



**ECDC opinion**

**Establishment of EU Reference Laboratories for public health – 2024**

Date: 12 March 2024

Version: 0.2

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List of acronyms

AF The ECDC Advisory Forum

AMR Antimicrobial Resistance

DSN Dedicated Surveillance Network

CCBs Coordinating Competent Bodies

ECDC The European Centre for Disease Prevention and Control

EC The European Commission

EURL EU Reference Laboratory

EQA External Quality Assessment

HaDEA The European Health and Digital Executive Agency

HSC TWG-Prep The Health Security Committee Technical Working Group on Preparedness

IMI Innovative Medicines Initiative

NFP National Focal Point

NFPS National Focal Points for Surveillance

NMFP National Focal Points for Microbiology

OCPs Operational Contact Points

SANTE The European Commission Directorate-General for Health and Food Safety

SRM ECDC’s Stakeholder Relationship Management system

WHO The World Health Organization

WHO CC A World Health Organization Collaborating Centre

1. Document purpose and preparation

The purpose of this document is to provide guidance for the European Commission’s Directorate-General for Health and Food Safety (SANTE) on the implementation of EURLs within the public health microbiology system This opinion will be revised and resubmitted to SANTE annually (at minimum until all current ECDC laboratory support contracts have been transitioned into the EURL system, where such transitions are supported), to present the current state of play with regards to EURL implementation issues, and to present the proposed list of diseases / health issues for which nomination and evaluation should be initiated each year. Revisions have also been made to this opinion to reflect experiences of and lessons learned from the selection and designation of the first set of EURLs for public health in 2023/2024. The NMFPs will be consulted on each revision of the ECDC opinion.

The number of diseases / health issues on the list included in each version of this opinion will depend on the budget allocated for EURL implementation in the EU4Health annual work programmes.

Decisions on EURL implementation issues will be made by SANTE.

1. Background
   1. Context of EURL implementation
      1. Legislative background

ECDC has been responsible for surveillance of communicable diseases at the European Union level since becoming operational in 2005. Its mandate gives ECDC the responsibility of creating, coordinating and operating EU surveillance networks. ECDC undertakes this work in collaboration with the Member States, and for some diseases with the World Health Organization (WHO) Regional Office for Europe.

In November 2022, two legislative documents were published that significantly impacted on ECDC’s mandate and activities with regards to EU-level laboratory support:

1. Regulation 2022/2370 that provides an amended mandate for ECDC that strengthens ECDC’s core mission to identify, assess and communicate current and emerging threats to human health from communicable diseases and related special health issues (1)
2. Regulation 2022/2371 on serious cross-border threats to health provided the legal mandate for the European Commission to designate EU reference laboratories also for public health (2).
   * 1. Disease and laboratory network model

One of the main modes of technical interaction between ECDC and the Member States is within the disease networks (3). Under its mandate, ECDC is given the responsibility for coordinating and operating EU surveillance networks, and also has a mandate to “encourage cooperation between expert and reference laboratories” and to “foster the development of sufficient capacity within the Community for the diagnosis, detection, identification and characterisation of infectious agents which may threaten public health” (1).

Before the creation of ECDC, dedicated surveillance networks (DSNs) in the field of public health were funded by the European Commission and operated through hubs in different Member States. Activities in most of the DSNs were transferred to ECDC at the end of 2011 and have been formalised as the ECDC disease networks composed, for a disease group, of National Focal Points (NFPs) and Operational Contact Points (OCPs) officially nominated by the Member States’ CCBs. These nominations are done through the ECDC Stakeholder Relationship Management (SRM) system as part of ECDC’s agreed process for managing the disease networks and Member State contacts (5).

As part of the disease networks, ECDC supports several sub-networks or consortia of public health microbiology laboratories in Member States, to enhance capabilities and strengthen capacity for pathogen detection, characterisation and surveillance of specific diseases and antimicrobial resistance. These laboratory (sub-)networks support activities, such as external quality assessments (EQAs) and training, that aim to strengthen capacity and harmonise methodologies to ensure comparability of data for surveillance purposes and to integrate epidemiological and microbiological surveillance of the EU notifiable communicable diseases.

* 1. EURL activity areas

The second subparagraph of Article 15 of Regulation 2022/2371 (2) describes the specific activity areas that the EURLs for public health may operate within:

1. reference diagnostics, including test protocols;
2. reference material resources;
3. external quality assessments;
4. scientific advice and technical assistance;
5. collaboration and research;
6. monitoring, alert notifications and support in outbreak response, including to emerging communicable diseases and pathogenic bacteria and viruses; and
7. training.

However, since the needs for laboratory support activities differ widely between individual diseases / health issues, the exact nature of the tasks of the individual EURLs will vary greatly and it is not expected that all EURLs will be asked to perform activities in all above listed areas. A detailed description of the tasks to be performed by each EURL will be specified in the calls for applications (see section 4.1.1 below).

* 1. Existing laboratory support through the ECDC disease networks

The laboratory networks have successfully implemented a range of activities to support EU-level public health microbiology, including in technical capacity building, quality assurance, epidemic intelligence and event response support, technology assessment, technical guidance and genomic surveillance.

A list of laboratory networks that ECDC is currently providing / has previously provided support for can be found in Table 1.

Table 1: List of laboratory networks that ECDC is currently providing / has previously provided support for

| **Network or project** | **Pathogens covered** |
| --- | --- |
| EARS-Net | *Staphylococcus aureus*, *Enterococcus faecalis*, *Enterococcus faecium*, *Streptococcus pneumoniae*, *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Acinetobacter baumannii* complex |
| EURGen-Net[[1]](#footnote-2) | Carbapenem- and/or colistin-resistant *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Acinetobacter baumannii* complex |
| HAI-Net CDI module | *Clostridioides* (*Clostridium*) *difficile* |
| EUCAST | Antimicrobial-resistant bacteria (standardisation of antimicrobial susceptibility testing) |
| EVD-LabNet | Emerging and vector-borne viral pathogens |
| FWD-Net[[2]](#footnote-3) | *Salmonella enterica*, Shiga toxin-producing *E. coli*, *Listeria monocytogenes, Campylobacter jejuni/ coli* |
| EuroCJD | vCJD |
| ERLI-Net | Influenza virus |
| Euro-GASP | *Neisseria gonorrhoeae* |
| Diphtheria-LabNet | *Corynebacterium diphtheriae* |
| EUPert-LabNet | *Bordetella pertussis* |
| IBD-LabNet | *Neisseria meningitidis, Streptococcus pneumoniae, Haemophilus influenzae* |
| ERLTB-Net | *Mycobacterium tuberculosis* complex |
| ELDSNet | *Legionella spp.* |
| ECOVID-LabNet | SARS-CoV-2 |

Prior to the introduction of EURLs for public health, the EU-level laboratory support is / has been funded from the ECDC budget but outsourced to a contractor through open procurement processes, with the disease networks and laboratory networks being coordinated by ECDC. In most cases, the contractor providing the laboratory support is also one or more of the laboratories in the respective laboratory networks.

