant. The applicant must be able to address all the pathogens / health issues included in the call. If a single laboratory is unable to do so, they may form a consortium together with other laboratories, and submit an application where the consortium as a whole is capable of addressing all of the pathogens / health issues included in the call.

WHAT IS THE PURPOSE OF THE SCENARIOS?

The scenarios give two different sets of constraints (i.e. limited budget and defined time period) within which the applicants must prepare and submit workplans that, in their views, would provide the laboratory network members with the best and most relevant laboratory support whilst still respecting the scenario constraints. This will facilitate the evaluation of the applications, by making the workplans submitted by the applicants more easily comparable.

How should we approach the sums of money stated in the fictitious scenarios? Is there an order of magnitude to consider?

At this stage, the budgets indicated in the scenarios are listed as inspiration for the applicant when drafting the proposal. The sums are presented for the purpose of this application procedure alone, and therefore do not constitute a commitment on the duration or amount of funding for the EURL designated under this procedure. At a later stage, designated EURLs will be invited to apply for funding when their designation through a legal act (implementing regulation) has been processed by the European Commission. A specific call for proposals will be launched for this purpose.

Why are there mandatory tasks in the call for applications?

There are a number of laboratory support tasks that are considered so essential to the network members, or to other on-going work at the EU level, that an EURL for public health will be required to provide them. These essential activities are included in the calls for applications as mandatory tasks, and their number and scope vary between the different calls for applications.

All workplans prepared in response to the scenarios must include all the mandatory tasks required for the EURL for public health in the specific field.

Why are potential additional activities listed in the call for applications?

These are activities that ECDC have identified as being potentially valuable to the laboratory network and complementary to the mandatory tasks of the EURL. These activities should be seen as suggestions, and it is up to each applicant to propose a set of additional activities within the scope of the EURL responsibility. This may include some of the potential additional activities listed in the call, and/or additional activities that the applicant deems to be of greater value to the network members.

Is there a limit of additional activities that the applicant may propose in their workplans?

There's no limit in terms of number of activities that the applicant may include in their scenario workplans; however, the applicant must be confident that the implementation of all the included activities is feasible within the constraints of each scenario.

Does the two-year scenarios mean that the EURL funding will also be for two years?

No – as stated in the call for applications, the scenarios are fictitious and presented for the purpose of the application procedure, and do not constitute a commitment on the duration or amount of funding for the EURL.

All the information related to the funding available under the EU4Health programme, including expected duration, will be made public when HaDEA launches the corresponding call for proposals. At the conclusion of the current application procedure, all the successful laboratories will be invited to submit a proposal for the abovementioned grants.

WHAT LEVEL OF DETAIL IS EXPECTED IN THE DESCRIPTION OF TASKS IN THE WORKPLAN?

Each application should describe the workplan as a whole, the activities included under it, and how the activities relate to each other. The activities should be described with a focus on why the activity is useful for the network members and/or EU-level public health, what the main outcomes of the activity would be, if/how the activity builds on other activities, etc. However, applicants are not obliged to organise their proposed workplans into formal work packages, nor present lists of reports and deliverables within their workplan descriptions.

Applicants are expected to strike the right balance between necessary detail and conciseness in their descriptions of the activities, and the page limits of the different parts of the Technical Description template have been set to give applicants enough room to describe the above, while avoiding excessive detail.

IS A BUDGET REQUIRED PER TASK OR ACTIVITY, WHEN LAYING OUT THE WORKPLANS ACCORDING TO THE FICTITIOUS SCENARIOS?

No - the scenario workplans do not ask for a breakdown of budget per task and per activity. Instead, the request is to present workplans for the total budget available under each scenario.

ARE CVS OF KEY PERSONNEL TO BE INCLUDED IN THE APPLICATION (AS APPENDIX)?

No, the relevant information about the key team members should be included in the 'Resources and Knowledge' section of the Technical Description (Annex III).

