



2024/2959

2.12.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2959

of 29 November 2024

designating European Union reference laboratories for public health on food- and water-borne bacteria; on food-, water- and vector-borne helminths and protozoa; and on food- and water-borne viruses

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ⁽¹⁾, and in particular Article 15(1) thereof,

Whereas:

- (1) Pursuant to Regulation (EU) 2022/2371, European Union reference laboratories ('EU reference laboratories') in the area of public health or for specific areas of public health relevant for the implementation of this Regulation are to provide support to national reference laboratories and to promote good practice and alignment by Member States on diagnostics, testing methods and use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States.
- (2) In accordance with Article 15(4) of Regulation (EU) 2022/2371, the Commission launched in April 2024 ⁽²⁾ calls for applications for the designation of EU reference laboratories in three areas of public health, namely on food- and water-borne bacteria; on food-, water- and vector-borne helminths and protozoa; and on food- and water-borne viruses.
- (3) In response to those calls, Member States submitted applications for designation by 14 August 2024, which were evaluated by a selection board set up by the Commission services.
- (4) The selection board took into account the requirements for EU reference laboratories set in Article 15(5) of Regulation (EU) 2022/2371 and in the calls for applications.
- (5) Following the completion of the selection procedure, the successful laboratories should be designated as EU reference laboratories and their responsibilities and tasks should be specified.
- (6) In order to use the funding allocated in the EU4Health annual work programme 2024 ⁽³⁾, the designation of EU reference laboratories in the field of public health should be provided for as soon as possible.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Committee on serious cross-border threats to health,

HAS ADOPTED THIS REGULATION:

Article 1

1. The consortium referred to in Annex I is designated as European Union reference laboratory for public health on food- and water-borne bacteria until 22 December 2031.
2. The responsibilities and tasks of that European Union reference laboratory are laid down in that Annex.

⁽¹⁾ OJ L 314, 6.12.2022, p. 26, ELI: <http://data.europa.eu/eli/reg/2022/2371/oj>.

⁽²⁾ https://health.ec.europa.eu/consultations/eu-reference-laboratories-public-health-2024-calls-applications_en.

⁽³⁾ https://health.ec.europa.eu/publications/2024-eu4health-work-programme_en.

Article 2

1. The consortium referred to in Annex II is designated as European Union reference laboratory for public health on food-, water- and vector-borne helminths and protozoa until 22 December 2031.
2. The responsibilities and tasks of that European Union reference laboratory are laid down in that Annex.

Article 3

1. The consortium referred to in Annex III is designated as European Union reference laboratory for public health on food- and water-borne viruses until 22 December 2031.
2. The responsibilities and tasks of that European Union reference laboratory are laid down in that Annex.

Article 4

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 29 November 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

The EU reference laboratory for public health on food- and water-borne bacteria, its responsibilities and tasks

1. The consortium designated as the EU reference laboratory for public health on food- and water-borne bacteria (hereinafter 'EURL'):

Consortium led by:

Statens Serum Institut, Artillerivej 5, 2300 København S, DENMARK;

Also composed of:

Rijksinstituut voor Volksgezondheid en Milieu, Antonie van Leeuwenhoeklaan 9, 3721 MA, Bilthoven, NETHERLANDS, as of May 2025: Helsinkilaan 1, 3584 CB, Utrecht, NETHERLANDS,

Istituto Superiore di Sanità, Viale Regina Elena 299, 00161, Roma RM, ITALY.

2. Responsibilities and tasks:

The EURL shall provide support to national reference laboratories and promote good practice and quality to strengthen public health microbiology in the field of food- and water-borne bacteria.

The EURL shall provide support to these national reference laboratories for activities in relation to the following food- and water-borne bacteria: *Salmonella* spp., shiga toxin-producing *E. coli* (STEC), *Listeria monocytogenes*, *Campylobacter* spp. and *Shigella* spp.. The scope of the EURL also includes *Vibrio* spp. and *Yersinia* spp. (excluding *Y. pestis*). Should there be an EU-level need related to other food- and water-borne bacteria of public health relevance, the EURL may also be requested to provide input and advice on those bacteria.