* 1. Preparatory action

To support the process of establishing the EURL implementation plan, in 2023 SANTE funded a preparatory action through the EU4Health 2023 Annual Work Programme. The EUHealthSupport consortium was contracted by the European Health and Digital Executive Agency (HaDEA) to carry out a number of support activities, and the consortium consisted of Nivel (Netherlands Institute for Health Services Research – consortium lead), RIVM (scientific co-lead), RCSI University of Medicine and Health Sciences, Infeurope S. A., Association of medical schools in Europe e.V (AMSE e.V), Royal college of surgeons in Ireland (RCSI) and LEGINDA GmbH (all scientific partners). The preparatory action contract ran between 21 April and 20 November 2023, and the work of the consortium was coordinated by SANTE in consultation with ECDC.

The preparatory action focused on the mapping of relevant ongoing and/or finished projects and on supporting stakeholder consultations, both in the form of surveys on disease and EURL activities prioritisation and as webinars / online workshops.

* 1. Selection and designation of first set of EURLs for public health in 2023

On 2 October 2023, SANTE launched calls for applications for the first six EURLs for public health (6). These calls for applications contained full descriptions of the selection and designation processes, including the eligibility and selection criteria that were used for the application evaluation.

These calls for applications were initially set to close on 30 November 2023; however, the submission deadline was later extended to 5 January 2024. The evaluation of the applications was performed in January 2024, and all applicants were informed of the evaluation results on 1 February 2024.

1. EURL structure and activities
   1. EURL composition

An EURL for public health is required to offer laboratory support activities for either a single disease / health issue, or for multiple ones. In addition, all EURLs are required to meet a set of general eligibility criteria (see section 4.1.5 below). To ensure that the EURLs meet the eligibility criteria, all candidate laboratories must be formally endorsed by a national competent authority in public health; see sections 4.1 and 4.1.2 below.

An EURL may be made up of a single laboratory or of a consortium of laboratories, as shown in Figure 1. To ensure the successful implementation of activities without an excess of administration, a consortium may include a maximum of five laboratories.

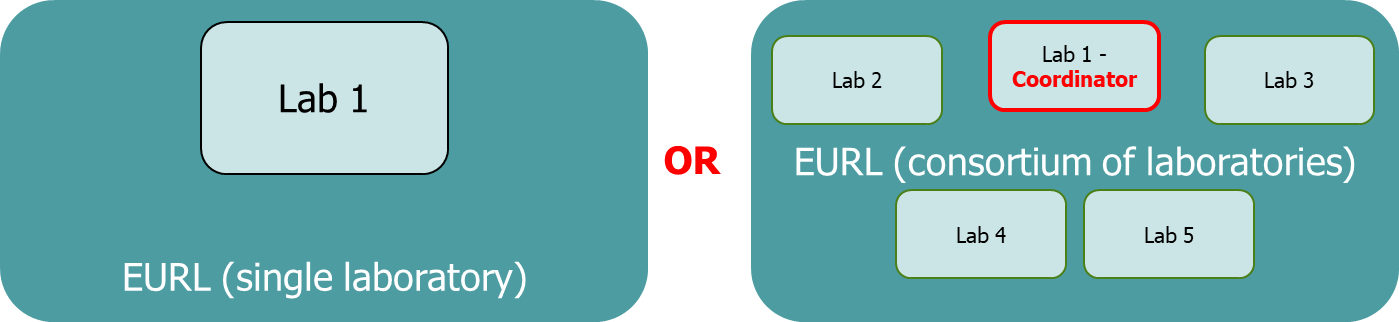


Figure 1: EURL composition – single laboratories vs consortia of maximum five laboratories

It is up to each candidate laboratory to decide if they alone meet the requirements and want to apply as a single laboratory, or if they prefer to join together with other nominated laboratories (from other countries or from within the same country) to submit a consortium application where the group of laboratories together meet the requirements and would jointly function as an EURL.

From an administrative point of view, a consortium approach requires one laboratory to be the administrative lead (i.e. the consortium coordinator) and main administrative contact point for HaDEA, with respect to the grant that should be allocated to all successful applicants (see section 4.4 below).

* 1. Integration into ECDC disease and laboratory   
     networks

The designated EURLs will be integrated into the disease and/or laboratory networks that ECDC will continue to coordinate, as shown in Figure 2:

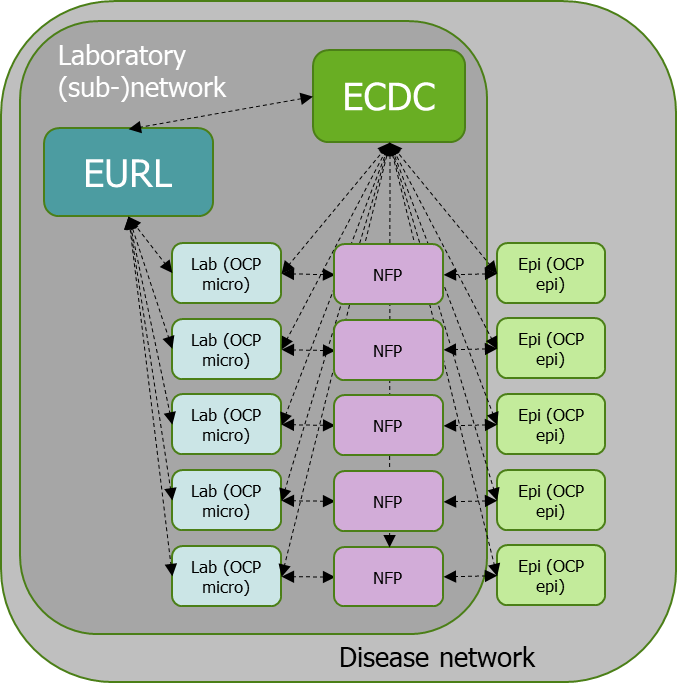


Figure 2: EURL integration into ECDC disease and laboratory (sub-)networks

While most of the laboratory networks will remain in their current forms, some modifications will be proposed for specific networks process. Some proposed changes are described in section 5.1.1 below.

* 1. EURL coordination

The EURLs shall have a coordination function and interact independently with the laboratory network members for the implementation of the activities under their agreed work plans.

