Call for Applications for the Designation of an EU Reference Laboratory for Public Health in the field of *Legionella*

Terms of Reference

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1.0	02.10.2023	▪ Initial version.
1.1	29.11.2023	▪ Submission deadline changed to 5 January 2024.

CALL FOR APPLICATIONS FOR THE DESIGNATION OF AN EU REFERENCE LABORATORY FOR PUBLIC HEALTH IN THE FIELD OF *LEGIONELLA*

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LIST OF ACRONYMS

CCB	Coordinating Competent Body
DNCC	Disease Network Coordination Committee
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EQA	External Quality Assessment
ELDSNet	European Legionnaires' Disease Surveillance Network
EU	European Union
EURL	EU Reference Laboratory
EVA	ECDC Virtual Academy
GDPR	General Data Protection Regulation
IVD	In Vitro Diagnostics
ISO	International Organization for Standardization
LD	Legionnaires' Disease
NFP	National Focal Point
OCP	Operational Contact Point
SRM	ECDC's Stakeholder Relationship Management system
TALD	Travel-associated Legionnaires' Disease
WGS	Whole Genome Sequencing
WHO	World Health Organization
WHO CC	A World Health Organization Collaborating Centre

1 INTRODUCTION

1.1 PURPOSE

The purpose of this call for applications is for the European Commission to invite laboratories in the EU Member States and EEA countries to submit applications in view of their possible designation as EU reference laboratory (EURL) for public health in the field of *Legionella*, in accordance with Article 15 of Regulation (EU) 2022/2371 on serious cross-border threats to health, adopted on 23 November 2022. (1)

1.2 LEGAL FRAMEWORK

The legal basis for the EURLs for public health is set out primarily in Article 15 of Regulation 2022/2371. (1) The ECDC role for coordination of dedicated networks is described in Regulation 2022/2370. (2)

1.2.1 Activity areas and characteristics of the EURLs

EURLs in the area of public health should 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.

Article 15(2) states that the EU reference laboratories shall be responsible for coordinating the network of national reference laboratories, in particular, in the following areas: (1)

(a) reference diagnostics, including test protocols;

(b) reference material resources;

(c) external quality assessments;

(d) scientific advice and technical assistance;

(e) collaboration and research;

(f) monitoring, alert notifications and support in outbreak response, including to emerging communicable diseases and pathogenic bacteria and viruses; and

(g) training.

Article 15(3) states that the harmonise activities across disease the ECDC, in cooperation with the WHO reference laboratories. The governance structure of that network shall cover cooperation and coordination with existing national and regional reference laboratories and networks. (1)

1.2.2 Designation of EURLs

In accordance with Article 15(1), the European Commission may, by means of implementing acts, designate EU reference laboratories in the area of public health or for specific areas of public health relevant for the implementation of Regulation 2022/2371 or of the national prevention, preparedness and response plans.

The designations provided shall follow a public selection process, be limited in time, with a minimum period for designation of four years, and be reviewed regularly. (1)

1.3 GENERAL INFORMATION

The call is available in English only. English will be the working language for this call, and applications must be completed in English. If requested, supporting documents should as much as possible be provided in English, except where it would be unavailable, such as national accreditation certificates or other proof of competence in the form of certificates.

Submission of an application following this call implies acceptance by the applicant(s) and the endorsing national competent authority/-ies of all provisions and conditions stipulated in this call.

No reimbursement will be provided for any expenses incurred in the preparation and submission of applications under this call.

This call does not constitute an obligation on the European Commission to designate an EURL in this field.

2 SCOPE OF THE CALL

2.1 EURL TOPIC

The field in which the EURL for public health is to be selected under this call is *Legionella*.

2.2 DESCRIPTION OF THE EURL AND RELEVANT DISEASE / LABORATORY NETWORK(S)

2.2.1 Description of the EURL

With the establishment of the EURL for public health in the field of *Legionella*, the European Commission aims to strengthen and support work in this field. The future EURL shall provide support to the members of the laboratory aspects of the ECDC European Legionnaires' Disease Surveillance Network (ELDSNet) on issues related to diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases.

As Regulation 2022/2371 designates ECDC to coordinate the EURLs' work, the selected EURLs will be integrated into and form an integral part of ECDC's existing networks and structures. For the implementation of the activities under their agreed workplan, the EURL for *Legionella* shall have a coordination function for the laboratory sub-network of ELDSNet consisting of the National Focal Points for Legionnaires' disease (NFP LD) and the Operational Contact Points (OCPs) for Microbiology for Legionnaires' disease.

The nomination of laboratory 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. (3)

2.2.2 Description of the relevant existing disease / laboratory network(s)

The European Legionnaires' disease Surveillance Network (ELDSNet) consists of NFP LD and OCPs for Epidemiology and Microbiology for Legionellosis. Epidemiological and microbiological surveillance data on *Legionella* related to surveillance activities for Legionnaires' disease are collected through the European Surveillance System TESSy.

Near 'real-time' surveillance of travel-associated Legionnaires' disease (TALD) is a

core activity of ELDSNet and the added value of international collaboration in detecting and investigating clusters including microbiological findings from clinical and environmental samples is evident. More details on these activities can be found in ELDSNet Operating Procedures. (4)

One of the objectives of ELDSNet is to promote the development of a laboratory network for Legionnaires' disease, including quality assurance and capacity-building. In an outbreak situation of Legionnaires' disease, timely source identification depends on epidemiological and environmental investigations, with a central role for laboratories in both clinical and environmental sample testing. In order to relate clinical and/or environmental specimens, microbiological investigations are conducted, including sequencing and typing of the isolates. Identification of a likely common source is important to reassure that implemented public health actions will prevent further cases and to follow up in monitoring of implemented measures.

