ECDC Terms of Reference

STI, Blood-borne viruses and TB (SBT)

Ad hoc scientific expert panel for developing ECDC technical guidelines on the prevention of transmission of communicable diseases through Substances of Human Origin

01 September 2025, Stockholm

On 6 August 2024, the Regulation on standards of quality and safety for substances of human origin (SoHO) intended for human application[1] (referred to as "the Regulation" in the remainder of this document) came into force. As of 7 August 2027, the substantive provisions of the Regulation will apply, and the Blood Directive (2002/98/EC) and the Tissues and Cells Directive (2004/23/EC) will be repealed. The Regulation will apply to blood and blood components, tissues and cells, including haematopoietic stem cells from peripheral blood, umbilical-cord blood or bone marrow, reproductive cells and tissues, embryos, foetal tissues and cells, adult and embryonic stem cells, and other substances of human origin for human application, such as human breast milk, intestinal microbiota, blood preparations that are not used for transfusion, and any other SoHO that might be applied to humans in the future. Solid organs are excluded from the scope of this Regulation.

The Regulation mandates the European Centre for Disease Prevention and Control (ECDC) to develop and update technical guidelines on the safety and quality of SoHO from a communicable disease threat perspective (Articles 56(4) and 59(4) of the Regulation (EU) 2024/1938). To fulfil this role, ECDC is developing technical guidelines for the prevention of transmission of communicable diseases through SoHO in the European Union and European Economic Area (EU/EEA)[2].

As part of the guidelines development process, expert panels are established to address specific topics related to microbial safety of SoHO and the assessment of SoHO donors, for a predefined group of pathogens. The expert panel complements ECDC's technical and scientific expertise and delivers expert opinions to support ECDC in drafting technical guidelines. The task of the panel is to provide expert opinion and reach agreements, based on available scientific evidence presented by ECDC. The agreements cover donor testing strategies, testing methods and the need for deferral where appropriate (including deferral period). These agreements serve as a basis for ECDC to draft the technical guidelines.

The present Terms of Reference (ToR) aim to establish an expert panel that will provide scientific opinion on the following pathogens in the context of SoHO safety: West Nile virus (WNV), dengue virus (DENV), Zika virus (ZIKV), chikungunya virus (CHIKV), tick-borne encephalitis virus (TBEV) and Crimean-Congo haemorrhagic fever virus (CCHFV). These pathogens were defined by the ECDC Network for the Microbial Safety of Substances of Human Origin (SoHO-Net) in 2025 as a priority for the development of ECDC technical guidelines for SoHO.

[1] Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC. Available from: http://data.europa.eu/eli/reg/2024/1938/oj.

[2] https://www.ecdc.europa.eu/en/infectious-disease-topics/related-public-health-topics/substances-human-origin/technical-guidelines

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Development of technical guidelines on the prevention of transmission of communicable diseases through SoHO **Purpose and scope**	This document details the ToR for a scientific expert panel that will provide scientific opinion to support the development of technical guidelines for the prevention of transmission of the following pathogens through SoHO: WNV, DENV, ZIKV, CHIKV, TBEV, and CCHFV. This ToR will cover the following SoHO types: blood and blood components, including plasma for industrial manufacturing, tissues and non-reproductive cells, and reproductive cells and tissues (human organs are out of scope). Since 2022, ECDC has been conducting a project covering the development of technical guidelines for the prevention of transmission of pathogens through SoHO in the EU/EEA. These guidelines will serve as a reference for SoHO entities to achieve the standards for the protection of SoHO recipients and offspring from medically assisted reproduction, concerning the prevention of communicable disease transmission. The guidelines cover the following topics, per pathogen, donor and SoHO type: • Events with increased risk of exposure to pathogens and donor infection to consider in donor assessment. • Screening strategies for SoHO donors, including considerations of the use of pathogen reduction/inactivation methods. • Laboratory testing methods for microbiological screening of SoHO donors. The guideline development process includes: a) Evidence synthesis by ECDC, covering description of pathogens and respective diseases, epidemiology worldwide and specifically in the EU/EEA, including risks factors for infection and/or risk of exposure to the pathogens, laboratory testing approaches, available recommendations for donor screening in EU/EEA countries and from other organisations, evidence of transmission of the pathogens through SoHO and pathogen reduction/inactivation methods. b) Assessment of the evidence synthesis by a scientific expert panel, and provision of expert opinion on: o Events to consider in the donor assessment. o SoHO donor screening strategies, including test methods limitations and deferral periods, based on the risk of pathogen transmission through different SoHO. o Available laboratory testing methods for each pathogen. c) Development of technical guidelines by ECDC, based on the assessments and opinion of the scientific expert panel The established process aims to ensure scientific quality, transparency, and consistency of the development and publication of the guidelines. ECDC will provide the scientific expert panel with a consolidated document ("pathogen data sheet") containing the evidence described in a). ECDC will gather and process relevant epidemiological, microbiological, clinical and other applicable data. This evidence will be based on structured targeted literature reviews, ECDC internal data and/or data from relevant EU/EEA country authorities. Additional evidence, including systematic literature reviews, can be requested by the scientific expert panel if deemed necessary. Further evidence may also be provided by the experts.

