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ANNEX IV

THE EU REFERENCE LABORATORY FOR PUBLIC HEALTH ON HIGH RISK, EMERGING AND ZOONOTIC BACTERIAL PATHOGENS, ITS RESPONSIBILITIES AND TASKS

1. The consortium designated as the EU reference laboratory for public health on high risk, emerging and zoonotic bacterial pathogens (hereinafter 'EURL'):

Consortium led by:

Robert Koch-Institut, Nordufer 20, 13353 Berlin, Germany

Also composed of:

Institut für Mikrobiologie der Bundeswehr, Neuherbergstraße 11, 80937 München, Germany

Folkhälsomyndigheten, Nobels väg 18, 171 82 Solna, Sweden

Instituto Nacional de Saúde Doutor Ricardo Jorge, Avenida Padre Cruz, 1649-016 Lisboa, Portugal

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 high risk, emerging and zoonotic bacterial pathogens.

This includes high risk, emerging and zoonotic bacterial diseases (such as anthrax, brucellosis, glanders, leptospirosis, Lyme borreliosis, melioidosis, plague, Q fever, rickettsiosis and tularaemia).

The EURL shall provide support to the members of the laboratory networks of the European Centre for Disease Prevention and Control (ECDC)'s European Emerging and Vector-borne Diseases Network (EVD-Net)¹ and 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 laboratory networks of of EVD-Net and FWD-Net consisting of the National Focal Points (NFPs) for Emerging and Vector-borne Diseases and NFPs for Food- and Waterborne Diseases and Zoonoses and the

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

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

Operational Contact Points (OCPs) for Microbiology for bacterial diseases under the scope of 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, including measures to prevent undue disclosure of confidential information.

The EURL shall be responsible for the following tasks:

- (a) Providing reference diagnostic and characterisation services in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by these network(s);
- (b) Providing reference materials in the field of the EURL to members of the network(s) supported by the EURL;
- (c) Providing external quality assessment schemes for diagnostics and characterisation of selected bacteria in the field of the EURL to members of the network(s) supported by the EURL, according to the needs defined by these 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 these network(s);
- (e) Providing technical reports in the field of the EURL, based on literature reviews, expert opinions and/or network surveys;
- (f) Providing contributions to ECDC technical reports in the field of the EURL;
- (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) Providing information, guidance and support to members of the network(s) supported by the EURL in case of unusual occurrences in the field of the EURL;
- (i) Providing information, guidance and support to the ECDC in outbreak situations in the field of the EURL, including providing contributions to ECDC risk assessments;
- (j) 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;
- (k) Organising and delivering twinning visits in the field of the EURL for members of the network(s) supported by the EURL;
- (1) Ensuring coordination, communication and dissemination with members of the network(s) supported by the EURL and with the ECDC;
- (m)Organising laboratory network meetings in the field of the EURL;
- (n) 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 or relevant initiatives in the field of the EURL;

- (o) Collaborating, in cooperation with the ECDC, with laboratories in third countries and with the European Food Safety Authority (EFSA) and/or the European Medicines Agency (EMA), as relevant;
- (p) Providing scientific and technical assistance on other issues relevant to members of the network(s) supported by the EURL.