An enhanced Legionnaires' disease genomic surveillance program utilising highly discriminatory WGS data to identify genomic cluster of isolates and support outbreak investigations, and its integration into EU/EEA surveillance reporting and outputs is currently under development.

Thus, laboratory diagnosis of Legionnaires' disease infection plays a crucial role in timely initiation of adequate treatment, prevention, and control measures as well as in supporting surveillance activities. It is important to strengthen the ELDSNet members' capacity for laboratory diagnosis and characterisation of Legionnaires' disease infections and ensure harmonised and well-established laboratory methodology.

2.3 SCENARIOS FOR EURL FOR PUBLIC HEALTH IN THE FIELD OF *LEGIONELLA*

The applicant is requested to present proposed tasks and activities based on two different hypothetical scenarios for the EURL for public health in the field of *Legionella*.

Please note that the scenarios as well as the funding amounts presented below are fictitious and 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.

For each scenario below, the applicant should present a workplan with short descriptions of the tasks and activities that they would execute under the scenario, considering the following requirements:

- The hypothetical workplan must include all the mandatory tasks described under section 2.4.1 below, as these tasks are all deemed essential for the EURL for public health in the field of *Legionella*.
- In addition to the mandatory tasks, an applicant's hypothetical workplan should also include descriptionsof additional activities that the applicant deems to be the most important and useful for the laboratory network(s), whilst feasible for implementation under the scenario parameters.
    - Such additional activities may be more ambitious (e.g. with higher frequency or volume) versions of the mandatory tasks, or new activities proposed by the applicants. However, please note that all additional activities need to fall under one of the activity areas as described under section 1.2.1 above, or be a coordination and communication-related

activity.

- Some potential additional activities are provided in section2.4.2 below.

- Justifications of the proposed added value of workplan tasks and explanations of task dependencies should be provided within the responses to the scenarios.

All activities and services provided by the EURL shall be free-of-charge for the laboratory network participants. This includes costs related to shipping of materials required for the implementation of EURL activities, both to and from the EURL. When required by the nature of the EURL activity, the EURL must also cover participants' costs for travel and accommodation.

The EURL is not requested to provide Whole Genome Sequencing (WGS) services to the laboratory network members, as such support is already available through a WGS support contract operated by ECDC.

2.3.1 Fictitious Scenario 1

The applicant is requested to present a cohesive hypothetical workplan with brief descriptions of the tasks and activities that they could execute in a **two year period** with a total amount of **650,000 EUR** of funding available for that two year period, taking into account the general instructions included under section 2.3 above.

2.3.2 Fictitious Scenario 2

The applicant is requested to present a brief hypothetical description of the additional tasks and activities (i.e. in addition to the tasks and activities already included under the workplan for scenario 1) that they could execute under a **two year period** with a total amount of **850,000 EUR** of funding available for that two year period (in other words, 200,000 EUR more than in Scenario 1, for the same duration), taking into account the general instructions included under section 2.3 above.

The tasks and activities described under the hypothetical workplan for scenario 2 should make a cohesive workplan together with the tasks and activities from scenario 1; however, tasks and activities described under the workplan for scenario 1 do not need to be described again under the workplan for scenario 2, unless they are changed or updated in a way that impacts on the scenario 2 workplan description.

2.4 TASKS AND ACTIVITIES OF THE EURL

2.4.1 Mandatory tasks for the EURL for public health in the field of Legionella

List of mandatory EURL tasks and activities

Task no	Task / Activity	Timing	Minimum volume over the two-year scenario period
Reference diagnostics, including test protocols			
1	Development and revision of a laboratory handbook on reference methods for detection and characterisation of *Legionella* spp. considering surveillance and outbreak investigation.	Once in year one, revision in year two	Development (one) and revision (one)

Task no	Task / Activity	Timing	Minimum volume over the two-year scenario period
2	Provision of reference diagnostic services for network laboratories.	Upon request	Approx. 100 specimens (i.e. 50 per year)
Reference material resources			
External quality assessments			
3	Provision of external quality assessment schemes for the detection, isolation, and characterisation of *Legionella* spp. from clinical and environmental specimens.	EQA on detection and characterisation: Once in year one and once in year two. EQA on molecular characterisation and sequencing: Once in year two.	EQA on detection and characterisation: Two rounds for approx. 50 network laboratories each EQA on molecular characterisation and sequencing: One round for approx. 50 network laboratories
Scientific advice and technical assistance			
4	Reference laboratory advice and technical support to network laboratories on diagnostic techniques, characterisation methods including genomic typing and other methods.	Upon request	Approx. 20 requests (i.e. ten per year)
5	Scientific advice and technical support to ECDC on laboratory topics, method developments including genomic typing, material availability and other topics related to Legionnaires' disease.	Upon request	Approx. ten request (i.e. five per year)
6	Country visits to review, evaluate, and improve laboratory surveillance for case and outbreaks detection.	Upon request	Four country visits (i.e. two per year), of minimum five working days each
Collaboration and research			
Monitoring, alert notifications and support in outbreak response			
7	Provide information, guidance and/or support to ECDC in outbreak situations, including contributions to ECDC risk assessments.	Ad hoc	Approx. ten requests (i.e. five per year)
Training			