According to Regulations 2022/2370 (1) and 2022/2371 (2), ECDC remains responsible for the overall coordination of infectious disease surveillance in the EU, including the coordination of the disease and laboratory (sub-)networks that the EURLs will be integrated into. This means that ECDC will continue to be responsible for infectious disease data collection and storage at the EU level, EU-level public health microbiology strategies, and coordination of the network of EURLs etc. All EURLs are required to coordinate their work with ECDC at regular intervals (see section 3.5.2.1 below).

* 1. Network of EURLs

As described in Regulation 2022/2371, ECDC should coordinate a network of the different EURLs to harmonise activities across disease areas and discuss cross-cutting aspects, such as templates, EQA reports, reporting to ECDC, Data and Material Transfer Agreements etc (2). The exact issues to be included under this work are proposed to be decided in collaboration with the designated EURLs.

Discussions on the structures and working processes for this network will be initiated in the second half of 2024 with the EURLs designated from the 2023 calls for applications.

* 1. EURL activities
     1. Disease-specific EURL activities

As described in section 2.2 above, all EURL activities must fall under one of the activity areas specified under the second subparagraph of Article 15 of Regulation 2022/2371 (2).

While all candidate laboratories will prepare and submit their own workplan(s) as part of the application process, it should be noted that each EURL will be required to perform a set of specific mandatory tasks, i.e. 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 in that field must provide them. These mandatory tasks are based on previous laboratory support activities carried out under contracts with ECDC, proposals for additional activities made by the laboratory network members and/or ECDC, and the outcome of the survey on EURL activities for each disease / group of diseases. Mandatory tasks are described in the calls for applications, and their number and scope vary between the different calls for applications.

* + 1. Activities common to all EURLs
       1. Communication with the laboratory network members

The EURLs for public health are required to communicate on a regular basis with the members of the network(s) that they are supporting, to inform the network members of their work and also get feedback on the EURL activities. The exact mode(s) of communication should be decided between each EURL and the disease network(s) in consultation with ECDC.

* + - 1. Coordination with ECDC

The EURLs must coordinate the implementation of their tasks with ECDC, to ensure alignment with other relevant activities coordinated by ECDC. The format of this coordination should be established between each EURL and ECDC, but could include regular coordination meetings, participation in meetings and events on relevant topics, etc. It is also anticipated that an EURL representative should participate as observer in the ECDC Disease Network Coordination Committee (DNCC) meetings of the network(s) that they are supporting (5).

All EURLs are required to prepare and submit annual work plans. These work plans will be reviewed and approved by ECDC to ensure alignment with related ECDC activities.

* + - 1. Coordination with other EURLs or relevant initiatives

Overlap and redundancy in activities between EURL and other laboratory support activities at international level should be avoided whenever possible. The EURLs are therefore required to exchange information and, where relevant, coordinate relevant activities with other bodies carrying EURLs for food, feed and animal health or in vitro diagnostics (IVD) addressing the same diseases / health issues, WHO Collaborating Centres (WHO CCs), or other relevant projects/initiatives.

For the implementation of the first set of EURLs in 2023/2024, ECDC will set up *ad hoc* procedures for the identification of complementary or overlapping activities. For EURLs to be implemented in 2024/2025 and beyond, more structured contacts with organisations setting up such activities should be organised by ECDC.

* + - 1. Organisation of laboratory network meetings

All EURLs should take an active role in organising (physical and/or virtual) network meetings for the laboratory network(s). These meetings could be separate meetings for the network, and/or be a part of / aligned with a full disease network meeting organised by ECDC. The call for applications document for each EURL will contain more specific information about meeting organisation requirements for each specific EURL.

EURLs will also be asked to propose meeting topics for full network meetings. These topics should be based on the work of the EURL and include the most relevant aspects for EU-level laboratory-based surveillance.

All network meeting dates and agendas must be decided upon after consultation and in agreement with ECDC.

* + - 1. Organisation of other meetings on topics under EURL remit

All EURLs may organise meetings for laboratory network members as needed for the implementation of their work plan. While ECDC should be consulted on and informed of all such plans, the EURLs will organise and execute such meetings independently.

* 1. EURL duration

While Regulation 2022/2371 on serious cross-border threats to health specifies that the EURLs shall be designated for a minimum of four years, the duration of each designation is specified in each call for applications (see section 4.1 below).

EURL performance will be regularly reviewed by SANTE in cooperation with ECDC and HaDEA, and each designation (and associated funding) may be terminated prematurely by SANTE (and HaDEA) if the EURL in question does not meet its contractual obligations.

* 1. Laboratory network members and contacts

The process for nomination of Member State laboratory network members will not change from the procedures already agreed with the ECDC CCBs (5).

ECDC will provide each EURL with the relevant contact information for the laboratory network(s) members from the ECDC SRM system. Appropriate GDPR-compliant measures should be put in place by the EURLs to ensure adequate data protection for the personal data that is included there.

* 1. Grant management, including reports and deliverables

Administrative questions and issues related to grant management should be discussed directly with HaDEA that will be managing the grants on behalf of SANTE. HaDEA may in turn consult SANTE and/or ECDC on any of these matters when they deem that such input would be useful.

Operational, technical and strategic questions should be discussed between the EURL and ECDC. Issues that are deemed to impact the grant management process will be referred to SANTE and/or HaDEA for further discussion.

All EURL reports and deliverables will formally be submitted by the EURL to HaDEA, as specified in the grant agreement. In collaboration with HaDEA and to ensure alignment between activities, ECDC should review and clear selected deliverables of the EURLs.

The EURLs should, whenever possible and relevant, share their reports and outputs with the laboratory network(s) they support. ECDC may provide templates and guidance for production of selected reports and outputs.

* 1. Data sharing and storage

The EURLs will collect and store data and information as needed for the implementation of the activities within their work plans. Although all information does not need to be systematically shared with ECDC, ECDC has the right to obtain any data or information collected by the EURL upon request.

Appropriate GDPR and national data protection measures must be put in place by the EURLs to ensure adequate data protection for the data it collects.

A Data Transfer Agreement defining aspects related to data sharing and use should be set up with each EURL. Generic Data Transfer Agreements and Material Transfer Agreements between EURLs and the laboratory network members should be discussed and set up through the network of EURLs (see section 3.4 above)

In its capacity as EURL, the EURLs should not conduct any systematic data collection related to surveillance or outbreak investigations. All such data should be collected through the ECDC systems, primarily EpiPulse.

* 1. Ownership of materials and data

As with data submitted by Member States to ECDC, ownership of materials (such as strains and samples) and data sent by Member States to the EURL remains with the sending/submitting country.

