



European Centre for Disease Prevention and Control

Microbial Safety of Substances of Human Origin: The ECDC SoHO Framework and the role of the SoHO Network

TRIP symposium for biovigilance officers in cell and tissue banks and hospitals in the Netherlands 6 November 2024

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ECDC – European Centre for Disease Prevention and Control



- An agency of the European Union located in Solna, Sweden
- Founded in 2005; 27 EU nationalities



EU and International partners



ECDC mission & role

To identify, assess and communicate current and emerging threats to human health posed by infectious diseases.

ECDC NORMAL

Disease
Surveillance &
Epidemic
intelligence

Response support
& Risk assessments
Preparedness &
capacity
strengthening

Scientific advice &
guidance

EU and external
stakeholders &
Country support

Public health
training

Communication

Vaccine-preventable diseases
and Immunisation

Sexually transmitted
infections, Blood-Borne Viruses
and Tuberculosis

ECDC SoHO team

Antimicrobial resistance and
healthcare-associated
infections

Emerging, Food and vector-
borne diseases



EU regulations relevant for SoHO

- 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
- 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

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

Disease and Laboratory Networks

and networks dedicated to health issues*

Antimicrobial resistance and healthcare-associated infections

- European Antimicrobial Resistance Surveillance Network (EARS-Net)
- European Surveillance of Antimicrobial Consumption Network (ESAC-Net)*
- Healthcare-associated Infections Surveillance Network (HAI-Net)*
- European Antimicrobial Resistance Genes Surveillance Network (EURGen-Net)

Emerging and vector-borne diseases

- Emerging and Vector-borne Diseases Network (EVD)
- Emerging Viral Disease-Expert Laboratory Network (EVD LabNet)
- European Network for sharing data on the geographic distribution of arthropod vector, transmitting human and animal disease agents (Vector-Net)*

Food- and waterborne diseases, zoonoses

- European Food- and Waterborne Diseases and Zoonoses Network (FWD-Net)
- European Legionnaires' disease Surveillance Network (ELDSNet)
- European Creutzfeldt-Jakob Disease Surveillance Network (EuroCJD)

Respiratory tract infections

- European Tuberculosis Surveillance Network
- European Reference Laboratory Network for TB (ERLTB-Net)
- European Influenza Surveillance Network (EISN)
- European Reference Laboratory Network for Human Influenza (ERLI-Net)
- European COVID-19 Surveillance Network (ECOVID-Net)
- European COVID-19 reference laboratory network (ECOVID-LabNet)

HIV, STI and blood-borne viruses

- European Sexually Transmitted Infections Network
- European Gonococcal Antimicrobial Surveillance Programme (Euro-GASP)
- European Network for HIV/AIDS
- European Network for hepatitis B and C surveillance