The EURL shall provide support to the members of the European Centre for Disease Prevention and Control (ECDC)'s European Food- and Waterborne Diseases and zoonoses Network (FWD-Net) ⁽¹⁾ on aspects related to diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases.

For the implementation of the activities under the EURL's work plan which the EURL shall develop and agree with the ECDC, the EURL shall coordinate the National Focal Points (NFPs) for Food and Waterborne Diseases and the Operational Contact Points (OCPs) for Microbiology relevant for the EURL.

Upon request from the ECDC, the EURL shall participate in relevant ECDC networks and structures. The EURL shall participate in the network of EU reference laboratories that is to be operated and coordinated by the ECDC in accordance with Article 15(3) of Regulation (EU) 2022/2371.

The EURL shall ensure that there is:

- a sufficient number of qualified staff in relation to the volume of the tasks that the EURL is to carry out in their scope of designation,
- adequate training of staff for the execution of the tasks of the EURL.

The EURL shall establish its confidentiality policy, including rules for the appropriate secure handling, storage and processing of samples and information, as well as measures to prevent undue disclosure of confidential information.

⁽¹⁾ <https://www.ecdc.europa.eu/en/about-us/partnerships-and-networks/disease-and-laboratory-networks/fwd-net>.

The EURL shall be responsible for the following tasks:

- (a) providing reference testing in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by the network(s);
- (b) providing physical and/or digital reference materials in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by the network(s);
- (c) providing external quality assessments, such as phenotypic or genomic proficiency testing, in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by the network(s);
- (d) providing scientific advice and technical assistance in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by the network(s);
- (e) participating in expert committees, e.g. the ECDC – European Food Safety Authority (EFSA) Advisory Board on the management and sharing of molecular typing data of isolates from human, food, feed, animals and the related environment in order to provide expert advice within the field of the EURL;
- (f) providing scientific advice and technical assistance in the field of the EURL to ECDC based on expert opinions and/or surveys among the members of the network(s) supported by the EURL;
- (g) providing information, guidance and support to the ECDC in outbreak situations in the field of the EURL, including providing contributions to ECDC risk assessments;
- (h) providing scientific and technical assistance to the Commission concerning the EURL's specific area of public health and in coordination with the ECDC;
- (i) organising and delivering training, such as workshops, webinars, simulation exercises, wet-lab trainings and/or pilot surveillance exercises, in the field of the EURL to members of the network(s) supported by the EURL;
- (j) ensuring coordination, communication and dissemination with members of the network(s) supported by the EURL, and with the ECDC, including the development of and agreement on annual work plans;
- (k) organising meetings for members of the network(s) supported by the EURL;
- (l) ensuring coordination with other EU reference laboratories in public health and/or in other areas such as feed, food and animal health and/or *in vitro* medical devices, the World Health Organization (WHO) Collaborating Centres and/or WHO reference laboratories, or relevant initiatives in the field of the EURL;
- (m) collaborating, in cooperation with the ECDC, with the EFSA and/or the European Medicines Agency (EMA), as relevant;
- (n) collaborating, in cooperation with the ECDC, with laboratories in third countries in an international context that benefits EU-level public health, as relevant;
- (o) providing scientific and technical assistance on other issues relevant to members of the network(s) supported by the EURL.

ANNEX II

The EU reference laboratory for public health on food-, water- and vector-borne helminths and protozoa, its responsibilities and tasks

1. The consortium designated as the EU reference laboratory for public health on food-, water- and vector-borne helminths and protozoa (hereinafter 'EURL'):

Consortium led by:

Istituto Superiore di Sanità, Viale Regina Elena 299, 00161, Roma RM, ITALY;

Also composed of:

Folkhälsomyndigheten, Nobels väg 18, SE-171 82 Solna, SWEDEN.

2. Responsibilities and tasks:

The EURL shall provide support to national reference laboratories and promote good practice and quality to strengthen public health microbiology in the field of food-, water- and vector-borne helminths and protozoa.