The EURL may make use of the data to fulfil their contractual obligations according to the grant agreement. However, publications and other use of the materials or data should not be authorised without the explicit consent of the materials/data owner.

1. Processes for application, evaluation and designation of EURLs for public health

The final processes for application, evaluation and designation of the first set of EURLs for public health were initially developed in August - September 2023, prior to the launch of the calls for applications on 2 October 2023. Since it is SANTE’s intention to continue to build upon these processes, this section has been revised to describe the processes of the 2023 calls for applications and, where relevant, propose changes and improvements to the different steps of the process.

* 1. Application process

This section contains a description of the application process as it was implemented in the EURLs for public health calls for applications published in 2023. Proposed changes to the various parts of this process can be found under each sub-section below.

* + 1. Calls for applications document

On 2 October 2023, the first calls for applications for EURLs in public health were published by SANTE; one call for each EURL under selection. Each call for applications document served as a detailed guide for the candidate laboratories to submit applications under the call, and included the following information:

* Field of the EURL, i.e. disease(s) / health issue(s) to be covered by the EURL
* Description of mandatory tasks for the EURL
* Description of scenarios to which the applicants were required to submit workplans, including scenario durations and indicative budgets
* Duration of the EURL designation
* EURL eligibility and selection criteria
* Description of the evaluation procedure
* Additional information / requirements pertaining to a consortium EURL applications
* Application form template and list of required supporting documentation
* Endorsement form template
* Application deadline

Once the calls had been published, ECDC notified its competent authorities (i.e. the ECDC Coordinating Competent Bodies [CCBs]), the NMFPs, and the members of the disease and/or laboratory networks that the EURLs under selection were expected to support.

Within their respective countries, the competent authorities were expected to share information about the call for applications promptly and equitably with all qualified laboratories that might have been interested in applying. In addition, three webinars (one public, one targeting potential applicants, and one targeting endorsing competent authorities) were organised to allow stakeholders and applicants to ask questions and get answers from SANTE and ECDC about the application processes.

**Suggested changes:**

For EURLs addressing multiple pathogens, the calls for applications document should be clearer about what pathogens applicants are required to address and what pathogens it will be considered as beneficial that the applicants address.

The concept and purpose of the so-called “fictitious scenarios” should be further described and explained, as these were the source of many questions from applicants. It is also suggested that the titles of the two scenarios should be changed to be more descriptive, for example “Basic scenario” (instead of “Fictitious scenario 1”) and “Expanded scenario” (instead of “Fictitious scenario 2”).

For the application form (Annex III of the calls for applications), it is suggested that a section should be added that asks applicants to describe their vision for the EURL and/or provide a description of the problems and issues their proposed activities will address. This would be particularly important for the “Expanded scenario” / “Fictitious scenario 2” where applicants’ workplans are expected to go further beyond the mandatory tasks.

The application form should also more clearly ask applicants to address resource prioritisation issues as a risk, i.e. describe how they would manage situations where EURL activities and priorities require the same resources at the same time (such as personnel) as the applicants’ own activities and priorities.

For some EURLs health crisis capacity is also of high importance, and where relevant this should be more directly addressed in the application form.

* + 1. Endorsement of candidate laboratories by competent authorities

Since many of the tasks of the EURLs for public health will require specialist expertise in public health microbiology, the 2023 calls for applications required that all applicants were endorsed by a national competent authority in public health. It was up to each country to decide which authority/-ies they deemed suited to provide these endorsements, although it was suggested in the call that the ECDC CCBs would be suitable since those had already been nominated by Member States to ECDC as national competent authorities in public health.

The national competent authorities endorsing applicants were asked to confirm that each candidate laboratory met the eligibility criteria of the call. To endorse an applicant, the national competent authority filled out and signed the endorsement form annexed (as Annex I) to the call for applications. The national competent authorities were allowed to endorse more than one candidate laboratory per topic (provided that each of them met the eligibility criteria), and candidate laboratories could be endorsed and apply for more than one EURL topic (i.e. for two different diseases / health issues).

While the national competent authorities endorsed the individual candidate laboratories, they were not required to see or review the applications that the candidate laboratories submitted.

**Suggested changes:**

The endorsement of applicants in the 2023 call was generally deemed successful, in that all applicants were deemed eligible by the evaluation panel. At the application stage however, not knowing the identity of the national competent authorities endorsing candidate laboratories (and potentially having multiple endorsing competent authorities for one country) was quite challenging in terms of communication, both for the applicants, the national competent authorities themselves, and for ECDC. It is therefore suggested that prior to the launch of the 2024 calls for application, each Member State should be asked to formally nominate one national competent authority in public health that will be responsible for the endorsement of applicants from that country for the calls for applications for EURLs for public health. These nominations could be done through a request by SANTE to the Permanent Representations to the EU along already established procedures.

While a majority of the applications received in response to the 2023 calls for applications were of high to very high quality, some applicants had not fully understood the purpose and role expected of them as an EURL for public health. To increase feedback on the evaluation outcome to the national competent authorities, it is therefore suggested that all national competent authorities should receive a copy of all application evaluation reports for which they have endorsed candidate laboratories.

* + 1. Preparation and submission of applications

For the 2023 calls for applications, applicants could be a single laboratory or a consortium of a maximum of five laboratories (as set out in section 3.1 above; see also section 4.1.4 below for more information on consortia). Each laboratory was only allowed to apply to each field once, i.e. either as a single laboratory applicant or as a member of a consortium applicant.

Applicants were asked to prepare their application in accordance with the information included in the call for applications document using the application form template that was annexed (as Annex III) to the call for applications document.

Applicants were required to submit their applications by the deadline specified in the call for applications through EUSurvey, the European Commission's official survey management tool (7). There was no requirement that the applicant representative that created and submitted the application must have a registered EU Login account; however, applicant representatives that created applications without being signed in to EUSurvey through EU Login did not receive confirmation emails that their applications had been successfully submitted.

**Suggested changes:**

To ensure that all applicants receive application submission confirmation emails, it is suggested that all applicant representatives that will be creating and submitting applications should be required to register and login to EUSurvey using EU Login.

To facilitate the preparation of the implementing act designating the successful applicants, it is suggested that the application form should be updated to request official addresses for all members of the consortium.

* + 1. Issues related to consortium applications

In the 2023 calls for applications and in line with section 3.1 above, a “consortium” was 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 for public health in the field <*specific field of the EURL*>”. Each consortium had to designate one of the consortium members as the coordinator, that submitted the application on behalf of the consortium. It was also stated that if their application would be successful, members of that consortium would be jointly and severally liable for carrying out the tasks of the EURL, something that all consortium members had to confirm through the submission of signed declarations (based on a templated annexed to the calls for applications).