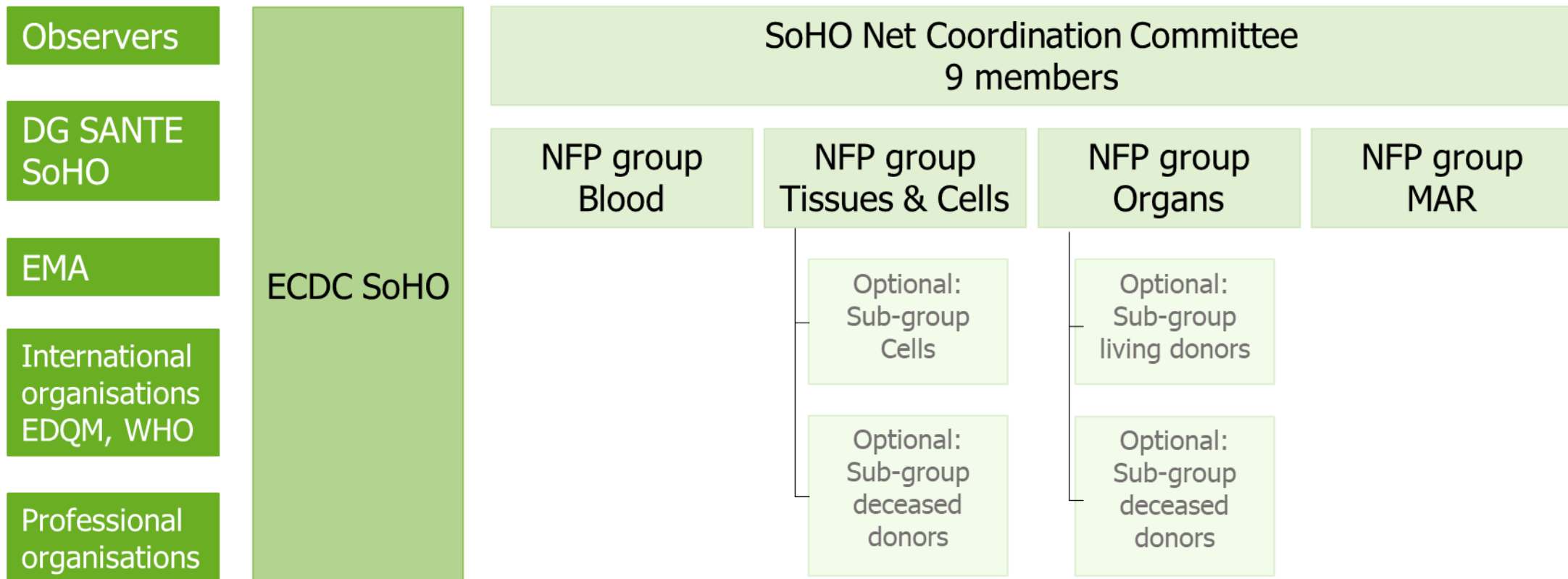
Vaccine-preventable diseases and invasive bacterial infections

- European Invasive Bacterial Diseases Surveillance Network (EU-IBD)
- EU laboratory Network for surveillance of Pertussis (EUPertNet)
- European Diphtheria Surveillance Network (EDSN)
- Network on measles, mumps, rubella surveillance (MMR)

Network for the Microbiological Safety of Substance of Human Origin (SoHO)*

ECDC SoHO network (SoHO-Net)

