

ECDC FRAMEWORK DOCUMENT

ECDC framework relating to substances of human origin (SoHO)

May 2024

This framework describes the building blocks being laid down by the European Centre for Disease Prevention and Control (ECDC) to support and empower European Union (EU)/European Economic Area (EEA) countries and the European Commission in achieving microbial safety for substances of human origin (SoHO).

ECDC activities related to SoHO are coordinated by the SoHO staff within the section on sexually transmitted infections, blood-borne viruses and tuberculosis (SBT), with close collaboration and input from other ECDC sections and units, EU/EEA countries, the European Commission, EU agencies and a broad range of key external stakeholders.

The focus of the framework is on implementing the relevant parts of [Regulation \(EC\) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control](#), [Regulation \(EU\) 2022/2370 of the European Parliament and the Council of 23 November 2022 amending Regulation \(EC\) No 851/2004 establishing a European Centre for Disease Prevention and Control](#), and [Regulation \(EU\) 2022/2371 of the European Parliament and the Council of 23 November 2022 amending Regulation \(EC\) of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU](#). In other words, it focuses on operating dedicated networks and networking activities, monitoring threats and performing public health risk assessment, and response coordination. It also refers to the relevant parts of the [Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation](#) and the [Regulation on standards of quality and safety for substances \(SoHO Regulation\)](#) – i.e. providing advice on serious adverse reactions, launching rapid alerts, and developing guidelines to protect SoHO donors, recipients and their offspring.

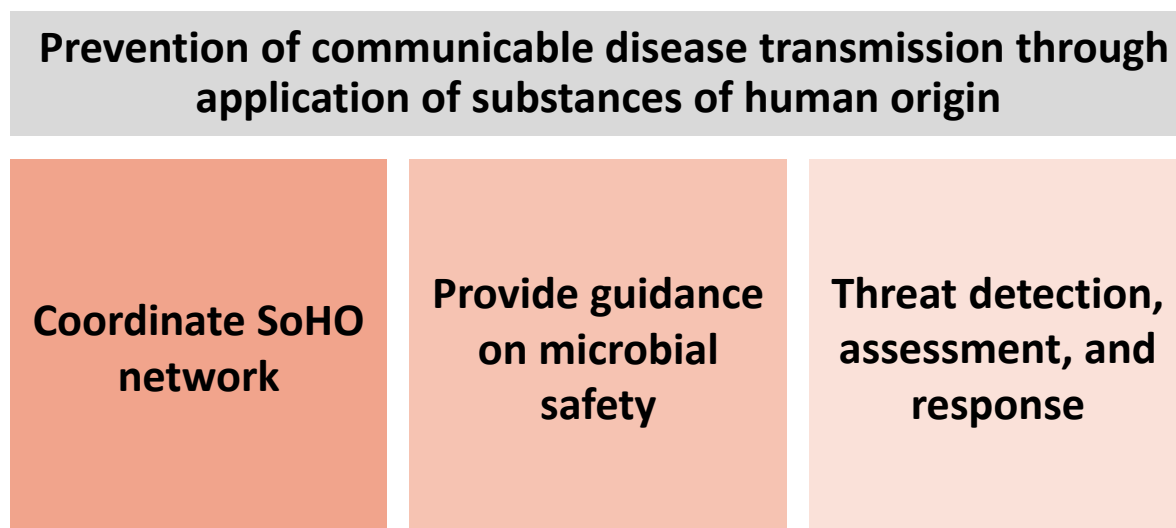
A substance of human origin is defined in the SoHO Regulation as any substance collected from the human body, whether it contains cells or not and whether those cells are living or not, including SoHO preparations resulting from the processing of that substance.

ECDC's work on SoHO encompasses those countries which come under the ECDC mandate, namely the EU/EEA, although some aspects of this work will be relevant to and include EU enlargement and neighbourhood policy countries.