Each member of the applicant consortium was required to meet the eligibility criteria and be individually endorsed by their respective national competent authorities. In addition, the consortium as a whole was required to cover the all the mandatory tasks of the EURL as specified in the calls for applications, and the work plan(s) of the consortium had to demonstrate coherence and complementarity within the consortium members including division of tasks and responsibilities and the exchange of knowledge. Consortium applicants were therefore assessed the selection criteria as a group; it was not required that members of the consortium meet all of the selection criteria individually.

**Suggested changes:**

No changes are suggested to the definition of consortia nor to the processes and mechanisms used for managing consortia in the 2023 calls for applications.

* + - 1. Finding consortium partners

For the 2023 calls for applications, ECDC operated a service to put laboratories in contact with other laboratories potentially interested forming a consortium and submitting an EURL application in a specific field.

Eligible laboratories interested in this service sent an email to ECDC indicating the call ID, EURL field, laboratory name, and contact details (name, email address and phone number) of the main contact person. ECDC then placed this information in a restricted access Excel file on an ECDC SharePoint site for which access was only granted to the named contact persons who received individual emails informing them on how to access the information.

**Suggested changes:**

While the service was set up within a few days of the publication of the 2023 calls for applications, there were some delays from the ECDC side in granting access, and some contact persons struggled to access the information even after access had been correctly granted from the IT side. It should be discussed with Member States (as represented by the NMFPs) whether there is sufficient added value of the consortium partner finding service to continue operating it for future calls, and if so what changes would need to be done to improve the usefulness of the service.

* + 1. Eligibility criteria

The 2023 calls for applications stated that eligible candidate laboratories must:

* Be based in an EU Member State or an EEA country; and
* Play an active role in a national public health microbiology system

In addition, the designated EURLs were required to meet the requirements specified in Article 15(5) of Regulation 2022/2371:

1. be impartial, free from any conflict of interest, and, in particular, not be in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as EU reference laboratories;
2. have, or have contractual access to, suitably qualified staff with adequate training in their area of competence;
3. possess, or have access to, the infrastructure, equipment and products necessary to carry out the tasks assigned to them;
4. ensure that their staff and any contractually engaged staff have good knowledge of international standards and practices, and that the latest developments in research at national, Union and international levels are taken into account in their work;
5. be equipped, or have access to, the necessary equipment to perform their tasks in emergency situations; and
6. where relevant, be equipped to comply with relevant biosecurity standards.

Clarifications were provided on these requirements as follows:

Regarding requirement (a): The aim was to ensure that the designated EURLs did not have any relevant conflict of interest which may affect the impartiality of their professional conduct or commitment as regards the exercise of their tasks as EURL. Such conflicts of interest may have existed due to reasons involving economic interest, political affinity, family or any other shared interest. While some conflicts of interest are direct, applicants were also asked consider any other situation that could cast doubt on their ability to perform the EURL tasks impartially, or that could reasonably appear to do so in the eyes of an outside third party.

Applicants were required to self-assess what relevant conflicts of interest may exist for them with regards to the required tasks of each EURL and document this assessment in the application. The applicants that found that such potential conflicts of interest existed, were requested to declare these in the application form for further assessment by the evaluation panel.

Regarding requirements (b) and (c): While outsourcing of minor parts of activities was not excluded, applicants were expected to carry out the main elements of the EURL activities within their own organisations.

Regarding requirement (d): It was up to the relevant national competent authorities to determine what international standards and practices were relevant for the requested work of the EURL, and to ensure that the applicant appropriately met these standards.

Regarding requirement (f): It was up to the relevant national competent authorities to determine what biosecurity standards were relevant for the requested work of the EURL, and to ensure that the applicant appropriately met these standards.

**Suggested changes:**

No changes are suggested to the eligibility criteria used for the 2023 calls for applications.

* + 1. Selection criteria

The selection criteria of the 2023 calls for applications were intended to allow evaluating the scientific excellence of the application, as well as applicant’s ability and capacity to perform the role of an EURL for public health in the field of AMR in bacteria. Up to 100 points were awarded for the four criteria below. There was a threshold of 60% for each individual criterion in order to pass the evaluation.

Table 2: Selection criteria and maximum points used for the evaluation of applications submitted in response to the 2023 calls for applications for EURLs for public health

| **Criterion** | **Sub-criteria** | **Max points  (pass threshold)** |
| --- | --- | --- |
| ***Understanding of the EURL purpose and role*** | **Purpose** – This sub-criterion assesses the extent to which the applicant demonstrates an appropriate understanding of the purpose of laboratory support activities within the EU-level public health landscape  **Role** – This sub-criterion assesses the extent to which the applicant appropriately identifies and describes the role of the EURL with regards to the relevant stakeholders at the EU and national level public health systems | **15 (9)** |
| ***Quality of the proposed activities and impact*** | **Quality of the workplans –** This sub-criterion assesses the quality and appropriateness of the applicant’s proposed workplans, i.e. the scope and ambition of the workplans, the relevance and pertinence of the included activities, the quality and appropriateness of the proposed methods for carrying out the tasks and actions, and the logic and cohesion of each workplan as a whole  **Organisation of the work –** This sub-criterion assesses the overall organisation of the work, i.e. overall planning (including, where relevant, within the consortium), and risk identification and mitigation  **Impact** – This sub-criterion assesses potential impact of the applicant’s proposed activities, i.e. how EU-level public health as well as the different stakeholders would benefit from the proposed activities | **45 (27)** |
| ***Team composition, knowledge and experience*** | **Scientific and technical qualifications** **and experience** – This sub-criterion assesses the degree to which the applicant demonstrates that their team possesses the scientific and technical qualifications required for carrying out the proposed activities, including any relevant experience of carrying out similar work  **Team composition** **and resource availability** – This sub-criterion assesses the degree to which the applicant demonstrates that organization of the team will allow the use of the appropriate resources (including equipment and infrastructure) to deliver the proposed activities as planned | **25 (15)** |
| ***Coordination capacity*** | **Coordination with the members of laboratory network(s)** – This sub-criterion assesses the quality and appropriateness of the applicant’s approach and plan for the coordination with the members of the laboratory network(s)  **Coordination with ECDC** – This sub-criterion will assess the quality and appropriateness of the applicant’s approach and plan for the coordination with ECDC | **15 (9)** |
| **Total maximum points** | | **100 (60)** |

**Suggested changes:**

During the evaluation of the applications submitted in response to the 2023 calls for applications, the evaluators found that the sub-criteria on EURL role and purpose were somewhat overlapping. The evaluation panel therefore recommended that these sub-criteria should be merged for future evaluations.