IF YOU APPLY AS A CONSORTIUM: WHAT IS MEANT IN THE SECOND PARAGRAPH BY "APPLICANTS TEAM". ("DESCRIBE THE APPLICANT TEAM AND HOW THE MEMBERS OF THIS TEAM WILL WORK TOGETHER TO IMPLEMENT THE PROPOSED WORKPLANS.") DO YOU NEED TO DESCRIBE THE ACTUAL TEAM MEMBERS AND THEIR EXPERTISE FOR EACH INSTITUTE IN THE CONSORTIUM? OR IS THE CONSORTIUM TEAM AS SUCH MEANT HERE? IN CONCLUSION, IS THIS DESCRIPTION AT THE INSTITUTE LEVEL OR AT THE CONSORTIUM LEVEL?

As described in section 4.1.4 in the Call for Application (4.1.4 Modalities relevant to EURL applications by a consortium), a "consortium" is defined as "between two and five eligible entities in one or more EU Member States and/or EEA countries working together to perform the tasks of the EURL". The applicant should present the group of experts required to cover the competencies needed to fulfil the EURL functions (this is referred to as the "Applicants team"). The application must include the relevant information to demonstrate how well the applicant team meets the selection criteria described under section 2.8 of the call for application.

IN THE SAME PARAGRAPH (SEE QUESTION ABOVE), WHAT IS MEANT BY "LIST THE REQUIRED FUNCTIONS BY EXPERTISE"?

"List the required functions by expertise" refers to the need to clearly define which entity is expected to conduct specific activities within the application team. This is linked to the requirement that each entity must be endorsed by a national competent authority to ensure that the entity "has or has contractual access to, suitably qualified staff with adequate training in their area of competence" and "Possesses, or has access to, the infrastructure, equipment and products necessary to carry out the tasks assigned to them" (Annex 1).

In case we need to describe the teams per institute: to what expertise level do you need to describe the teams? Is expert level sufficient and can ECDC assume that at the technician and lab support level everything will be satisfactory if you are a functional NRL?

Regarding the level of detail in the application in describing the teams. It is up to the applicant to, within the text limitation described in the Call for Application, describe the team composition and the competences required to fulfil the EURL functions. The goal of this description should be to, in a convincing way, show that the application fulfils the criterion on "Team composition, knowledge and experience", see section 2.8 of the call for application.

Is it expected that EURL applicants insert references to scientific articles, relevant EU policies and regulations, ECDC reports etc. in the application text?

References are not requested in the call for application. Please be aware, if you choose to include references at your own discretion, they must be included in the text for each section, and therefore bound by the same font size and page limit. Please note also that submission of supporting documents for the selection criteria may be requested at a later stage.

If references are expected, what would be the preferred format for insertion of the references (footnotes, hyperlinks or use of citation and reference manager software applications, such as Endnote or Reference Manager other)?

There is no preferred format as references are not requested in the call for application. Please be aware, if you choose to include references at your own discretion, they must be included in the text for each section, and therefore bound by the same font size and page limit.

Is there any page or numerical limit for the references?

References are not requested in the call for application. If you choose to include references at your own discretion, they would be included in the page limits stipulated for that section.

With regards to Annex 3 (Technical description): May the applicant modify the margins of the document?

The applications should follow the structure of the Annex III template as stated in the GENERAL INSTRUCTIONS AND GUIDELINES of the document. This includes to not significantly modify the page margins.

QUESTIONS SPECIFIC TO ONE CALL FOR APPLICATIONS:

EURL-PH-2023-01: ANTIMICROBIAL RESISTANCE (AMR) IN BACTERIA

Are isolates to be analysed under Task 9 part of the number of isolates (N=1000/2000) mentioned in Task 1?

Yes, the isolates that are to be analysed under task 9 would fall under the number of isolates denoted under task 1, which means that they would be included in approximately 1000 isolates per year or 2000 isolates over scenario period.

Can a submission be a consortium on antimicrobial resistance to include TB antimicrobial resistance and other pathogens?

With reference to section 2.2 in the Call for Applications (Description of the EURL and relevant disease/laboratory networks), the scope of the EURL for AMR does not include TB. The future EURL shall provide support to the members of the laboratory sub-networks of ECDC's European Antimicrobial Resistance Surveillance Network (EARS-Net) and the European Antimicrobial Resistance Genes Surveillance Network (EURGen-Net) on issues related to diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases. At present, the pathogens included in EARS-Net surveillance are *Acinetobacter spp., Enterococcus faecalis, Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Staphylococcus aureus, and Streptococcus pneumoniae*. EURGen-Net focuses on surveillance of healthcare-associated multidrug-resistant bacteria of public health importance. The current species listed under this programme includes carbapenem- and/or colistin-resistant Enterobacterales (*K. pneumoniae and E. coli*), *Acinetobacter baumannii* (CRAb) and carbapenem-resistant *P. aeruginosa* (CRPa).

