



Brussels, 22.3.2024
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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of 22.3.2024

designating European Union reference laboratories for certain specific areas of public health

(Text with EEA relevance)

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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/EU¹, 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 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 October 2023², calls for applications for EU reference laboratories in six areas of public health, namely antimicrobial resistance (AMR) in bacteria; vector-borne viral pathogens; emerging, rodent-borne and zoonotic viral pathogens; high-risk, emerging and zoonotic bacterial pathogens; *Legionella*; and diphtheria and pertussis.
- (3) In response to those calls, Member States submitted applications for designation by 5 January 2024, which were evaluated by a selection board set up by the Commission services.
- (4) The selection board took into account the criteria for EU reference laboratories set in Article 15(5) of Regulation (EU) 2022/2371 and in the call for application.
- (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 2023³, 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,

¹ OJ L 314, 6.12.2022, p. 26–63.

² https://health.ec.europa.eu/health-security-and-infectious-diseases/surveillance-and-early-warning/eu-reference-laboratories-public-health-calls-application_en

³ https://health.ec.europa.eu/publications/2023-eu4health-work-programme_en; reference CP-g-23-05-01

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 antimicrobial resistance in bacteria until *[OP: please insert, 7 years from the date of entry into force.]*
2. The responsibilities and tasks of that European Union reference laboratory are laid down in that Annex.

Article 2

1. The consortium referred to in Annex II is designated as European Union reference laboratory for public health on vector-borne viral pathogens until *[OP: please insert, 7 years from the date of entry into force.]*
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 emerging, rodent-borne and zoonotic viral pathogens until *[OP: please insert, 7 years from the date of entry into force.]*
2. The responsibilities and tasks of that European Union reference laboratory are laid down in that Annex.

Article 4

1. The consortium referred to in Annex IV is designated as European Union reference laboratory for public health on high-risk, emerging and zoonotic bacterial pathogens until *[OP: please insert, 7 years from the date of entry into force.]*
2. The responsibilities and tasks of that European Union reference laboratory are laid down in that Annex.

Article 5

1. The consortium referred to in Annex V is designated as European Union reference laboratory for public health on *Legionella* until *[OP: please insert, 7 years from the date of entry into force.]*
2. The responsibilities and tasks of that European Union reference laboratory are laid down in that Annex.

Article 6

1. The consortium referred to in Annex VI is designated as European Union reference laboratory for public health on diphtheria and pertussis until *[OP: please insert, 7 years from the date of entry into force.]*
2. The responsibilities and tasks of that European Union reference laboratory are laid down in that Annex.

Article 7

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, 22.3.2024

For the Commission
The President
Ursula VON DER LEYEN