* 1. Evaluation process

To evaluate the 2023 EURL for public health applications, an evaluation panel was set up that consisted of experts from ECDC and SANTE, as well as of external, independent experts with specific expertise beneficial to the EURL evaluation. These external experts were contracted by SANTE according to standard European Commission guidelines on expert contracting. The independence and lack of conflicts of interest of all members of the evaluation panel was checked partly based on CVs and partly on self-declaration on potential conflicts of interest by the experts, again according to standard European Commission guidelines.

The evaluation panel verified the applicants’ compliance with the eligibility criteria and assessed each application against the selection criteria. For each application an application evaluation report was drawn up, which included the assessment scores and comments made by the evaluators on each of the selection criteria, as well as (for applications above all pass thresholds) recommendations for changes and/or additions in case the application would be successful.

The successful applicants were the eligible applicants whose applications were awarded individual criterion scores that exceeded all pass thresholds for the selection criteria and were awarded the highest total score against the selection criteria out of all the applications evaluated within each field.

All applicants received their application evaluation report together with an evaluation result letter with information on whether their application has been successful or unsuccessful. The evaluation result letters to the unsuccessful applicants also described a complaints procedure if they believed that the evaluation of their application had been flawed in some way.

**Suggested changes:**

No significant changes are proposed to the overall evaluation process. Some minor changes (e.g. the inclusion into the application evaluation report of recommendations for changes and/or additions in case the application would be successful) were implemented during the evaluation of the 2023 EURL for public health applications.

* 1. Designation process

Following the evaluation of the applications received in response to the 2023 calls for applications, the list of successful applicants (one for each EURL topic) was included by SANTE in the draft Implementing Act for designation of EURLs for public health. The act identifies the laboratories (or consortium of laboratories) and the scope of their designation, i.e. the disease(s) / health issue(s) each of them will cover. It is expected that this act should be adopted in early April 2024.

**Suggested changes:**

There are no suggested changes to the designation process, since the process for adopting an Implementing Act is a legally regulated process agreed between the EU and its Member States.

* 1. Funding process

Designated EURLs will be invited to submit a proposal under the EU4Health program to cover the costs they will incur when implementing their EURL activities. Standard EU4Health rules and procedures will apply for the evaluation and grant preparation phases, with the end result being a grant agreement established between each designated EURL and HaDEA.

The EU4Health funding should be provided as EU action grants with a 100% reimbursement rate for incurred costs, up to a maximum amount specified in the call for proposals.

**Suggested changes:**

There are no suggested changes to the funding process, since the rules and processes for the EU4Health programme have been agreed between the EU and its Member States through a legal act (8).

1. Diseases / groups of diseases for EURL implementation
   1. Proposed list of public health EURLs for implementation

Table 3 contains ECDC’s current proposed list of EURLs for public health for implementation. It should be noted that this list exclusively covers communicable diseases / health issues under ECDC’s mandate. All discussions on EURLs for other areas (e.g. threats of chemical or environmental origin) of relevance for the implementation of Regulation 2022/2371 should be managed by SANTE (2).

In terms of establishing the public health EURLs, ECDC proposes to prioritise the transition of the current laboratory support from ECDC outsourced contracts to the EURL model whilst also looking at the wider needs for communicable diseases under EU surveillance.

The list in Table 3 has been revised to indicate which EURLs are in the process of being designated following the 2023 calls for applications. ECDC also proposes that this list should continue to be reviewed and revised on an annual basis until at minimum all current ECDC laboratory support contracts have been successfully transitioned to the EURL model.

Table 3: ECDC’s current proposed list of EURLs for public health for implementation

