

European Centre for Disease Prevention and Control

An overview of the new and upcoming EU legislation on substances of human origin and pharmaceuticals: Perspectives and implications

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EU regulations relevant for SoHO and ECDC

- 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**
- 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
- 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
- Proposal for a Regulation 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

Framework for ECDC action on microbial safety of SoHO



Prevention of communicable disease transmission through application of substances of human origin

Coordinate SoHO network

Provide guidance on microbial safety

Threat detection, assessment, and response

Coordinate SoHO network

- Network of Member State services supporting the use of substances of human origin (SoHO-Net). Four sub-networks with National Focal Points and observers:
 - Blood
 - Tissues and cells
 - Organs
 - Medically assisted reproduction
- Regular meetings of the SoHO Network Coordination Committee and of the four SoHO sub-networks
- EpiPulse platform for information exchange and collaboration between countries

Provide guidance on microbial safety

- Develop and update guidelines as referred to in the SoHO Regulation
 - Guideline development process according to ECDC procedures for developing guidelines
 - Collaboration with the European Directorate for the Quality of Medicines & HealthCare (EDQM) to ensure that technical guidelines published by EDQM and ECDC are aligned
- Develop guidance and recommendations on topics relevant to the microbial safety of SoHO at the request of the SoHO network, the European Commission or on own initiative

ECDC guidelines – SoHO regulation

Article 56 (4) and 59 (4)

For those standards concerning [donor protection or elements thereof]/[recipient and offspring protection] for which no implementing act has been adopted, in order to apply such standards or elements thereof, SoHO entities shall follow:

- (a) the most recent technical guidelines, as indicated on the EU SoHO Platform referred to in Chapter XI, as follows:
 - (i) Published by the ECDC concerning the prevention of communicable disease transmission through SoHO donation

ECDC guidelines – SoHO regulation

Pathogens

- Listed in current blood and tissues and cells directives

First batch: HIV, HBV, HCV, *Treponema pallidum*, West Nile Virus

- With current relevance (e.g., Dengue virus)

Second batch: SoHO network consultation

SoHOs

As defined in the Regulation (i.e., not including organs)

Topics

- Testing strategies and laboratory testing methods
- Deferral strategies (including deferral periods)

ECDC guidelines development process

- Collection of **evidence** and development of **statements** regarding testing methods and strategies and deferral strategies
- Assessment of evidence and statements by **expert panel**
- **ECDC to draft the guidelines** using evidence and advice of expert panel
- Review of draft guidelines by
 - SoHO-Net
 - Stakeholders on list maintained by SANTE¹ and EDQM, EMA, WHO
 - ECDC advisory forum

1. List of stakeholder organisations interested in participating in ad-hoc meetings with representatives of members of the Competent Authorities on Substances of Human Origin Expert Group

Ad hoc scientific expert panel

- Panel established for each batch
- Call for interest to
 - ECDC networks: SoHO-Net and others
 - National Competent Authorities for Blood and Tissues/Cells
 - Relevant professional associations (EBA, EATCB, ESHRE, ...)
- Nomination procedure
 - Selection by ECDC based on knowledge and experience (taking into account gender and geographical representation)
 - Assessment of conflicts of interest
 - Panel members approved by ECDC Advisory Forum
 - Final nomination by the ECDC Director

Threat detection, assessment, and response: Monitor threats and outbreaks



Detect, monitor, and report on serious cross-border threats to health related to SoHO.

- Results of daily screening of various information sources
- Reports of cases of infectious diseases and pathogens that may threaten microbial safety of SoHO in the EU/EEA in EpiPulse
- Monitoring of serious adverse reactions related to pathogen transmission*

→ Discussion of identified threats and an initial assessment of appropriate ECDC actions.

* Serious adverse reaction (SAR) is defined in the Proposal for a 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.

Threat detection, assessment, and response: Perform risk assessments and launch alerts



- Provide risk assessments including science-based recommendations and options for response in the case of a serious cross-border threat to health
- Launch an alert in the EU SoHO Platform when the risk assessment indicates a new risk to the safety of SoHOs
- Support response coordination in the Health Security Committee
- Provide advice for emergencies related to epidemiological outbreaks to Member States in support of establishing national SoHO emergency plans

Threat detection, assessment, and response: Provide advice on serious adverse reactions*



SoHO National Authority will inform ECDC of serious adverse reactions concerning a transmission of a communicable disease that is rare, or unexpected for that SoHO type.

ECDC will implement relevant follow-up actions including providing advice or information to SoHO National Authorities on options for response.

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Other activities within ECDC mandate

- Scientific studies and projects.
- Providing scientific and technical expertise in the development, regular examination and updating of preparedness plans.
- Country visits or consultations.
- Stress tests and in-action and after-action reviews.
- Support and coordinate training programmes.
- Communicate information about activities related to SoHO.

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