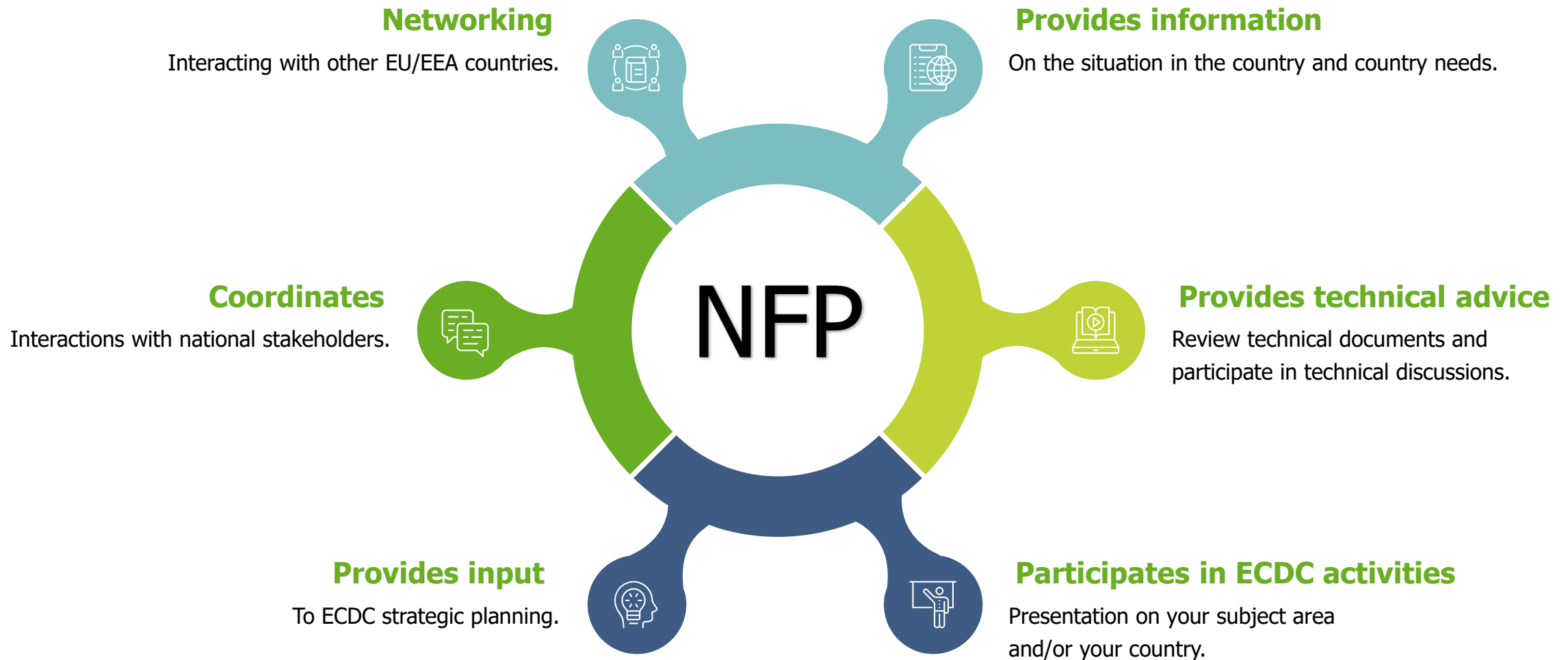
SoHO-Net



SoHO-Net: members

- National focal points (NFPs)
- Nominated by National Coordinators, in collaboration with national SoHO competent authorities
- Call for nomination:
“individuals with technical expertise in assurance of microbial safety of SoHOs, preferably working in... establishments. Also, we propose that nominees have expertise in donor assessment and/or biovigilance and/or quality assurance”

ECDC networks- The role of the National Focal Point (NFP)



ECDC SoHO Network (SoHO-Net): main objectives

- 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
- 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
- **Safeguard patients in need of SoHO**