Task no	Task / Activity	Timing	Minimum volume over the two-year scenario period
8	Organisation and delivery of wet lab trainings.	Annually	Two trainings (i.e. one per year) of minimum three working days for up to eight participants
9	Organisation and delivery of scientific webinars (virtual).	One per year	Two webinars (i.e. one per year) of minimum two hours for approx. 150 participants each
Coordination and communication			
10	Coordination with laboratory network members and ECDC.	Continuous	
11	Coordination with other EURLs or relevant initiatives.	Continuous	
12	Communication and dissemination.	Continuous	
13	Organisation of laboratory network meetings.	In year one or two	One physical meeting in the two-year period

Description of mandatory EURL tasks and activities

2.4.1.1 Reference diagnostics, including test protocols

Task 1: Development and revision of a laboratory handbook on reference methods for detection and characterisation of *Legionella* spp. considering surveillance and outbreak investigation

The EURL shall develop and revise a laboratory handbook on reference methods for detection and characterisation of *Legionella* spp., considering surveillance and outbreak investigation. International guidelines and existing standards as well as any ECDC materials shall be taken into account.

The handbook shall be developed in the first year and be revised in the second year if there is such a need. After creation and whenever updated or revised, the handbook shall be made available to ECDC for publication under a Creative Commons (CC BY) license.

Task 2: Provision of reference diagnostic and characterisation services for network laboratories

The EURL shall provide reference services to network laboratories for confirmation and characterisation of *Legionella* upon request. The scope of this centralised laboratory support is to validate diagnostic test results, provide advice and support, investigate atypical specimens, and assist in characterisation of new *Legionella* species pathogens. These requests are envisioned as a supplementary service to support national reference services. Where equivalent national reference laboratory services for *Legionella* may not exist or where such reference services are not available the network laboratories may request the service from the EURL. Service requests for approximately 40 specimens are estimated over the scenario period.

2.4.1.2 Reference material resources

No mandatory tasks are foreseen within the area of reference material resources.

2.4.1.3 External quality assessments

Task 3: Provision of external quality assessment schemes for the detection, isolation, and characterisation of *Legionella* spp. from clinical and environmental specimens

The EURL shall develop, provide, and conduct External Quality Assessment (EQA) schemes as follows:

i. The applicant shall plan for an EQA scheme for *Legionella* detection and characterisation – The EQA shall include at least ten samples including clinical and environmental samples. The EQA shall cover detection, isolation, and characterisation of *Legionella* spp., the applicant may consider reserving inclusion of antimicrobial susceptibility testing for when an appropriate method should be in place. Two rounds of EQA must be planned over the scenario period.

ii. The applicant shall plan for an EQA scheme for *Legionella* molecular characterisation and sequencing – The EQA shall include at least five samples including clinical and environmental samples. The EQA shall cover molecular characterisation techniques and sequencing of *Legionella* spp., the applicant may consider reserving inclusion of genomic-based typing for when an appropriate method and scheme should be in place. One round of EQA must be planned over the scenario period.

These two schemes may be distributed separately or may be combined in a single EQA scheme with separate parts that allow participation also in only one of the two parts and receiving clinical or environmental samples or both. The EURL will define the scope and performance indicators and prepare a comprehensive EQA laboratory and reporting protocol plan per round, which should be in alignment with the ECDC Strategy for the external quality assessment of public health microbiology laboratories (5) and must be agreed with ECDC before implementation of the EQA(s). The EQA shall be available for participation of at least one laboratory per country.

The EQAs organised by the EURL shall complement existing EQA programmes, which are organised at national or international levels.

EQA participation may help laboratories to meet some of the requirements needed for national accreditation. Therefore, an applicant's ISO certification as EQA providers (e.g. ISO 17043 (6)), would be advantageous.

2.4.1.4 Scientific advice and technical assistance

Task 4: Reference laboratory advice and technical support to network laboratories on diagnostic techniques, characterisation methods including genomic typing and other methods

The EURL shall upon request provide reference laboratory advice and technical support to network laboratories on diagnostic techniques, characterisation methods including genomic typing, and on other methods relevant to Legionnaires' disease. The scope of this activity is to assist and support network laboratories with implementation, optimisation, and troubleshooting. Communication may occur in all forms e.g. phone, in-person, by email or virtual consultation. Approximately 20 requests are estimated over the scenario period.

Task 5: Scientific advice and technical support to ECDC on laboratory topics, method developments including genomic typing, material availability and other topics related to Legionnaires' disease

The EURL shall upon request provide scientific advice and, if applicable, technical support to ECDC on laboratory topics related to the diagnostics and characterisation of *Legionella* spp., method developments including genomic typing, reference material availability, and other topics related to laboratory aspects of Legionnaires' disease. The scope of this activity is to assist and support ECDC on the disease specific work. Approximately ten requests for advice are estimated over the scenario period.

Task 6: Country visits to review, evaluate, and improve laboratory surveillance for case and outbreak detection

The EURL shall perform, upon requests agreed with ECDC, country visits to support the network member countries to review, evaluate, and improve laboratory surveillance for case and outbreak detection. To perform a country visit, a minimum of five working days may be anticipated, involving pre-visit and post-visit actions. Four country visits are estimated over the scenario period.

2.4.1.5 Collaboration and research

No mandatory tasks are foreseen within the area of collaboration and research.

2.4.1.6 Monitoring, alert notifications and support in outbreak response

Task 7: Provide information, guidance and/or support to ECDC in outbreak situations, including contributions to ECDC risk assessments

In case of a (confirmed) multi-country outbreak or other unusual event, the EURL will be asked to provide information, guidance and/or support to ECDC on microbiology-related matters relevant to the outbreak / event. The EURL shall, upon request, contribute to ECDC risk assessments in scope of the EURL. The requests may consist of preparing sections of these documents related to the pathogen properties and its detection and characterisation. The EURL contribution will be acknowledged in the documents produced; however, ECDC will be responsible for the final content of the document. Depending on the urgency for ECDC to produce the document, the EURL may be required to provide its contribution within 24 hours (one working day). Approximately five requests are estimated per year, i.e., approximately ten requests over the scenario period.