EURL-PH-2023-02: VECTOR-BORNE VIRAL PATHOGENS:

The area of Vector-borne viral pathogens includes several important pathogens (11 of them are explicitly listed in point 2.2.1). However, the table in point 2.4.1 does not indicate whether the required number of reference materials, samples or organised EQAs refers to each of the listed viruses (e.g. in task Nr1 60 samples x 11) or whether it is in sum for all or whether EURL can select some viruses at its discretion.

Section 2.4.1 in the Call for Application (Mandatory tasks for the EURL for public health in the field of Vector-borne viral pathogens) provides the minimum volume of support activities over the two-year scenario period. It is up to the applicant to ensure that there is capacity available to cover any of the listed viruses. That being said, it will be up to the applicant to propose how to best distribute these activities in the application. In this proposal the applicant can indicate for what viruses the focus should be over the two-year scenario. With regards to the EQA targets, these will be agreed upon by the EURL and ECDC in response to needs of the network laboratories or specific epidemiological situations. A detailed EQA plan must be agreed upon with ECDC before implementation of the EQA.

EURL-PH-2023-04: HIGH RISK, EMERGING AND ZOONOTIC BACTERIAL PATHOGENS

Is it necessary to apply in the health area „EURL for high-risk, emerging and zoonotic bacterial pathogens" for all pathogens mentioned?

As described in section 4.1.4 in the Call for Applications (Modalities relevant to

EURL applications by a consortium): "The consortium as a whole must cover the all the tasks of the EURL, and the work programme of the consortium must contain a demonstration of coherence and complementarity within the consortium members including division of tasks and responsibilities and the exchange of knowledge." It will therefore not be possible to only apply for only some of the pathogens listed of the future EURL. Such application needs to be part of a consortium covering all the tasks described.

Is it an absolute requirement that the EURL has to be able to cover all of the bacterial pathogens listed under the "e.g." in the first statement? These pathogens seem to be stated as an example (e.g.) but it is not clear if they are a requirement. Would it be possible to be designated as the EURL if covering all except two of the pathogens listed under the "e.g."?

The application needs to cover all of the diseases mentioned in the Call for Application. If your institute can not cover all of the diseases mentioned then we would recommend to seek a consortium to form a part of.

EURL-PH-2023-06: Diphtheria and Pertussis

Under Task 6, the applicant is asked to perform a population immunity study for Diphtheria and Pertussis. This task is very challenging to perform within the two year scenario period.

It is correct that the seroprevalence study described under Task 6 is expected to be performed within the two year scenario period. Provided that the study is planned and prepared within the first year of the scenario period, it should be possible to perform the study during the second year of the scenario period.

Please note that although the seroprevalence study is required to be included in the workplans responding to the scenarios, it is however acknowledged that there may be limited value in systematically performing this study on a biennial basis.

SUBMITTING THE APPLICATION

Do I need to create an account in EUSurvey to submit an application?

You do not need to create an EU Login account to be able to submit an application. However, there are some advantages to doing so, including receiving an email confirmation of application submission from EUSurvey.

I'm a member of a consortium, but not the coordinator – do I need to submit an application in EUSurvey?

No – only the main contact point of the coordinator will be required to submit the application in EUSurvey on behalf of the consortium.

EVALUATION OF APPLICATIONS

WHO WILL EVALUATE THE APPLICATIONS?

The applications will be evaluated by evaluation panels consisting of European Commission staff members, ECDC staff members as well as of independent, external experts.

The members of the evaluation panels will be appointed to be complementary in terms of the specific expertise needed to evaluate applications for the EURL for public health in each specific field.

WHO WILL BE PART OF THE EVALUATION PANEL AND HOW CAN CONFLICTS OF INTEREST BE AVOIDED IN THE EVALUATION?