Framework for ECDC action on the microbial safety of SoHO

ECDC will organise its work to support EU/EEA countries and the European Commission on microbial safety of SoHO through a series of linked building blocks (see Figure 1).

Figure 1. Framework for ECDC support to EU/EEA countries and the European Commission to reach microbial safety of substances of human origin



Building block 1. Coordinate SoHO network

ECDC will coordinate and operate a network of Member State services supporting the use of substances of human origin (SoHO-Net). The network consists of four sub-networks – blood, tissues and cells, organs, and medically assisted reproduction – with officially nominated National Focal Points (NFPs) for each sub-network. SoHO-Net also includes a network coordination committee, with nine elected members from the network. NFPs are nominated by the national coordinators of the ECDC Coordinating Competent Bodies (CCB) and asked to cooperate closely and communicate with the national competent authorities for SoHO in their country. The network will help to ensure that SoHO are microbiologically safe by monitoring, assessing and helping to address relevant disease outbreaks with the potential to pose serious cross-border threats to health, in order to safeguard patients in need of SoHO. The network also has observers who are relevant key stakeholders.

ECDC will organise regular meetings of the SoHO Network Coordination Committee and the four SoHO sub-networks. In addition to network meetings, information exchange and collaboration between countries will be promoted through the use of the EpiPulse platform and bilateral initiatives facilitated by ECDC. EpiPulse is the ECDC online portal for European public health authorities and partner organisations to collect, analyse, share and discuss infectious disease data for threat detection, monitoring, risk assessment and outbreak response. Other systems, not owned by ECDC (the EU Early Warning and Response System (EWRS), the Rapid Alert platform for human Blood and Blood Components (RAB), and the Rapid Alert platform for human Tissues and Cells (RATC)) require Member States and the European Commission to notify serious cross-border threats to health (EWRS) or serious adverse reactions and events (RAB/RATC) and exchange information to coordinate the response.

Building block 2. Provide guidance on microbial safety

ECDC will develop and update guidelines on the prevention of communicable disease transmission to help protect SoHO recipients, their offspring resulting from medically assisted reproduction, and donors, as referred to in the SoHO Regulation. The guideline development process will follow ECDC procedures and include an expert panel and a consultation process with SoHO-Net and the ECDC Advisory Forum, as well as stakeholders on the European Commission list¹, and the European Directorate for the Quality of Medicines & HealthCare (EDQM), European Medicines Agency, and World Health Organization. ECDC will work closely with the EDQM to ensure that technical guidelines published by EDQM and ECDC are aligned.

At the request of the SoHO network, the European Commission, or on its own initiative, ECDC may develop guidance and recommendations on other topics relevant to the microbial safety of SoHO.

¹ List of eligible stakeholder organisations interested in participating in ad-hoc meetings with representatives/members of the Competent Authorities on Substances of Human Origin Expert Group: https://health.ec.europa.eu/consultations/ad-hoc-stakeholder-meetings-call-expressions-interest-0_en

Building block 3. Threat detection, assessment, and response

3a: Monitor threats and outbreaks

ECDC will detect, monitor, and report on serious cross-border threats to health related to SoHO. This will be done by screening various information sources on a daily basis, monitoring serious adverse reactions² (rare, or unexpected for the SoHO type reported to ECDC by the SoHO national authorities), and perusing notifications from formal sources – e.g. the Early Warning and Response System (EWRS). Appointed experts from the EU/EEA and non-EU countries, ECDC staff, and representatives of European authorities and international organisations can also report cases of infectious diseases and pathogens that may threaten microbial safety of SoHO in the EU/EEA via EpiPulse. ECDC can collect additional information in EpiPulse to support its assessment of a signal and consider whether it should be evaluated as a threat. Any threats identified are discussed at the daily ECDC round table meeting, where an initial assessment of appropriate ECDC action is made.

3b: Perform risk assessments and launch alerts

In the event of a serious cross-border threat to health relating to SoHO, ECDC will provide risk assessments. The risk assessments will include guidance and targeted science-based recommendations and options for response.