Under this task the EURL may be requested by ECDC to contribute to presentations to the Health Security Committee and/or the Advisory Committee on Public Health meetings convened and coordinated by the European Commission, in coordination with ECDC.

2.4.1.7 Training

All training activities should be aligned with and fall under the overall training programme on prevention, preparedness, and response to serious cross-border health threats, that is currently developed to implement Article 11 of the Regulation 2022/2371. (1)

Task 8: Organisation and delivery of wet-lab trainings

The EURL shall develop, organise, and deliver an in-person training activity in the format of a wet-lab training on a laboratory topic related to Legionnaires' disease.

The applicant must plan to organise two such activities with a duration of minimum three working days for up to eight participants over the scenario period.

A detailed training plan (including topic, training objectives, agenda etc.) shall be agreed with ECDC prior to the launch of the activity. Within their workplan, the applicant is expected to present thoughts on and suggestions of topics for which training activities would have a high added value for the network members.

If possible, the training activity should utilize the ECDC Virtual Academy (EVA) as a training environment.

Task 9: Organisation and delivery of scientific webinars (virtual)

The EURL shall develop, organise, and deliver a virtual training activity in the format of a scientific webinar on a laboratory topic related to Legionnaires' disease. The applicant must plan for organising two such activities with a duration of minimum two hours for approximately 150 participants over the scenario period. A detailed training plan (including topic, training objectives, agenda etc.) shall be agreed with ECDC prior to the launch of the activity.

If possible, the training activity should utilize the ECDC Virtual Academy (EVA) as a training environment.

2.4.1.8 Coordination and communication

Task 10: Coordination of activities with laboratory network members and ECDC

The EURL is expected to be an integral part of the disease and/or laboratory network(s) that are under the overall coordination by ECDC. The EURL will have a coordination function with regards to the implementation of the activities under its agreed work plan, and should interact independently with the laboratory network members to carry out this work. Where applicable, EURL representatives will be invited to participate as observers in the ECDC Disease Network Coordination Committee (DNCC) meetings of the laboratory network(s) that they are supporting. ECDC will also provide the EURL with the relevant contact information for the laboratory network(s) members from the ECDC Stakeholder Relationship Management (SRM) system. Appropriate GDPR-compliant measures must be put in place by the EURL to ensure adequate data protection for this personal data.

The EURL must coordinate the implementation of their tasks with ECDC to ensure alignment with other relevant activities coordinated by ECDC. This coordination could be done through regular coordination meetings, participation in meetings and events on relevant topics etc. Within their application, the applicant is expected to present their plan for how this coordination would be best organised.

Task 11: Coordination with other EURLs or relevant initiatives

Overlap leading to redundancy in activities between EURL and other laboratory support activities at supra-national level in the EU/EEA should be avoided whenever possible. The EURL will therefore be required to, following consultation with ECDC, exchange information and (where relevant) coordinate activities with other bodies carrying out work in similar areas. These bodies may include other public health EURLs supporting the same network(s), or any future EURLs for in vitro diagnostics (IVD) addressing *Legionella*, or World Health Organisation Collaborating Centres (WHO CCs) with relevant scope as identified by the EURL together with ECDC, or other relevant projects/initiatives.

Task 12: Communication and dissemination

The EURL must communicate on a regular basis with the members of the laboratory network(s) that they are supporting, to inform the network members of their work and planned EURL activities, and get feedback on the EURL activities.

The exact nature, frequency and mode(s) of communication depends on the planned activities, and the applicant is expected to present a plan for their communication and dissemination activities within their application. Within this plan, applicants should also consider what communication with other relevant stakeholders would be beneficial to the successful execution of their activities.

In serious outbreak situations, in particular if several EU/EEA countries are involved or an EU public health emergency is declared, the EURL may be requested by ECDC to support ECDC and the European Commission on risk communication.

Task 13: Organisation of laboratory network meetings

The EURL must plan for the organisation of one face-to-face network meeting for the laboratory network(s) within the scenario period. Invited participants must include at least one representative from each country that participates in the network(s), as well as invited speakers (if applicable) and relevant ECDC contact points. Additional participants may be invited as observers, but at their own expense.

The network meetings should enhance networking activities and collaboration between laboratories, discuss achievements and results, review upcoming tasks and allow network members to provide feedback on these, and/or the exchange of scientific and technical expertise on relevant selected topics. Agendas for the network meetings shall be prepared by the EURL, and the EURL shall also prepare meeting minutes and share presentations and minutes with all participants.

Should there be full ELDSNet network meetings organised by ECDC during the EURL's designation period, the EURL will be expected to contribute to content and agenda of these meetings but will not have operational meeting organisation responsibility. By agreement with ECDC it may be possible to organise EURL laboratory network meetings back-to-back to the ELDSNet network meetings.

2.4.2 Potential additional activities for the EURL for public health in the field of Legionella

The following activities are not mandatory to be covered in the application, but should serve as an inspiration for the applicant to use or develop further activities in their application.

Collection and maintenance of reference materials and relevant *Legionella* species and strains associated to pathogenicity in human as well as provision to network laboratories

The applicant may consider the collection, maintenance, and provision of relevant reference materials and relevant *Legionella* species and strains associated to pathogenicity in humans. The scope of this activity would be to build a reference collection which is currently lacking as a European resource.