The EURL shall provide support to these national reference laboratories for activities in relation to the following food-, water- and vector-borne helminths and protozoa: *Echinococcus* spp., *Toxoplasma gondii*, *Trichinella* spp., and *Plasmodium* spp.. Should there be an EU-level need related to other food-, water- and vector-borne parasites of public health relevance (e.g. *Cryptosporidium* spp., *Giardia lamblia*, *Leishmania* spp., *Strongyloides stercoralis*, and *Taenia solium*), the EURL may also be requested to provide input and advice on those helminths and protozoa.

The EURL shall provide support to the members of the European Centre for Disease Prevention and Control (ECDC)'s European Emerging and Vector-borne Diseases Network (EVD-Net)⁽¹⁾ and European Food- and Waterborne Diseases and zoonoses Network (FWD-Net)⁽²⁾ on aspects related to diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases.

For the implementation of the activities under the EURL's work plan which the EURL shall develop and agree with the ECDC, the EURL shall coordinate the National Focal Points (NFPs) for Food and Waterborne Diseases and for Emerging and Vector-borne Diseases, and the Operational Contact Points (OCPs) for Microbiology relevant for the EURL.

Upon request from the ECDC, the EURL shall participate in relevant ECDC networks and structures. The EURL shall participate in the network of EU reference laboratories that is to be operated and coordinated by the ECDC in accordance with Article 15(3) of Regulation (EU) 2022/2371.

The EURL shall ensure that there is:

- a sufficient number of qualified staff in relation to the volume of the tasks that the EURL is to carry out in their scope of designation,
- adequate training of staff for the execution of the tasks of the EURL.

The EURL shall establish its confidentiality policy, including rules for the appropriate secure handling, storage and processing of samples and information, as well as measures to prevent undue disclosure of confidential information.

⁽¹⁾ <https://www.ecdc.europa.eu/en/about-ecdc/what-we-do/partners-and-networks/disease-and-laboratory-networks/european-emerging-and->

⁽²⁾ <https://www.ecdc.europa.eu/en/about-us/partnerships-and-networks/disease-and-laboratory-networks/fwd-net>.

The EURL shall be responsible for the following tasks:

- (a) providing reference diagnostic and pathogen characterisation services in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by the network(s);
- (b) providing reference materials in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by the network(s);
- (c) providing external quality assessment schemes for diagnostics and characterisation of selected helminths and protozoa in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by the network(s);
- (d) providing scientific advice and technical assistance in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by the network(s);
- (e) participating in expert committees, e.g. the ECDC – European Food Safety Authority (EFSA) Advisory Board on the management and sharing of molecular typing data of isolates from human, food, feed, animals and the related environment, in order to provide expert advice within the field of the EURL;
- (f) providing scientific advice and technical assistance in the field of the EURL to ECDC based on expert opinions and/or surveys among the members of the network(s) supported by the EURL;
- (g) providing information, guidance and support to the ECDC in outbreak situations in the field of the EURL, including providing contributions to ECDC risk assessments;
- (h) providing scientific and technical assistance to the Commission concerning the EURL's specific area of public health and in coordination with the ECDC;
- (i) organising and delivering training, such as workshops, webinars and wet-lab trainings, in the field of the EURL to members of the network(s) supported by the EURL;
- (j) ensuring coordination, communication and dissemination with members of the network(s) supported by the EURL, and with the ECDC, including the development of and agreement on annual work plans;
- (k) organising meetings for members of the network(s) supported by the EURL;
- (l) ensuring coordination with other EU reference laboratories in public health and/or in other areas such as feed, food and animal health and/or *in vitro* medical devices, the World Health Organization (WHO) Collaborating Centres and/or WHO reference laboratories, or relevant initiatives in the field of the EURL;
- (m) collaborating, in cooperation with the ECDC, with the EFSA and/or the European Medicines Agency (EMA), as relevant;
- (n) collaborating, in cooperation with the ECDC, with laboratories in third countries in an international context that benefits EU-level public health, as relevant;
- (o) providing scientific and technical assistance on other issues relevant to members of the network(s) supported by the EURL.