If surveillance of communicable diseases and the risk assessment indicate a new risk to the safety of SoHO, ECDC may launch an alert on the EU SoHO platform, with the support of the SoHO network. The EU SoHO platform will be established by the European Commission and will build on the RAB and RATC (already established) which are currently hosted by the European Commission.

When ECDC launches an alert on the SoHO platform, or when ECDC is informed of a SoHO-specific alert launched in one or more of the EU Member States, it may indicate that it has provided guidelines on the mitigation of risks associated with communicable disease outbreaks, particularly as regards the eligibility and testing of SoHO donors. ECDC will consider the relevant best practices agreed upon and documented by the SoHO Coordination Board (Board to be established to promote a coordinated application of the SoHO Regulation, with participation of the Commission and the Member States) when launching and handling a SoHO rapid alert.

ECDC will also support response coordination in the Health Security Committee in the event of a serious cross-border threat to health relating to SoHO that can potentially be affected by communicable diseases. This support will consist of science-based recommendations and options for: (a) national or cross-border inter-regional responses to the serious cross-border threat to health; (b) the adoption of guidelines for the Member States to prevent and control the serious cross-border threat to health.

Furthermore, for emergencies related to epidemiological outbreaks, ECDC can provide advice to Member States on the establishment of national SoHO emergency plans.

3c: Provide advice on serious adverse reactions

ECDC will be informed by the SoHO national authority of any serious adverse reactions concerning transmission of a communicable disease that is rare, or unexpected for a particular type of SoHO. ECDC will support the implementation of follow-up action, which could involve providing advice or information for SoHO national authorities on options for response, with the help of the relevant SoHO sub-network(s).

Other activities within ECDC's mandate

ECDC will focus its SoHO work on the mandatory activities included in Regulation (EC) No 851/2004, Regulation (EU) 2022/2370 and Regulation (EU) 2022/2370 and the SoHO Regulation. If more resources are made available, ECDC can initiate work on other activities mentioned in the Regulations.

ECDC may initiate scientific studies and applied scientific studies and projects. These studies and projects could target the microbial safety of SoHO, or provide essential knowledge for the development of SoHO guidelines.

ECDC can support countries and the Commission by providing scientific and technical expertise in the development, regular examination and updating of preparedness plans to ensure microbial safety of SoHO in the event of an outbreak of a communicable disease. For example, this may be done through virtual or actual country visits or consultations. In addition, the microbial safety of SoHO can be included in stress tests and in-action and after-action reviews.

ECDC is also tasked with supporting and coordinating training programmes, particularly those relating to epidemiological surveillance, field investigations, preparedness and prevention, response to public health emergencies, public health research and risk communication. These training programmes can include or specifically focus on the microbial safety of SoHO.

In coordination with European Commission, ECDC can communicate information on its SoHO-related activities. This can include specific communications to SoHO experts, clinicians, policy makers, potential donors, and the general public.

² A serious adverse reaction (SAR) is defined in the SoHO Regulation as an adverse reaction that results in death, a life-threatening, disabling or incapacitating condition, including transmission of a pathogen, hospitalisation or prolongation of hospitalisation, or the need for a major clinical intervention to prevent or reduce the effects.

Empowering EU/EEA countries, the European Commission and other partners to drive public health policy and practice

Through the building blocks detailed in this framework, ECDC aims to achieve the following:

- A robust SoHO network and mechanisms for the exchange of information and support, providing added benefits for EU/EEA countries to ensure the microbial safety of SoHO.
- Guidelines available and updated as required for the prevention of donor-derived communicable disease transmission through the application of SoHO.
- A well-functioning system for identification and information-sharing of serious adverse reactions and communicable disease outbreaks relevant to the microbial safety of SoHO.
- High-quality risk assessments with science-based recommendations and options for response and timely alerts when a new risk to the safety of SoHO is identified.