For such activities, the applicant should put forward a plan for from where and how the reference materials would be collected and provided to the network laboratories, and how the reference materials collection would be of added value to the laboratory network members.

Develop or quality assure additional relevant antisera for agglutination tests

The applicant may consider the development and validation, or quality assurance of, relevant antisera for *Legionella* spp. agglutination tests. The scope of this activity would be to alleviate availability issues of sera for serology testing for the different *Legionella pneumophila* serogroups (2-15) where it currently is limited.

Support to pan-European studies on performance characteristics of laboratory methods relevant for surveillance objectives

The applicant may consider planning to provide support for pan-European studies on assessing performance characteristics of laboratory methods to inform their impact to or effect on surveillance data, reporting, and interpretation in respect to EU/EEA surveillance objectives. The scope is to assist in the understanding and interpretation of surveillance data quality and trends by assessing suitability or performance of methods in Legionnaires' disease detection/characterisation. This activity should be limited to providing technical advice and insights to ECDC and the laboratory network on proposed or implemented studies.

Evaluate the impact of laboratory methods performance on EU/EEA surveillance data

The applicant may consider performing validation studies for laboratory methods considering the range of specimen types and/or *Legionella* species and/or *Legionella pneumophila* serogroups to inform on and evaluate their impact to EU/EEA surveillance data, reporting and interpretation in respect to EU/EEA surveillance objectives. The scope is to assist in the understanding and interpretation of surveillance data quality and trends by evaluating the impact of methods suitability or performance to Legionnaires' disease detection/characterisation. The applicant should plan for the preparation of validation protocols for laboratory methods to evaluate and include coordination of this work with ECDC.

Advice to genomic characterisation and typing for identifying matching isolates between clinical and environmental samples in specific outbreak situations

The applicant may consider the provision of advice to network members on genomic characterisation and typing for identifying matching isolates between clinical and environmental samples in specific outbreak situations. Since not all members of the disease network have capacities and/or methods established to cover all *Legionella* species or serogroups, sequence-based typing, or genomic-based typing, tailored advisory or training support to disease or laboratory network members would be beneficial.

Organisation of additional[1] meetings on topics under EURL remit

An applicant could, where deemed necessary and appropriate, plan for the organisation of additional meetings on specific topics for laboratory network members. While ECDC should be kept informed of all such plans, the EURL would be expected to organise and execute such meetings independently.

2.5 USE AND PUBLICATION OF DATA AND RESULTS

Beyond the contractually agreed reports and deliverables of the EURL, the use of data or data analysis results obtained or made by the EURL in their role as an EURL

[1] I.e. in addition to the mandatory laboratory network meeting task described under section 2.4.1

shall require written agreement by the laboratories that generated and/or shared the data, and by ECDC, prior to publication. Such publications may include peer-reviewed manuscripts, and/or disclosure of information to third parties.

Manuscripts for submission to relevant peer review scientific journals shall follow the ECDC authorship policy according to the guiding principles described in the ECDC authorship policy (7) and the Internal Policy on open access publication of scientific content, including articles submitted to peer review journals. (8)

2.6 DESIGNATION PERIOD

The EURL for public health in the field of *Legionella* will be designated for a period of seven (7) years. However, 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.

2.7 ELIGIBILITY CRITERIA

Laboratories to be designated as an EURL for public health must meet all of the eligibility criteria listed below. For consortium applications (see section 4.1.4 below), each individual laboratory within the consortium must meet all of the eligibility criteria.

Eligible candidate laboratories must:

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

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

(a) 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;

(b) have, or have contractual access to, suitably qualified staff with adequate training in their area of competence;

(c) possess, or have access to, the infrastructure, equipment and products necessary to carry out the tasks assigned to them;

(d) 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;

(e) be equipped, or have access to, the necessary equipment to perform their tasks in emergency situations; and

(f) where relevant, be equipped to comply with relevant biosecurity standards.

Clarifications on these requirements:

Regarding requirement (a): The aim is to ensure that the designated EURLs do 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 exist due to reasons involving economic interest,

political affinity, family, or any other shared interest. While some conflicts of interest are direct, applicants should also 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 are 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. Should applicants find that such potential conflicts of interest exist, they are 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 is not excluded, applicants are expected to carry out the main elements of the EURL activities within their own organisations.

Regarding requirement (d): It is up to each national competent authority to determine what international standards and practices are relevant for the requested work of the EURL, and to ensure that the applicant appropriately meets these standards.

Regarding requirement (f): It is up to each national competent authority to determine what biosecurity standards are relevant for the requested work of the EURL, and to ensure that the applicant appropriately meets these standards.

2.8 SELECTION CRITERIA

The selection criteria are intended to allow evaluating the scientific excellence of the applicant, as well as applicant's ability and capacity to perform the role of an EURL for public health in the field of *Legionella*. Up to 100 points may be awarded for the four criteria below. There is a threshold of 60% for each individual criterion in order to pass the selection criteria.

Submission of supporting documents for the selection criteria is not necessary at the application stage. Applicants may however be requested to submit this additional documentation at a later stage.

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)**

3 TIMETABLE AND DEADLINES

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

4 APPLICATION, EVALUATION, DESIGNATION AND FUNDING PROCEDURES

4.1 APPLICATION PROCEDURE

4.1.1 Publication of call for applications

The call for application is published by the European Commission on its website and advertised via social media. ECDC will equally promote the call via social media.