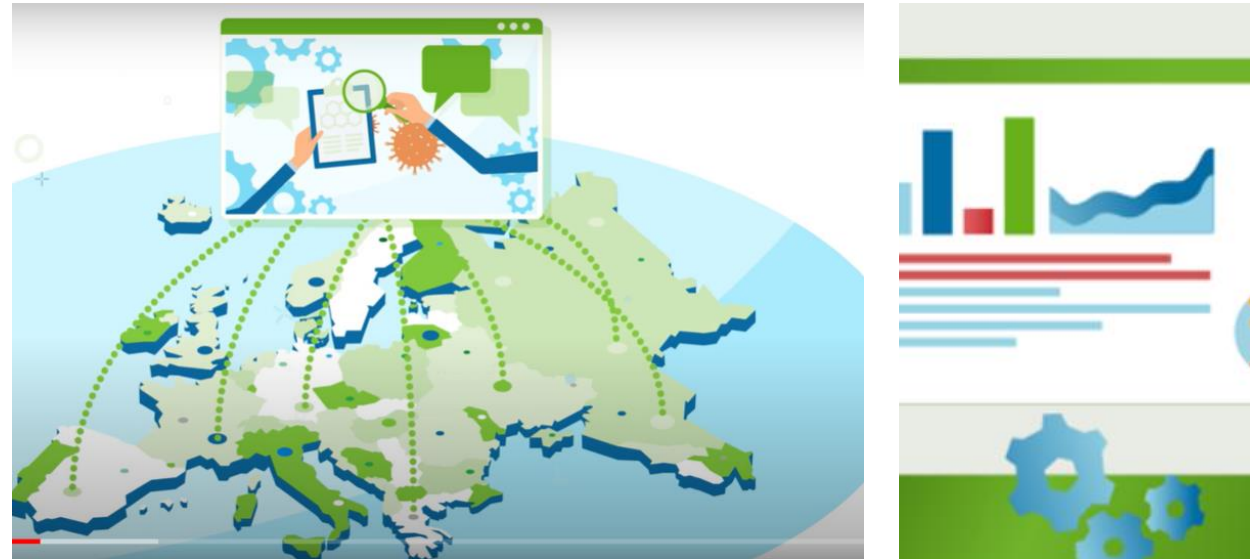
Coordinate SoHO network

- Regular meetings of the SoHO Network Coordination Committee and of the four SoHO sub-networks
- EpiPulse platform for information exchange and collaboration between countries

Epipulse

An online portal to collect, analyse, share, and discuss infectious disease data for threat detection, monitoring, risk assessment and outbreak response

Accessible for nominated experts from EU/EEA and non-EU countries within ECDC's cooperation framework, ECDC staff and representatives of European authorities and international organisations



Provide guidance on microbial safety

- Develop and update guidelines as referred to in the SoHO Regulation
 - 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 EC or on own initiative

ECDC guidelines – SoHO regulation

Document 32024R1938

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 (Text with EEA relevance)

PE/8/2024/REV/1

Article 59, paragraph 4

For those standards, or elements thereof, concerning protection of SoHO recipients and offspring from medically assisted reproduction for which no implementing act has been adopted, SoHO entities shall *take into account*:

- a) The most recent technical guidelines, as indicated on the EU SoHO Platform [...] :
 - (i) **published by the ECDC concerning the prevention of communicable disease transmission;**

ECDC guidelines – SoHO regulation

Pathogens

- Listed in current blood and tissues and cells directives

First batch: HIV, HBV, HCV and *Treponema pallidum*

Second batch: Future pathogens will be prioritised with input from SoHO-Net.