| **EURL** | **Disease(s) / Health issues** | **Supporting laboratory network(s)** | **Status** | **Rationale for proposed modification (compared to 2023 version of ECDC opinion)** |
| --- | --- | --- | --- | --- |
| Antimicrobial Resistance (AMR) in bacteria[[3]](#footnote-4) | Antimicrobial Resistance (AMR) in *Staphylococcus aureus*, *Enterococcus faecalis*, *Enterococcus faecium*, *Streptococcus pneumoniae*, etc.  Antimicrobial Resistance (AMR) in *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Acinetobacter* spp., etc. | EARS-Net EURGen-Net | Under designation (2023 call for applications) |  |
| Vector-borne viral pathogens | Vector-borne viral diseases caused by flaviviruses (e.g. dengue virus, Japanese encephalitis virus, tick-borne encephalitis virus, West Nile virus, yellow fever virus, Zika virus), alphaviruses (e.g. chikungunya virus, Sindbis virus), bunyaviruses (e.g. Crimean-Congo haemorrhagic fever virus, Rift Valley fever virus, Toscana virus), and arboviruses in other virus families | Laboratory sub-network of EVD network | Under designation (2023 call for applications) |  |
| Emerging, rodent-borne and zoonotic viral pathogens | Emerging, rodent-borne and zoonotic viral diseases caused by arenaviruses, filoviruses, hantaviruses, henipaviruses, lyssaviruses, poxviruses and viral “Disease X” | Laboratory sub-network of EVD network | Under designation (2023 call for applications) |  |
| High risk, emerging and zoonotic bacterial pathogens | High risk, emerging and zoonotic bacterial diseases (e.g., anthrax, brucellosis, glanders, leptospirosis, Lyme borreliosis, melioidosis, plague, Q fever, rickettsiosis, tularaemia) that are not covered by other planned EURLs for public health | Laboratory sub-network of EVD and FWD network | Under designation (2023 call for applications) |  |
| Diphtheria and Pertussis | Diphtheria and Pertussis | To-be-joined network of Diphtheria-LabNet AND EUPert-LabNet | Under designation (2023 call for applications) |  |
| Legionella | Legionellosis | ELDSNet | Under designation (2023 call for applications) |  |
| Food- and water-borne bacteria | Infections with *Salmonella* spp. (including AMR), shiga toxin-producing *E. coli* (STEC), *Listeria monocytogenes*, *Campylobacter* spp. (including AMR), *Shigella* spp. (including AMR) and other food- and waterborne bacteria of public health relevance (e.g. *Vibrio* spp., *Yersinia* spp. (excluding *Y. pestis*)) | FWD-Net | Proposed for implementation under 2024 call for applications | A merge is proposed of the previously pathogen-specific EURLs for the key food- and water-borne bacteria. The merge is intended to facilitate the coordination and harmonisation of activities for these pathogens, many of which are handled by the same laboratories in the Member States. In addition, many of the expected EURL tasks are similar across the pathogens, where activities on typing has been in focus for the EU level surveillance and outbreak detection for these bacteria. A merge would also allow the addition of *Shigella* spp. a common food-borne pathogen within the EU/EEA where typing is important in investigation of cross border outbreaks, and to a lesser extent *Yersinia* spp. (excluding *Y. pestis*) and *Vibrio* spp (*Vibrio* *cholerae* and non-cholerae *Vibrio* spp.). where the latter poses a threat connected to climate change with increasing water temperatures.  As antimicrobial resistance surveillance is another backbone of FWD surveillance, with joint One Health reports together with both EFSA and EMA and provision of data to WHO GLASS, it is proposed that AMR typing support, both phenotypic and genotypic, for *Salmonella*, *Campylobacter* and *Shigella* should also be covered by this EURL. |
| Food- and water-borne viruses | Infections with hepatitis A virus and other food- and water-borne viruses of public health relevance (e.g. Hepatitis E virus) and other food- and water-borne viruses of public health relevance | FWD-Net | Proposed for implementation under 2024 call for applications | Added from list of “Additional diseases / health issues under consideration for EU-level laboratory support” (see section 5.1.2 below).  Hepatitis A is a notifiable disease in the majority of EU/EEA countries and under EU level surveillance. The virus is a common foodborne pathogen with a high frequency of national and cross border outbreaks, some also caused by sexual transmission. For the investigation of outbreaks, when doing source attribution or when assessing the exposure for different risk groups, typing of the virus is necessary and the current typing capacity varies a lot between countries.  Hepatitis E can also cause national and cross border foodborne outbreaks and subtyping is often needed to verify sources and routes for transmission. In addition, over the last ten years, hepatitis E cases have been increasingly reported in Europe, thus justifying enhanced laboratory preparedness support. For outbreak detection and investigation, harmonised typing methods and capacity building support for typing is needed both for national and EU level surveillance purposes. |
| Food-, water- and vector-borne helminths and protozoa[[4]](#footnote-5) | Infections with *Echinococcus spp., Toxoplasma gondii, Trichinella spp.,* and *Plasmodium spp.* but also other helminths and protozoa of public health relevance (e.g. *Cryptosporidium*, *Giardia*, *Leishmania*, *Trypanosoma*, *Schistosoma*, and *Taenia solium*) | FWD-Net | Proposed for implementation under 2024 call for applications | Added from list of “Additional diseases / health issues under consideration for EU-level laboratory support” (see section 5.1.2 below)  While several of the food-, water- and vector-borne helminths and protozoa are currently rare in the EU/EEA, some cause very severe disease and the rate of underdiagnosis is large. There is therefore a need to improve the diagnostic capacity in the Member States and for some diseases, the typing capability to be able to trace emerging types. The prevalence and exposure to several of these pathogens is also anticipated to increase in the EU/EEA with climate change. |
| Healthcare-associated infections caused by *Clostridioides* (*Clostridium*) *difficile* | *Clostridioides* (*Clostridium*) *difficile* infections | HAI-Net CDI | To be scheduled at a later date |  |
| (Antimicrobial resistant) Gonorrhoea | Gonorrhoea | Euro-GASP | To be scheduled at a later date |  |
| Influenza | Influenza | To-be-joined network of ERLI-Net AND ECOVID-LabNet | To be scheduled at a later date |  |
| SARS-CoV-2 | COVID-19 | To-be-joined network of ERLI-Net AND ECOVID-LabNet | To be scheduled at a later date |  |
| Tuberculosis | Tuberculosis | ERLTB-Net | To be scheduled at a later date |  |
| Invasive Bacterial Diseases | Meningococcal Disease, Haemophilus Influenzae Type B Infection, Invasive Pneumococcal Disease | IBD-LabNet | To be scheduled at a later date |  |

* + 1. Proposed changes to the laboratory networks

In general, part of the EURL implementation process will involve working with Member States to review and, if necessary, identify potential changes to the nominations for the roles affected by each implementation. More specifically, the following laboratory networks are proposed to be merged due to strong synergy effects identified between the network activities, and a high degree of overlap between network members:

* ERLI-Net and ECOVID-LabNet
* Diphtheria-LabNet and EUPert-LabNet

In-depth discussions with the concerned networks should be initiated with the goal to discuss and agree on a plan for these network merges could be managed.

* + 1. Additional diseases / health issues under consideration for EURL implementation

In addition to the proposed list of EURLs for implementation, Table 4 contains a list of additional diseases / health issues under consideration for EU-level laboratory support under the EURL system.

Depending on the stakeholders’ opinion on the usefulness and public health added value of laboratory support for these diseases, these may be added to the list of proposed EURLs for implementation in future revisions of this opinion.

Table 4: Additional diseases / health issues under consideration for EU-level laboratory support under the EURL system

| **Potential EURL function** | **Disease(s) / Health issues** | **Network** | **Rationale for proposed modification (compared to 2023 version of ECDC opinion)** |
| --- | --- | --- | --- |
| Arthropod vectors | Arthropod vectors, including mosquitoes, fleas, sand flies, lice, fleas, ticks, mites, etc. | EVD network | VectorNet will continue covering several aspects of arthropod vectors of infectious diseases. Therefore, the public health need for EU-level expertise on arthropod vectors will be partially covered by VectorNet; but in longer term, the establishment of an EURL with arachno-entomology profile remains relevant. |
| RSV | Respiratory syncytial virus infection | EISN AND ECOVID-Net | Activities of IMI project PROMISE[[5]](#footnote-6) to be taken into account.  If implemented, to be included in an EURL with Influenza. |
| vCJD | Variant Creutzfeldt-Jakob Disease | FWD-Net | Previous laboratory support terminated based on ECDC priorities |
| Food- and waterborne parasites | Echinococcosis, cyclosporiasis, cryptosporidiosis, trichinellosis, giardiasis | FWD-Net | Proposed for implementation in 2024 |
| Food- and waterborne viruses | Hepatitis A, hepatitis E, Norovirus infection | FWD-Net | Proposed for implementation in 2024 |
| Shigella | Shigellosis | FWD-Net | Proposed for implementation in 2024 |

* 1. Proposed EURLs for implementation in 2024/2025

There are EUR 7.5 M available under the EU4Health 2024 Work Programme (topic CP-g-24-1) for the implementation of grants for the funding of EURLs selected and designated in 2024 (4).

ECDC has prepared the proposal in Table 5 on the public health EURLs for implementation in 2024/2025. This list takes into account factors such as EC priority areas, current public health needs, and results from the stakeholder survey and from the public webinar held in August 2023.