4.1.2 Preparation of EURL application

An applicant to the call may be a single laboratory or a consortium of laboratories. However, please note that a laboratory may only apply to each topic once, i.e. either as a single laboratory applicant or as a member of a consortium applicant. For information specifically related to consortium applicants, please see section 4.1.4 below.

Applicants must complete the application form in EUSurvey, including the Technical Description whose template is found under Annex III. Please note that some sections of the application form have page limits, and that any application texts exceeding these page limits will be disregarded.

In their applications, applicants must include the relevant information to demonstrate how well they meet the selection criteria described under section 2.8 above. Please see Annex III for more detailed instructions on filling out the Technical Description.

4.1.3 Endorsement of candidate laboratories by national competent authorities

All applicants, whether they are single laboratories applying separately or members of a consortium applying jointly, must be endorsed by a national competent authority. The ECDC Coordinating Competent Bodies (CCBs), that have already been nominated by Member States as national competent authorities in public health, are proposed as the main competent authorities for endorsement of applicants. However, other authorities such as the Ministry of Health can also endorse applicants, if the country so decides. In certain cases, further documentation may be required regarding the endorsing body's position as a national competent authority in public health (to be assessed on a case-by-case basis).

Prior to endorsing an applicant, each national competent authority is required to confirm that the applicant meets 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 applicants in this process.

To endorse an applicant, the national competent authority fills out and signs the endorsement form found in Annex I. The signed endorsement form is then attached to the application by the applicant. Please see Annex I for more detailed instructions on filling out the endorsement form.

A national competent authority may endorse more than one applicant per topic, provided that each applicant meets the eligibility criteria set out in section 2.7 above.

4.1.4 Modalities relevant to EURL applications by a consortium

4.1.4.1 General

For the purpose of this call, 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 for public health in the field of *Legionella*". Each consortium must designate a coordinator that is submitting the proposal on behalf of the consortium.

If designated, the consortium members will be jointly and severally liable for carrying out the tasks of the EURL. If one consortium member were to fail to implement its part of the tasks, the other members would become responsible for implementing this part. The application of a consortium must be accompanied by (an) agreement letter(s) regarding the joint and several liability and the authorisation for the coordinator to submit the application on behalf of the consortium and represent the consortium during the application and evaluation phases of the selection procedure. This is done by each non-coordinator consortium member filling out and submitting a copy of the letter found in Annex II together with the rest of the application documents.

The coordinator will be the administrative contact point of the consortium and the sole contact point for the European Commission. Depending on the areas of responsibility within the consortium, ECDC may make direct contacts with other consortium members on scientific and/or technical matters, in particular in outbreak situations.

Each member of the applicant consortium has to meet the eligibility criteria, and be endorsed by their respective national competent authorities (see sections 2.7 and 4.1.3 above). Consortium applications must therefore include the same number of endorsement form as there are total members of the consortium (including the coordinator).

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.

A single, jointly elaborated, application must be submitted for a consortium, and the application must be submitted by the coordinator on behalf of all the consortium members.

4.1.4.2 Finding consortium partners

While it is assumed that some consortia may be formed directly between laboratories on the basis of previous or existing collaborations, ECDC will operate 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 should send an email to ECDC using the contact email address specified under section 5 below, 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. Laboratories will receive separate emails informing them on how to access this information.

4.1.5 Submission of EURL application

Applications are submitted through EUSurvey, and the link to the application form for the EURL for public health in the field of *Legionella* is:

https://ec.europa.eu/eusurvey/runner/Call_for_Applications_EU_Reference_Laboratory_for_Public_Health_Legionella

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

Certain application information, such as administrative information about the applicant and information about potential conflicts of interest, must be entered directly in the application form in EUSurvey, whereas other information is entered into the different application templates and, when completed, uploaded to EUSurvey as files.

Applications will only be considered as complete if all sections of the application form in EUSurvey have been filled out, all required files have been successfully uploaded, and the application has been successfully submitted in EUSurvey by the main contact person of the single lab / consortium applicant before the application submission deadline specified under section 3 above. Applicants are strongly encouraged not to wait until deadline day with their submissions in order to ensure minimise the risk of submission issues.

No modification to the application is allowed once the application has been submitted in EUSurvey or after the deadline for submission has passed. However, if there is a need to clarify clerical or obvious errors, such as the uploading of the wrong file etc, the applicant may be contacted during the evaluation procedure.

4.2 EVALUATION PROCEDURE

The evaluation panel consists of the European Commission staff members, ECDC staff members as well as of independent, external experts.

The evaluation panel confirms the eligibility of the applicants, as well as evaluates each application against the selection criteria set out in section 2.8 above. For each application an application evaluation report is drawn up, which includes the scores given on the selection criteria as well as comments made by the evaluation panel.

The successful applicant is the eligible applicant whose application is awarded individual criterion scores that exceed all pass thresholds for the selection criteria and is awarded the highest total score against the selection criteria out of all the applications evaluated in this field. Where relevant, successful applicants may also 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.

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. 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.

4.3 DESIGNATION OF EURL

Once the evaluation is concluded, ECDC will notify the European Commission of the outcome of the evaluation and propose that the successful applicant is designated as an EURL for public health in the field of the call. The European Commission will further proceed with the designation of the EURL following the procedure for an implementing act, i.e. a secondary legislation following a Regulation.

4.4 FINANCIAL SUPPORT FOR EURL ACTIVITIES

The EURL selected through this call and then designated through an implementing act, will be able to apply for a grant under the EU4Health 2023 work programme, topic CP-g-23-05-01. (11)

Designated EURLs will be invited to apply for funding when their designation through the implementing act has been processed by the European Commission. A specific call for proposals will be prepared for this purpose.