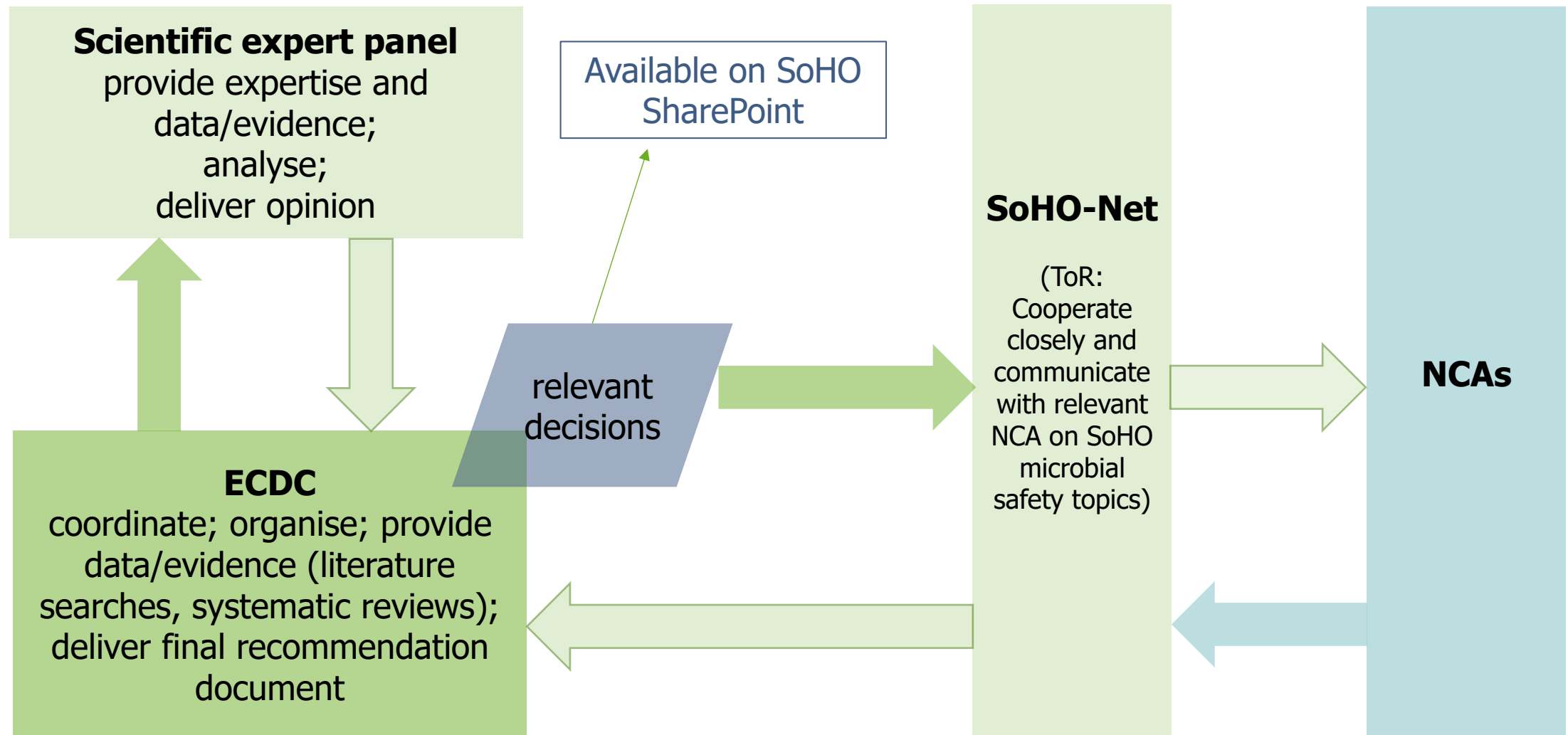
SoHOs

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

Topics

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

Overall project plan



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

Guideline content development process

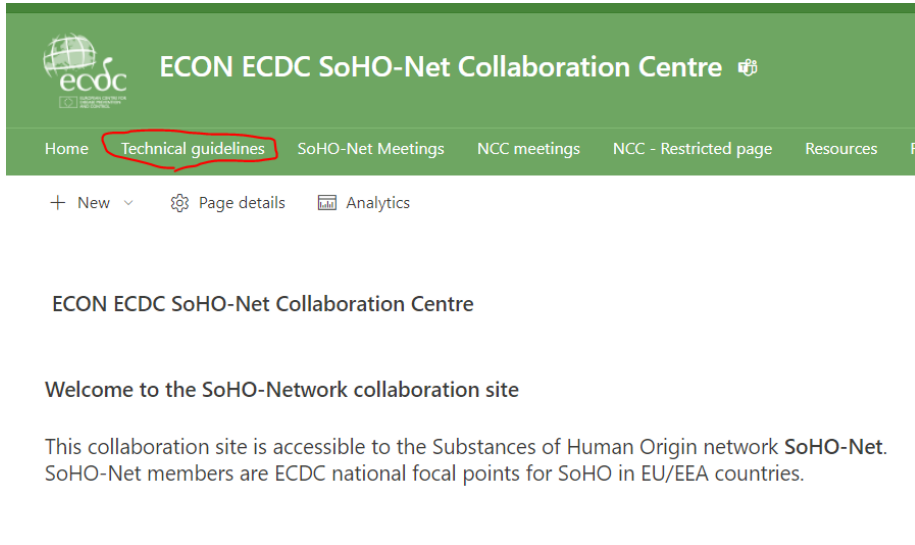
Discussions of the expert panel **is supported** by evidence in the form of **pathogen data sheets** created by the ECDC SoHO team and covering:

- Description of the pathogen
- Disease description
- Epidemiology
- Laboratory testing approaches
- Current testing requirements in Member States
- Recommendations from other organizations (e.g., EDQM, FDA...)
- Data/knowledge on transmission through SoHO
- Pathogen reduction/inactivation methods

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

ECON ECDC SoHO-Net Collaboration Centre



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Welcome to the SoHO-Network collaboration site

This collaboration site is accessible to the Substances of Human Origin network SoHO-Net. SoHO-Net members are ECDC national focal points for SoHO in EU/EEA countries.