The evaluation panel will consist of people from the European Commission, the ECDC, as well as independent, external experts. All participants will have to declare any conflicts of interest before being assigned a role in the evaluation.

HOW WILL WE BE INFORMED OF THE EVALUATION RESULTS?

Each applicant will receive their application evaluation report together with an evaluation result letter with information on whether their application has been successful or unsuccessful.

WHAT DO WE DO IF WE BELIEVE THAT AN ERROR HAS OCCURRED IN THE EVALUATION PROCESS?

If an applicant believes that the evaluation procedure is flawed, they may submit a complaint following the deadlines and procedures set out in the evaluation result letter.

DESIGNATION AND FUNDING OF SUCCESSFUL APPLICANTS

HOW WILL THE SUCCESSFUL APPLICANTS BE DESIGNATED AS EURLS?

The European Commission will designate EURLs for public health following the procedure for an implementing act, i.e. a secondary legislation following a Regulation. This is a formal procedure with a number of set steps and timelines that the European Commission is legally required to respect and follow.

WHAT IS THE DIFFERENCE BETWEEN THE CALL FOR APPLICATION AND THE PLANNED CALL FOR PROPOSALS UNDER EU4HEALTH?

The call for applications asks laboratories in the EU Member States and the EEA countries to indicate their interest in being appointed as an EURL for public health by submitting an application. This application and the subsequent evaluation will focus on the applicants' ability and capacity to carry out the EURL work as described in the scenarios of the call for application, resulting in the selection of the applicant with the highest evaluation score. Following this, an implementing regulation must be carried out by the European Commission for the formal designation of the selected laboratory as the EU reference laboratory for the specific field of public health.

Only then will HaDEA launch the calls for proposals under the EU4Health programme, for designated EURLs to apply for grants to cover the cost of their activities. The goal of the planned call for proposals is therefore to provide the designated EURLs for public health with funding for carrying out their activities.

WHAT WILL BE THE REIMBURSEMENT RATE OF THE GRANTS FUNDING THE EURLS FOR PUBLIC HEALTH THAT ARE DESIGNATED UNDER THESE CALLS?

The grants funding the EURL activities are expected to have a 100% reimbursement rate for eligible costs (up until the maximum amount of the grant); however, the reimbursement rate will only be formally stated in the call for proposals.

IS THE BUDGET AVAILABLE THROUGH THE EU4HEALTH ANNUAL WORKING PROGRAMME 2023 (EUR 12.4 MILLION) LINKED TO A SPECIFIC DURATION, E.G. FOR TWO YEARS OR FOUR YEARS?

No - the budget is not tied to any specific duration at this time. The expected duration of the grants will be

BETWEEN THE MOMENT THAT A LABORATORY IS APPOINTED AS AN EURL AND LATER RECEIVING FUNDING, IS THE EURL EXPECTED TO START ITS ACTIVITIES?

No – EURLs are not expected to start their work straight away, without financial support. While the designation of a EURL is a process that does not involve funding, the EC is committed to ensuring that funding is available for the nominated EURLs. That is why 12.4 million has been secured for these activities in the EU4Health Annual Working Programme 2023.

FURTHER INFORMATION

WHAT DO I DO IF I HAVE QUESTIONS DURING THE APPLICATION PROCESS?

All questions on these calls should be made in writing only, to the following email address:

EURL-PH@ecdc.europa.eu

with the EURL call ID in the subject line.

There will also be a webinar organised on Friday 20 October at 10:00-13:00 CEST for clarifications and questions on the calls for applications and application procedures.

Please note that applicants are particularly requested not to discuss or seek to elicit any further information on this procedure through contacts that they may have with European Commission or ECDC staff on matters other than EURLs for public health during the call application and evaluation period.

WHERE CAN I FIND ANSWERED QUESTIONS FOR THESE CALLS FOR APPLICATIONS?

All questions for which answers are provided that are of interest to all applicants will be published as a Q&A on the website below:

https://health.ec.europa.eu/health-security-and-infectious-diseases/surveillance-and-early-warning/eu-reference-laboratories-public-health-calls-application_en

Once the information has been published on this website, it is considered to have been made available to all applicants. It is the responsibility of the applicants to regularly check and review the Q&A to use the provided information in the course of preparing their application.