



European Centre for Disease Prevention and Control

ECDC's plan for ensuring microbiological safety of SoHO within its extended mandate

IPFA/PEI 29th International Workshop on Surveillance and Screening of Blood-borne Pathogens
10-11 May, 2023 in Bologna, Italy

REGULATION (EU) 2022/2370 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control

Main categories of topics related to the SoHO, addressed in the new Regulation

- ❖ communication and cooperation between the countries
- ❖ scientific advice
- ❖ vigilance & response

REGULATION (EU) 2022/2370 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 November 2022

CHAPTER 2 OPERATIONAL PROCEDURES

Article 5

Operation of dedicated networks and networking activities

9. The Centre shall ensure the operation and coordination of the **network of Member State services supporting the use of substances of human origin**, in order to help **to ensure** that such substances are **microbiologically safe**, by monitoring, assessing and helping to address relevant disease outbreaks that have the potential to pose serious cross-border threats to health, and to safeguard patients in need of such substances.

REGULATION (EU) 2022/2370 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 November 2022

CHAPTER 2 OPERATIONAL PROCEDURES

Article 5

Operation of dedicated networks and networking activities

3. The Centre, through the operation of the network for epidemiological surveillance, shall:
- (b) **detect, monitor and report** on serious cross-border **threats to health** referred to in Article 2(1), points (a)(i) and (a)(ii), of Regulation (EU) 2022/2371, including threats to **substances of human origin**, or in Article 2(1), point (d), of that Regulation, with regard to source, time, population and place in order to provide a rationale for public health action;

Establishment of the SoHO Net - Objectives

Objectives of SoHO Net are to:

- **Encourage cooperation between Member States**
- **Help to ensure that SoHO are microbially safe** by monitoring, assessing and helping to address relevant disease outbreaks that can pose cross-border threats to health
- **Safeguard patients in need of SoHO**
- Support the detection, monitoring and reporting on serious cross-border threats to health related to SoHO
- Enhance preparedness and response planning activities in the Union