Technical guidelines

+ New ▾ ↑ Upload ▾ Edit in grid

- | Name ▾ |
|----------------------|
| Guidelines |
| Meetings |
| Pathogen data sheets |



Guidelines: latest version of draft guidelines



Meetings: "short minutes" of expert panel with decisions and agreements



Pathogen data sheets: Latest versions of the evidence base for the guidelines

SoHO-Net review of the HIV guidelines

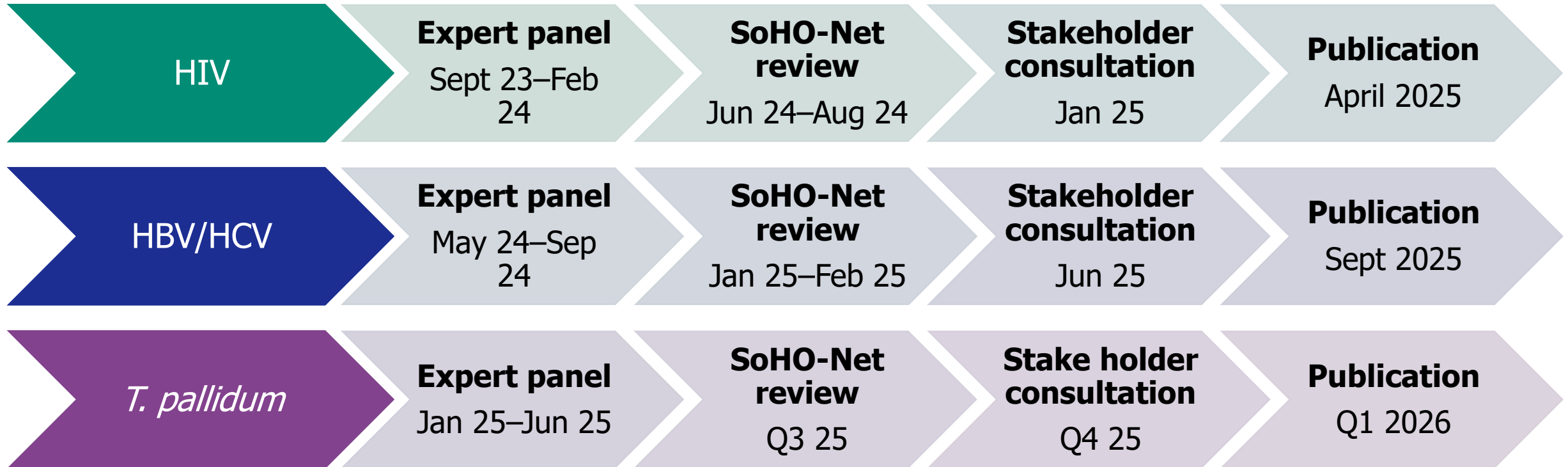
Review period ranged from 03 June to 28 August 2024:

- **14 countries** provided feedback
- 232 comments received
 - Comment resolution led by ECDC with support from expert panel
- Replies and final draft will be shared with SoHO-Net

ECDC SoHO guidelines – update

Overview

Note: All timelines are according to current plan



The process and timelines of guideline development are published on the ECDC website:
<https://www.ecdc.europa.eu/en/infectious-disease-topics/related-public-health-topics/substances-human-origin/technical-guidelines>

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

* 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.