5 CONTACTS AND FURTHER INFORMATION

All contacts on this call should be made in writing only, to the following email address:

EURL-PH@ecdc.europa.eu

with "EURL-PH-2023-05" in the subject line.

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

All questions received to the above e-mail address for which answers are provided that are of interest to all possible 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 information there during the preparation of their application.

6 REFERENCES

1. **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. [Online] https://eur-**

lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R2371.
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. [Online] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32022R2370.
3. Coordinating Competent Bodies: structures, interactions and terms of reference, 7 December 2012. [Online] 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.
4. ECDC. European Legionnaires' Disease Surveillance Network (ELDSNet) - Operating procedures. [Online] 12 2017. https://www.ecdc.europa.eu/en/publications-data/european-legionnaires-disease-surveillance-network-eldsnet-operating-procedures.
5. ECDC strategy for the external quality assessment of public health microbiology laboratories. [Online] https://www.ecdc.europa.eu/en/publications-data/strategy-external-quality-assessment-public-health-microbiology-laboratories.
6. ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories. [Online] https://www.iso.org/standard/66912.html.
7. Internal Policy on authorship and acknowledgement of contribution to scientific work and related outputs – ECDC/IP/104. [Online] https://www.ecdc.europa.eu/sites/default/files/documents/ECDC-authorship-internal-policy.pdf.
8. ECDC policy on open access publication of scientific content, including articles submitted to peer review journals. [Online] https://www.ecdc.europa.eu/en/publications-data/ecdc-policy-open-access-publication-scientific-content-including-articles.
9. Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work. [Online] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02000L0054-20200624.
10. List of ECDC Coordinating Competent Bodies. [Online] https://www.ecdc.europa.eu/en/about-ecdc/who-we-are/governance/competent-bodies.
11. EU4Health 2023 Work Programme. [Online] https://health.ec.europa.eu/publications/2023-eu4health-work-programme_en.

ANNEX I: TEMPLATE FOR LETTER OF ENDORSEMENT

Template for letter of endorsement

[Header]

[Name of institution e.g. national competent authority]

[Date]

[Addressee (i.e. the applicant)]

This letter of endorsement is provided to the above-mentioned addressee (i.e. applicant) in accordance with the requirements of the "Call for applications for designation of an EU Reference Laboratory (EURL) for public health in the field of *Legionella*" (ref: EURL-PH-2023-05), hereafter referred to as "the Invitation".

I, undersigned, as representative of the national competent authority [name of national competent authority] of [name of country], confirm endorsement of the applicant [name of the applicant] submitting an application for EURL for public health in the field of *Legionella*.

By ticking the boxes below, I specifically confirm that the applicant:

☐ Is based in an EU Member State or an EEA country

☐ Plays an active role in a national public health microbiology system

☐ Is impartial, free from any conflict of interest, and, in particular, not in a situation which may, directly or indirectly, affect the impartiality of their professional conduct as regards the exercise of their tasks as an EU reference laboratory;

☐ Has, or has contractual access to, suitably qualified staff with adequate training in their area of competence;

☐ Possesses, or has access to, the infrastructure, equipment and products necessary to carry out the tasks assigned to them;

☐ Ensures 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;

☐ Is equipped, or has access to, the necessary equipment to perform their tasks in emergency situations; and

☐ Where relevant, is equipped to comply with relevant biosecurity standards.

[Signature, name(s) and function(s) of signatory, name of national competent authority represented]

ANNEX II: TEMPLATE FOR AUTHORISATION OF COORDINATOR BY BENEFICIARY, AND CONFIRMATION OF JOINT AND SEVERAL LIABILITY FOR THE EXECUTION OF THE TASKS

For consortium applications, one copy of this form must be filled out by **all members of the consortium that are not identified as the Coordinator**.

These authorisations should be signed by the respective contact persons of the beneficiaries as identified under Part A section 1.2.

[Header]

[Name of institution]

[Date]

This is provided in accordance with the requirements of the "Call for applications for designation of an EU Reference Laboratory (EURL) for public health in the field of *Legionella* (ref: EURL-PH-2023-05)", hereafter referred to as "the Invitation".

I, undersigned, hereby authorise [coordinator organisation full name], as represented by [name of coordinator main contact person] and hereafter referred to as "the Coordinator", to submit an application with my organisation as one of the beneficiaries. I also mandate the Coordinator to represent my organisation in contacts with the European Commission and/or ECDC on issues directly related to the above-mentioned application during the application and evaluation processes.

In addition, I confirm my understanding and acceptance that, should our application be successful, my organisation and the other members of the consortium (including the Coordinator) will be jointly and severally liable for the technical implementation of the tasks of the EURL.

[Signature, Date, Name and function(s), Institution represented]

ANNEX III: TEMPLATE FOR TECHNICAL DESCRIPTION

Technical Description

Annex III to the Call for applications for the Designation of an EU Reference Laboratory for Public Health

GENERAL INSTRUCTIONS AND GUIDELINES

Please follow the structure of this template when preparing your Technical Description. It has been designed to ensure that the important aspects of your planned work are presented in a way that will enable the evaluators to make an effective assessment of your application against the selection criteria. Please read carefully also the guidance provided for each section on the information expected within that section.

Please be aware that applications will be evaluated as they were submitted, rather than on their potential if certain additions / changes were to be made. This means that only applications that successfully address all the required aspects will have a chance of being successful.

Applicants should take note of the page limits for each section, and strike the right balance between necessary detail and conciseness. Excess pages will be disregarded.