Table 5: Proposed diseases for EURL implementation in 2024/2025

|  |  |
| --- | --- |
| **EURL** | **Disease(s) / Health issues** |
| Food- and water-borne bacteria | Infections with Salmonella spp. (including AMR), Shiga toxin-producing E. coli (STEC), Listeria monocytogenes, Campylobacter spp. (including AMR), Shigella spp. (including AMR) and other food- and waterborne bacteria of public health relevance (e.g. Vibrio spp. and Yersinia spp. (excluding Y. pestis) |
| Food- and water-borne viruses | Infections with hepatitis A virus and other food- and water-borne viruses of public health relevance (e.g. HEV) |
| Food-, water- and vector-borne helminths and protozoa | Infections with Echinococcus spp., Toxoplasma gondii, Trichinella spp., and Plasmodium spp. but also other helminths and protozoa of public health relevance (e.g. Cryptosporidium spp., Giardia lamblia, Leishmania, Schistosoma, and Taenia solium) |

* 1. Timelines
     1. EURLs implemented in 2024/2025

It is estimated that the call for applications for the EURLs to be implemented in 2024/2025 will be published by SANTE in early May 2024, with an indicative application submission deadline mid-August 2024.

The evaluation of applications is anticipated to take place in late August-September 2024, followed by the formal designation of EURLs by mid-December 2024.

The call for proposals for the funding of the designated EURLs is currently planned to be launched in late December 2024.

The operational launch of these EURLs is anticipated to take place towards the end of 2025 or early 2026.

* + 1. EURLs implemented in 2025/2026 and onwards

Detailed timetables for each respective implementation will be included in the revised ECDC opinions.

1. Outstanding / On-going issues
   1. Role and involvement of WHO

For some diseases/disease areas, ECDC are currently undertaking surveillance, network coordination and support activities in collaboration with the World Health Organization (WHO) Regional Office for Europe. This includes for example networks for influenza, SARS-CoV-2, tuberculosis and HIV/AIDS. Collaborative activities between WHO and ECDC include joint (physical and virtual) network and technical meetings, data collections from wider European region for surveillance and outbreak investigation purposes, etc.

Higher-level meetings and discussions regarding the collaboration and coordination with WHO on EURL implementation have been had between SANTE, ECDC and WHO, and it is anticipated that these should continue at regular intervals. Discussions on coordination, information exchanges and collaboration mechanisms for specific diseases / in specific fields will be elaborated through dedicated meetings between designated EURL(s), ECDC, WHO and the relevant WHO CCs.

* 1. Inclusion of laboratories in Western Balkan countries in EURL-managed activities

Most of the current and previous laboratory support contracts managed by ECDC has allowed the participation of laboratories from the Western Balkan countries (i.e. Albania, Bosnia and Herzegovina, Kosovo[[6]](#footnote-7), Montenegro, North Macedonia, and Serbia) in the support activities offered to members of the laboratory networks.

The EU4Health programme does not currently support the systematic funding of participants from all the Western Balkan countries. However, the continued inclusion of national reference laboratories of the Western Balkan countries in laboratory support activities organised by the EURLs for public health could be considered on a case-by-case basis, provided that this is justified by EU public health needs. Longer-term, options for funding mechanisms for laboratory support to these countries should be discussed with the relevant EU services.

* 1. Standardisation of EURL (and disease network) naming and structures

In the past, as part of defining the CCB structures (5), ECDC undertook work to standardise the structure and processes of its disease networks. The EURL implementation provides an opportunity to further reduce the remaining differences in how its disease and laboratory networks are named and managed (where such differences are not justified by specific contexts), in order to create a more harmonised approach to network management and EURL integration. Affected networks will be invited to contribute to this work as needed.

* 1. Cross-sectoral (One Health) EURLs

The creation of cross-sectoral EURLs, i.e. EURLs that address certain diseases across more than one sector such as public health, food- feed- and animal health, etc., may be of interest for promoting a One Health approach. From discussions with relevant EC services this would however be a longer-term goal, as several implementation issues (funding programme(s), duration, selection mechanisms and processes, etc.) would need to be carefully coordinated.

Advantages of and challenges with cross-sectoral EURLs have been identified as one of the longer-term topics for discussion at future stakeholder meetings.

1. References
2. Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control;   
   <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32022R2370>
3. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU; <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R2371>
4. ECDC Disease and laboratory networks;   
   [https://www.ecdc.europa.eu/en/about-ecdc/what-we-do/partners-and-networks/disease-and-laboratory-networks](https://www.ecdc.europa.eu/en/about-ecdc/what-we-do/partners-and-networks/disease-and-laboratory-networks%20)
5. EU4Health 2024 Work Programme;  
   <https://health.ec.europa.eu/publications/2024-eu4health-work-programme_en>
6. Coordinating Competent Bodies: structures, interactions and terms of reference, 7 December 2012; <https://www.ecdc.europa.eu/sites/default/files/media/en/aboutus/governance/competent-bodies/Documents/coordinating-competent-bodies-structures-terms-of-reference-and-interactions-w-Annexes.pdf>
7. EU Reference Laboratories for public health - calls for application; European Commission Directorate-General for Health and Food Safety;   
   <https://health.ec.europa.eu/health-security-and-infectious-diseases/surveillance-and-early-warning/eu-reference-laboratories-public-health-calls-application_en>
8. EUSurvey;   
   <https://ec.europa.eu/eusurvey/home/welcome>
9. Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health (‘EU4Health Programme’) for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (Text with EEA relevance)  
   <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2021.107.01.0001.01.ENG>

1. Capacity-building support also provided in 2021-2024 through the EURGen-RefLabCap project managed by HaDEA; <https://www.eurgen-reflabcap.eu/> [↑](#footnote-ref-2)
2. Capacity-building support also provided in 2021-2024 through the FWD-AMR-RefLabCap project managed by HaDEA; <https://www.fwdamr-reflabcap.eu/> [↑](#footnote-ref-3)
3. Except for AMR issues related to *Salmonella* spp., *Campylobacter* spp. and *Neisseria gonorrhoeae* [↑](#footnote-ref-4)
4. As currently no fungal diseases are under indicator-based epidemiological surveillance in the EU/EEA, the EURL function for fungal diseases was removed from the proposal. However, should the epidemiological situation justify it, the establishment of an EURL for fungal pathogens could be considered in the future. [↑](#footnote-ref-5)
5. PROMISE (Preparing for RSV Immunisation and Surveillance in Europe) is a research and innovation action funded by IMI 2021-2024; <https://imi-promise.eu/> [↑](#footnote-ref-6)
6. This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence [↑](#footnote-ref-7)