Surveillance (ECDC general)

ECDC processes surveillance data on some 60 communicable diseases and related special health issues from EU/EEA countries

- Epidemiological updates
e. g. West Nile virus transmission season
- Weekly threats reports
- Annual Epidemiological Report
- Surveillance Atlas of Infectious Diseases



Daily threat monitoring (ECDC general)



Epidemic intelligence

- Detecting, monitoring and **assessing threats**
- **Systematic collection and collation of information** from a variety of sources, **which is then validated and analysed**

Response support

- **Risk assessments** with options for public health measures
- **Coordinate and support** the timely assessment of risks and response options
- Support to **national and international field response** through missions

Microbial safety of SoHO

**Threat detection,
assessment, and
response**

Monitor threats and outbreaks

Perform risk assessments and launch alerts

Provide advice on serious adverse reactions

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 reported to ECDC

→ Discussion of identified threats and an initial assessment of appropriate ECDC actions (considering advice from SoHO-Net).

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



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

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

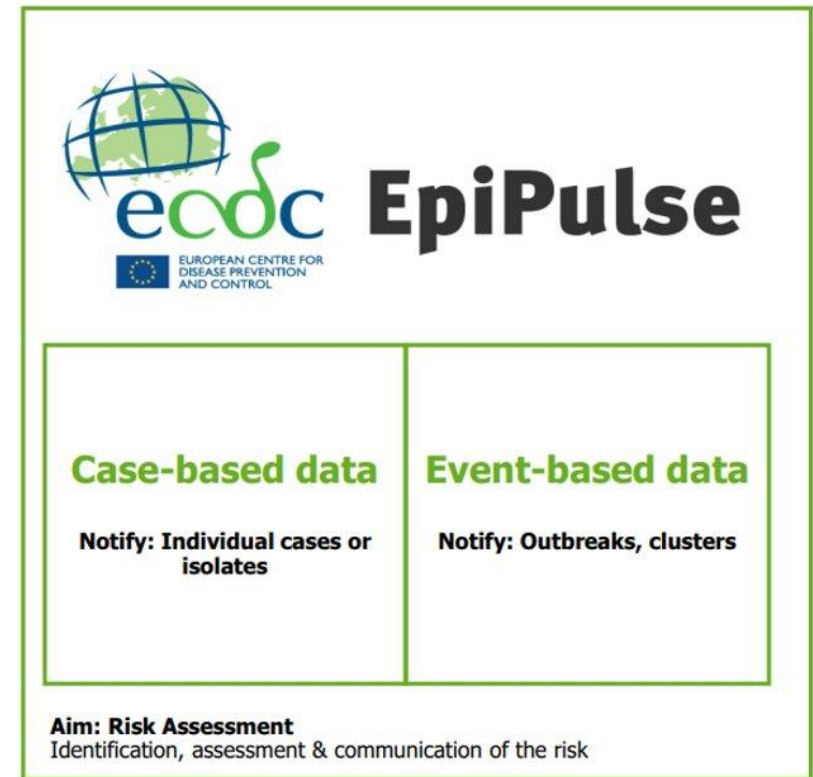
ECDC may publish the SAR on **EpiPulse** (with approval of the competent authority) for information exchange with SoHO-Net

Threat detection, assessment, and response: The EpiPulse platform



What is EpiPulse? The European surveillance portal for infectious diseases

- Online portal for EU/EEA public health authorities, public health stakeholders and international partners
 - forum for information exchange and collaboration between countries
 - up-to-date-overview on potential cross-border threats to health
- Collect, analyse, share, and discuss data for **threat detection, monitoring, risk assessment** and outbreak response.



Integrates indicator-based and event-based surveillance, including molecular typing.

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



ECDC actions may:

- Provide risk assessments in the case of a serious cross-border threat to health
- Launch alerts 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

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



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

- Robust SoHO network and mechanisms for the exchange of information.
- Guidelines for the prevention of donor-derived communicable disease transmission through the application of SoHO available and updated as needed.
- 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 SoHOs is identified.

Thank you!