Fill in the template with text in black font colour of minimum font size 12.

When referring to the applicant organisation(s), please use the same organisation name(s) and acronym(s) as in the Administrative Information sections in EUSurvey.

Please read carefully all the documents and instructions provided.

These guidelines and all text in <blue> in the subsequent sections *are instructions on how to use the template.* ***Please ensure that you delete this section and all text in <blue> from the final document prior to submission****.*

Application for the designation of an EURL for public health in the field of *Legionella* (ref: EURL-PH-2023-05)

Applicant / Coordinator: <organisation name of single laboratory applicant or coordinator of consortium applicant>

1. PURPOSE AND ROLE OF THE EURL

<Describe your vision for the purpose and role of the EURL, in line with the requirements of the call.

This description should include a description of the EU-level public health landscape that the EURL will operate within, and how EURL fits in within it.

This section is limited to maximum two pages of text. Excess pages will be disregarded.>

[Your text here…]

2. COMPLEMENTARITY WITH OTHER ACTIONS — EUROPEAN ADDED VALUE

<Illustrate the EU added value of the proposed activities, and explain how the proposed activities are complementary to other supra-national activities carried out by other organisations, in particular relevant EURLs for food, feed and animal health and/or for in vitro diagnostics (IVD); relevant World Health Organization (WHO) Collaborating Centres (CCs) etc.

It is expected that applicants address the relevant organisations identified in the calls for applications, but applicants should also include additional activities / organisations as they find appropriate.

This section is limited to maximum two pages in total. Excess pages will be disregarded.>

[Your text here…]

3. SCENARIO WORKPLANS

<This section must describe the proposed workplans of the EURL in response to each of the two scenarios described in the call for applications, i.e. the tasks and activities that the applicant would implement as EURL over a two year period if the amount of funding specified in each scenario was made available.

Each workplan should include the following components:

- *An outline of the approach and methodology behind the workplan. Explain why the proposed approach and methodology are the most suitable.*

- *Descriptions of and justifications for the proposed activities included in the workplan.*
    - *Where relevant, this should also include the proposed methods for carrying out the tasks and actions*
    - *It is required that the mandatory tasks included under section 2.4.1 of the call for applications are covered by both scenarios; however, tasks and activities described under the workplan for scenario 1 do not need to be described again under the workplan for scenario 2, unless they are changed or updated in a way that impacts on the scenario 2 workplan description*
- *Information on interlinking and dependencies between activities, and how the included tasks and activities form a cohesive workplan*
- *(For consortium applications) Information on what consortium partner will lead on which activities / parts of the work plan*
- *Please mention any foreseen outsourcing of minor parts of the planned activities outside of the applicant's organisation(s)*

Please note that applicants are not obliged to organise their proposed workplans into formal work packages, nor present lists of reports and deliverables within their workplan descriptions.>

3.1 PROPOSED WORKPLAN UNDER SCENARIO 1

<The description of this section is limited to maximum eight pages in total. Excess pages will be disregarded.>

[Your text here…]

3.2 PROPOSED WORKPLAN UNDER SCENARIO 2

<The description of this section is limited to maximum five pages in total. Excess pages will be disregarded.>

[Your text here…]

4. RISK MANAGEMENT

<The applicant should provide a simple risk analysis, to predict the risks that could prevent the successful execution of the workplans. Identify the most relevant external and internal risks and briefly describe some proposed risk mitigation actions.

The description of this section is limited to maximum one page in total. Excess pages will be disregarded.>

[Your text here…]

5. RESOURCES AND KNOWLEDGE

<Provide a brief description of the applicant's organisation(s), and how the profile(s) and expertise(s) of the organisation(s) fit(s) with the requirements of the proposed activities and of the call for applications, including access to the equipment and infrastructure needed for carrying out the proposed work. Include also a description of any experience that the organisation(s) has of carrying out similar work, and how this experience would benefit the implementation of the proposed activities.

Describe the applicant team and how the members of this team will work together to implement the proposed workplans. List the required functions by expertise, and provide short descriptions of the profiles of the key team members for these functions, with a focus on demonstrating the scientific and technical expertise and competence needed for carrying out the proposed work.

This section is limited to maximum two pages per applicant organisation, i.e. a single laboratory applicant has a maximum of two pages whereas a consortium of five laboratories has a maximum of ten pages. Excess pages will be disregarded.>

[Your text here…]

5.1 CONSORTIUM SET-UP

<Only for consortium applications. Single laboratory applicants should leave this section blank.

Describe how each organisation has a clear role in the consortium, how the organisations in the consortium complement each other in terms of the required expertise, and how they will work together to implement the proposed workplans.

This section is limited to maximum one page in total. Excess pages will be disregarded.>

[Your text here…]

6. IMPACT

<Define the short, medium and long-term effects of the proposed work. Identify the key stakeholder groups that would be impacted by the work of the EURL, and explain how they would benefit concretely from the proposed workplan activities.

This section is limited to maximum two pages in total. Excess pages will be disregarded.>

[Your text here…]

7. COMMUNICATION AND DISSEMINATION

< Describe the communication and dissemination activities which are planned in

order to communicate with the key stakeholders, promote the activities/results, and maximise the impact (to whom, which format, how many, etc.). Clarify how you will reach the relevant stakeholders and policymakers and explain the choice of communication and/or dissemination channels.

At minimum, a communication plan for

a) the relevant laboratory network(s) members, and
b) ECDC

must be presented.

This section is limited to maximum two pages in total. Excess pages will be disregarded.>

[Your text here…]