Establishment of the SoHO Net - Members

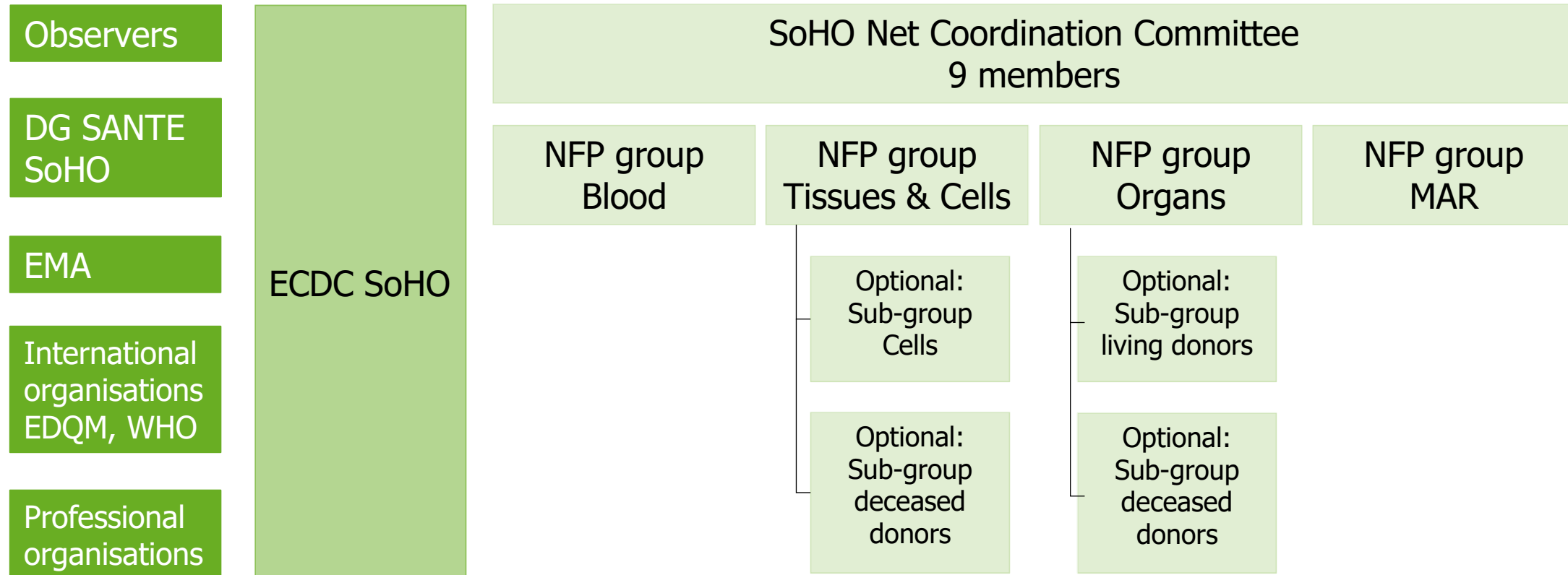
Members of SoHO-Net

National Focal Points (NFP) nominated by National Coordinators, in cooperation with National SoHO Competent Authorities

Call for nominations:

- *"individuals with technical expertise in assurance of microbial safety of SoHOs, preferably working inestablishments ... Also, we propose that nominees have expertise in donor assessment and/or bio-vigilance and/or quality assurance"*

SoHO Net



DG SANTE SoHO - Directorate General Health and Food Safety; EDQM - European Directorate for the Quality of Medicines & HealthCare (Council of Europe); EMA - European Medicines Agency; MAR - Medically Assisted Reproduction; NFP - National Focal Point; SoHO - Substances of Human Origin; WHO - World Health Organization

SoHO-Net members' terms of reference

Specific responsibilities of the NFP for SoHO

- ❖ **Cooperate closely and communicate with relevant National Competent Authorities** (NCA) on all topics relevant for the microbial safety of SoHO
- ❖ **Support and advise NCA** in the establishment of the national communication networks, encompassing all SoHO entities
- ❖ **Support ECDC** in regular **monitoring** of microbial safety measures
- ❖ **Contribute** to the assessment of the impact of **scientific advice** produced by ECDC
- ❖ **Report to EpiPulse** and **analyse** cases of infectious diseases and pathogens (potentially) related to SoHO that may threaten public health in the EU/EEA

SoHO-Net - activities

1st plenary meeting of the SoHO Network

- held virtually on 6 December 2022
- informative character

1st meeting of the Blood group

- held in hybrid mode 14-15 February 2023
- main topics related to communicable diseases covered:
 - hepatitis B, C and E in blood donation
 - sexually transmitted infections in blood donation
 - vector borne diseases in blood donation

1st meeting of Tissues & Cells and MAR group

- foreseen for 5-6 September, f2f
- agenda under development

Technical guidelines on the prevention of donor-derived transmission of communicable diseases through SoHO

Proposal for a Regulation on substances of human origin

Art 56 (4(a)(i))

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

.....the most recent technical guidelines,.....published by the ECDC concerning the prevention of communicable disease transmission through SoHO donation

Technical guidelines

- plan for the development

Key documents:

1. Project plan
2. Terms of reference for the expert panel
3. Pathogen data sheet

Technical guidelines -project plan

1. Relevant pathogens will be grouped

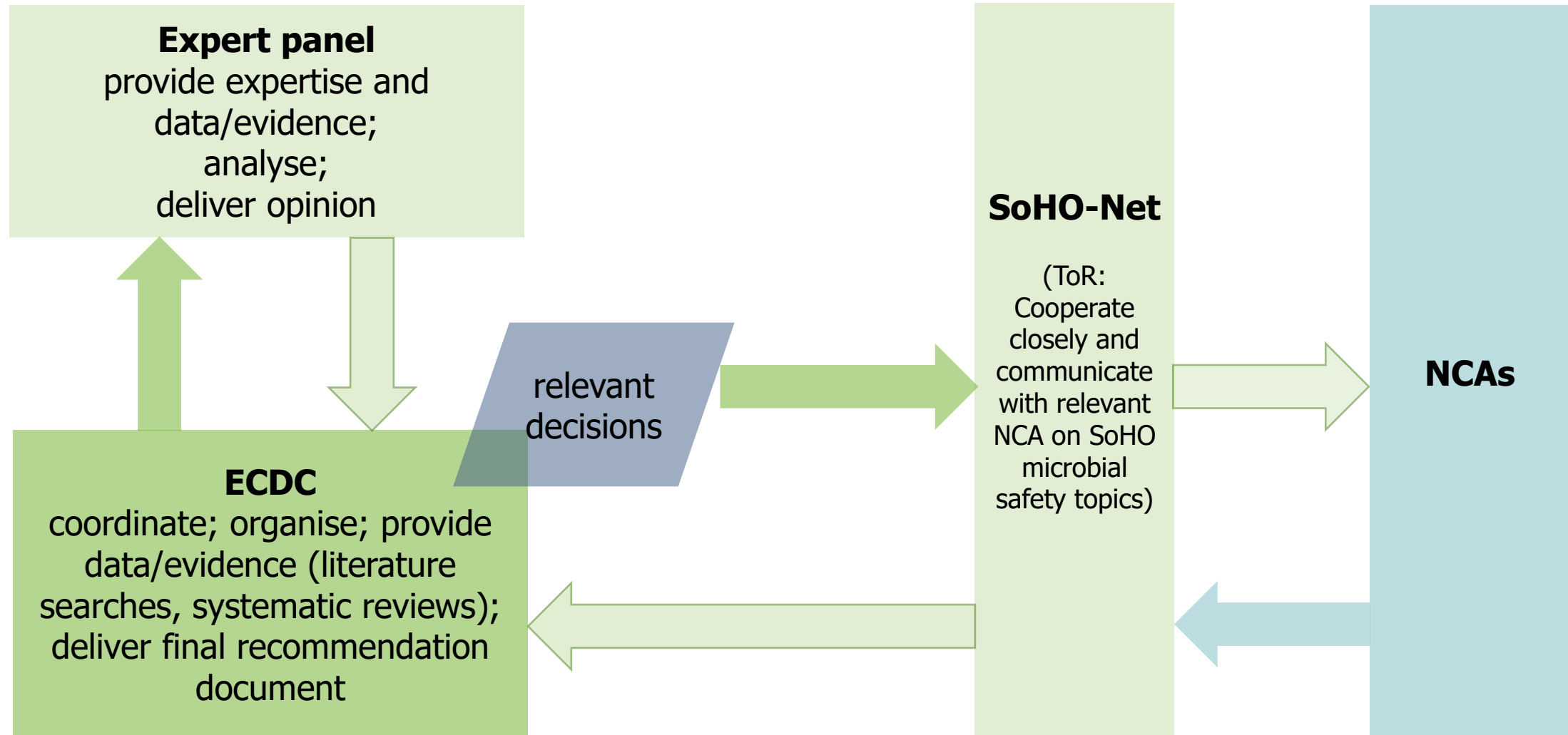
First group:

HIV, HBV, HCV, T. pallidum, WNV

2. ECDC will be supported by ad hoc scientific expert panel

3. Regular communication with SoHO-Net

Technical guidelines - project plan



Technical guidelines -expert panel call for interest

Launched in March 2023

- ECDC SoHO Network
- ECDC Emergency and Vector Born Diseases Laboratories Network
- National Competent Authorities for Blood and Tissues/Cells
- ECDC National Focal Point for HIV/AIDS, STI and hepatitis B/C
- ECDC Advisory Forum
- Relevant professional associations (EBA, EATB, ESHRE...)

Technical guidelines -pathogen data sheet

Contents:

- Description of the pathogen
- Disease description
- Epidemiology
- Laboratory testing approaches
- Current testing requirements in Member States
- Recommendations from other organizations
- Transmission through SoHO
- Pathogen reduction/inactivation methods

Technical guidelines -time-line

First meeting of the first expert panel

- foreseen for June/July 2023

Technical guidelines for the first group of pathogens finalised by the end of 2025

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And of course, ECDC will continue providing rapid risk assessments

CHAPTER 2 OPERATIONAL PROCEDURES

Article 8a

Public health risk assessment

1. The Centre shall provide risk assessments, in accordance with Article 20 of Regulation (EU) 2022/2371, in the case of a serious cross-border threat to health referred to in Article 2(1), points (a)(i) and (a)(ii), of that Regulation, including where it relates to **substances of human origin** that can potentially be impacted by communicable diseases, or in Article 2(1), point (d), of that Regulation. Such risk assessments shall be provided in a timely manner.

Thank you