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	The outputs of the scientific expert panel, in the form of meeting minutes, will be taken into account for the development of technical guidelines covering these pathogens. The requirements and recommendations included in the guidelines are drafted by ECDC, based on the input provided by the expert panel. The final guidelines document will be published by ECDC on its website. The European Directorate for the Quality of Medicines and HealthCare (EDQM) is also cited as an expert body establishing guidelines in the Regulation (EU) 2024/1938. To ensure consistency with the guidelines produced by ECDC, EDQM will be represented by up to two observers in the scientific expert panel.
ECDC responsibilities	ECDC is responsible for: • Providing data on current SoHO donor testing requirements and testing methods used in EU/EEA countries for the pathogens under discussion. • Providing a consolidated "pathogen data sheet" for the pathogens under discussion. • Providing additional evidence upon request of the scientific expert panel. • Providing technical and administrative support to the expert panel meetings. • Producing meeting minutes, with the agreements reached by the scientific expert panel during the meetings. • Producing technical guidelines on the prevention of transmission of communicable diseases through SoHO for the group of pathogens covered by the ToR.
Expert Panel tasks and responsibilities	The members of the scientific expert panel will be asked to: • Attend the meetings, according to availability, or provide their contribution by other means. • Critically review the scientific evidence provided by ECDC. • Provide additional evidence relevant to the discussions. • Define needs for additional evidence, if required, to support panel discussions on specific topics related to the covered pathogens. • Provide expert opinion on donor selection, donor screening strategies and deferrals (including deferral periods), and testing methods, for the pathogens under discussion. • Provide feedback on draft proposals on donor selection, testing and deferral strategies as requested via pre-meeting surveys sent out by the ECDC SoHO team. • Contribute to the development of and agreement on proposals on donor selection, testing and deferral strategies. These agreements will serve as a basis for drafting the guidelines. • Review draft meeting minutes covering discussions and agreements reached by the panel, to ensure alignment with the best practices in the field. • Support ECDC in the resolution of comments from the SoHO network and external stakeholders on the technical guidelines, including additional ad hoc virtual meetings (if necessary). In addition, the members of the scientific panel will be responsible for: • Maintaining the confidentiality of all information, documents and data related to the tasks of the scientific expert panel, including no unauthorised usage and no disclosure or communication of such

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	information to any third party, unless explicitly authorised to do so. This confidentiality obligation shall remain in force after the completion of the tasks, unless the information in question enters the public domain. By accepting this undertaking, the individual acknowledges that they shall continue to be bound by this obligation, even after the termination of their involvement with the scientific expert panel. • Provide and keep up to date, at least on a yearly basis, declarations of interest throughout the guideline development process, including informing ECDC in a timely fashion of any potential conflict of interest that might affect their decisions and/or actions. The responsibilities of the EDQM observers are to: • Attend the meetings, according to availability, or provide their contribution by other means. • Liaise with the EDQM guide working groups to avoid gaps and inconsistencies between the ECDC technical guidelines and the EDQM blood and tissues and cells guides. • Maintaining the confidentiality of all information, documents and data related to the tasks of the scientific expert panel, including no unauthorised usage and no disclosure or communication of such information to any third party, unless explicitly authorised to do so. This confidentiality obligation shall remain in force after the completion of the tasks, unless the information in question enters the public domain. By accepting this undertaking, the individual acknowledges that they shall continue to be bound by this obligation, even after the termination of their involvement with the scientific expert panel. • Provide and keep up to date, at least on a yearly basis, declarations of interest throughout the guideline development process, including informing ECDC in a timely fashion of any potential conflict of interest that might affect their decisions and/or actions.
Format and frequency of the scientific expert panel meetings	The scientific expert panel meetings will take place virtually, starting Q2 2026 for an estimated period of approximately 24 months, corresponding to ten meetings. General structure: Bimonthly or quarterly virtual meetings from Spring 2026 until agreements have been recorded for topics related to each pathogen covered by the present ToR, and a first closed consultation on the meeting minutes has been concluded. The meeting plan will include: 1. Meetings to discuss and provide expert opinion on donor screening strategies for WNV, DENV, ZIKV, CHIKV, TBEV, and CCHFV. Topics will cover: - *Events with increased risk of exposure to pathogens and donor infection to consider in donor assessment.* - *Screening strategies, including considerations on the role of pathogen reduction technologies.* 2. Meetings to discuss and provide expert opinion on testing methods for WNV, DENV, ZIKV, CHIKV, TBEV, and CCHFV. Topics will cover:

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	- *Testing methods to perform laboratory screening for the considered pathogens.* - *Testing methods to perform confirmatory tests for the considered pathogens (when relevant).* 3. Ad hoc virtual meetings, called as needed for the resolution of comments during the guideline's review process. Agreements will be considered reached by the expert panel by consensus on specific questions on the topics described above, or in the absence of major disagreements among members of the panel on statements to be included in the technical guidelines and presented by ECDC. The major disagreements/objections and minority opinions will be described in the minutes. Agreements will be extracted from meeting records and included in meeting minutes (see section "Work Procedures"). The expert panel members are expected to review these minutes. They will serve as reference documents for supporting ECDC's decisions on requirements and recommendations while drafting the guidelines. The duration of the meetings will be based on an agreed meeting agenda, but is estimated to be half a working day. Meetings will be recorded for the purpose of drafting meeting minutes. Ad-hoc technical consultation and coordination meetings can be organised when/if needed to address smaller, focused topics, to ensure continuity of the work and prevent unnecessary delays.
Composition of the scientific expert panel	The scientific expert panel will be composed of a maximum of 20 experts from EU/EEA countries with experience with different types of SoHO and/or different types of pathogens covered by this ToR considered under the Regulation (EU) 2024/1938. Members of the scientific expert panels shall meet the following requirements: o possess a university or corresponding degree in the field of medical or biological sciences. o have at least five years of experience working in blood, tissue, cells or medically assisted reproduction establishments, including donor testing laboratories, on donor selection, donor testing, quality assurance or as a responsible person (in accordance with Article 36 of the Regulation (EU) 2024/1938). or, alternatively, at least five years of experience in infectious diseases covered by these ToR, and an additional good understanding of the field of SoHO. o have experience in evidence-based medicine. o comply with the ECDC policy on scientific integrity and independence[3] as assessed by ECDC on the basis of the annual declaration of interest (DoI) completed via the ECDC E-DoI platform.

[3] https://www.ecdc.europa.eu/sites/default/files/documents/ECDC-scientific-integrity-independence-march-2023.pdf

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	Prior experience in, and contributions to, the development of technical standards/guides/guidelines documents, including as part of relevant EU projects, are desirable. In the case of departures or noncompliance with responsibilities listed in these ToR, experts can be replaced, or vacant positions can be refilled. Requirements for selecting these experts shall remain the same as for the original post. The recruited experts will not represent countries or institutions but will be appointed in their own capacity and areas of expertise. The scientific expert panel will act exclusively as an independent technical advisory body.
Selection procedure	Calls for interest are sent to relevant ECDC expert networks (SoHO-Net and disease and laboratory networks), relevant professional associations, and to the national competent authorities for blood, tissues/cells, and medically assisted reproduction. In addition, the ECDC Expert directory will be consulted for potential candidates. The scientific expert panel members will be selected and proposed for appointment by ECDC, considering the requirements listed above, and ensuring reasonable geographical and gender representativeness. Within the selection procedure, individual declarations of conflict of interest will be thoroughly reviewed and assessed against the ECDC policy on scientific integrity and independence. In addition, ECDC will aim to ensure sufficient representativeness of each SoHO type (i.e., blood and blood components, including plasma for industrial manufacturing, tissues and non-reproductive cells and reproductive cells and tissues) in the scientific expert panel. Once a proposed list of scientific expert panel members has been drawn up, the ECDC Advisory Forum will be consulted, prior to formal appointment by the ECDC Director. Selection of additional or replacement/refill experts shall follow the same procedure.
Work procedures	Meetings of the scientific expert panel will be virtual and audio-recorded for the purpose of drafting meeting minutes (as per ECDC Data Privacy Statement for virtual meetings). Acceptance of the ToR during the first meeting will involve agreement to the audio-recording of subsequent scientific expert panel meetings. All meetings will have minutes or action points drafted by ECDC. Several expert panel meetings are expected before covering and reaching agreements on the topics described in the ToR for the whole group of pathogens. The total number of meetings required in the context of this project and details of their content may be subject to change, and the ToR will be updated accordingly. Similarly, the creation of working groups focused on specific topics (e.g., laboratory testing methods) may be considered. Quality aspects of each meeting will be evaluated, and based on the results of these evaluations, the necessary organisational changes (e.g., more frequent, shorter meetings, subgroup meetings, etc.) will be implemented.
Terms and conditions of panel members	The members of the scientific expert panel will not be remunerated for the work performed. ECDC will acquire all intellectual property rights on any outputs of work performed by the scientific expert panel on its behalf. ECDC will acknowledge all members for their work as having been a part of the

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	guidance scientific expert panel. The final documents will be in the public domain.

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