ANNEX III

The EU reference laboratory for public health on food- and water-borne viruses, its responsibilities and tasks

1. The consortium designated as the EU reference laboratory for public health on food- and water-borne viruses (hereinafter 'EURL'):

Consortium led by:

Norwegian Institute of Public Health (NIPH), Lovisenberggata 6, 0456 Oslo, NORWAY;

Also composed of:

Rijksinstituut voor Volksgezondheid en Milieu, Antonie van Leeuwenhoeklaan 9, 3721 MA, Bilthoven, NETHERLANDS, as of May 2025: Helsinkilaan 1, 3584 CB, Utrecht, NETHERLANDS,

Regensburg University Medical Center, Franz-Josef-Strauss-Allee 11, D-93053 Regensburg, GERMANY.

2. Responsibilities and tasks:

The EURL shall provide support to national reference laboratories and promote good practice and quality to strengthen public health microbiology in the field of food- and water-borne viruses.

The EURL shall provide support to these national reference laboratories for activities in relation to hepatitis A virus. The scope of the EURL also includes hepatitis E virus. Should there be an EU-level need related to other food- and water-borne viruses of public health relevance, the EURL may also be requested to provide input and advice on those viruses.

The EURL shall provide support to the members of the European Centre for Disease Prevention and Control (ECDC)'s European Food- and Waterborne Diseases and zoonoses Network (FWD-Net) ⁽¹⁾ on aspects related to diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases.

For the implementation of the activities under the EURL's work plan which the EURL shall develop and agree with the ECDC, the EURL shall coordinate the National Focal Points (NFPs) for Food and Waterborne Diseases and the Operational Contact Points (OCPs) for Microbiology relevant for the EURL.

Upon request from the ECDC, the EURL shall participate in relevant ECDC networks and structures. The EURL shall participate in the network of EU reference laboratories that is to be operated and coordinated by the ECDC in accordance with Article 15(3) of Regulation (EU) 2022/2371.

The EURL shall ensure that there is:

- a sufficient number of qualified staff in relation to the volume of the tasks that the EURL is to carry out in their scope of designation,
- adequate training of staff for the execution of the tasks of the EURL.

The EURL shall establish its confidentiality policy, including rules for the appropriate secure handling, storage and processing of samples and information, as well as measures to prevent undue disclosure of confidential information.

⁽¹⁾ <https://www.ecdc.europa.eu/en/about-us/partnerships-and-networks/disease-and-laboratory-networks/fwd-net>.

The EURL shall be responsible for the following tasks:

- (a) providing reference diagnostic and pathogen characterisation services in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by the network(s);
- (b) providing external quality assessment schemes for diagnostics and characterisation of selected viruses or virus groups, in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by the network(s);
- (c) providing scientific advice and technical assistance in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by the network(s);
- (d) participating in expert committees, e.g. the ECDC – European Food Safety Authority (EFSA) Advisory Board on the management and sharing of molecular typing data of isolates from human, food, feed, animals and the related environment, in order to provide expert advice within the field of the EURL;
- (e) providing scientific advice and technical assistance in the field of the EURL to ECDC based on expert opinions and/or surveys among the members of the network(s) supported by the EURL;
- (f) providing information, guidance and support to the ECDC in outbreak situations in the field of the EURL, including providing contributions to ECDC risk assessments;
- (g) providing scientific and technical assistance to the Commission concerning the EURL's specific area of public health and in coordination with the ECDC;
- (h) organising and delivering training, such as workshops, webinars, simulation exercises, wet-lab trainings and/or pilot surveillance exercises, in the field of the EURL to members of the network(s) supported by the EURL;
- (i) ensuring coordination, communication and dissemination with members of the network(s) supported by the EURL, and with the ECDC, including the development of and agreement on annual work plans;
- (j) organising meetings for members of the network(s) supported by the EURL;
- (k) ensuring coordination with other EU reference laboratories in public health and/or in other areas such as feed, food and animal health and/or *in vitro* medical devices, the World Health Organization (WHO) Collaborating Centres and/or WHO reference laboratories, or relevant initiatives in the field of the EURL;
- (l) collaborating, in cooperation with the ECDC, with the EFSA and/or the European Medicines Agency (EMA), as relevant;
- (m) collaborating, in cooperation with the ECDC, with laboratories in third countries in an international context that benefits EU-level public health, as relevant;
- (n) providing scientific and technical assistance on other issues relevant to members of the network(s) supported by the EURL.