

## ECDC Coordinating Competent Bodies

# ECDC Coordinating Competent Bodies: Structures, Interactions and Terms of Reference

<b>Summary:</b>	<p>In order to efficiently work with the EU/EEA Member States the ECDC Management Board has adopted a “One Coordinating Competent Body” approach (MB20) and Terms of Reference for the Competent Bodies (MB21). For each EU/EEA Member State, one Coordinating Competent Body and one National Coordinator, acting as the main entry point for interactions between the country and ECDC, have been identified.</p> <p>This document provides key information on the structures, terms of reference, and interactions of ECDC Coordinating Competent Bodies.</p>
<b>Background:</b>	<p>Meeting Report, ECDC Coordinating Competent Bodies, Stockholm (7 December 2012)</p> <p>Document AF28/7 Rev.1 – One national Coordinating Competent Body: Structures and terms of reference</p> <p>Document MB 23/16 – One Competent Body for ECDC: Structures and terms of reference</p> <p>Document MB21/10 - Terms of Reference for the Competent Bodies</p> <p>Document MB20/13 Rev.1 - ECDC Work with EU Member States</p> <p>Document MB19/12 - ECDC Work with EU Member States</p> <p><a href="#">Regulation (EU) 2022/2370 - ECDC's strengthened mandate</a></p> <p><a href="#">Regulation (EU) 2022/2371 – serious cross-border health threats to health</a></p>

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## Background

- Based on the ECDC Founding Regulation, the main focus of ECDC's collaboration with the EU/EEA Member States (hereafter referred to as Member States) is through Competent Bodies (CBs), their respective Director's office and their nominated experts. The main mode for ECDC to interact on scientific and technical work with the Member States is within networks and working groups with members being nominated by their respective CB.
- During the first years of interactions between the ECDC and the Member States their complexity increased due to the growth of the Centre's activities and multiplication of different types of contact points.
- In September 2010, in response to this need for a more streamlined cooperation with the Member States, ECDC Director tasked a Working Group to "develop a clear approach for efficient customer relationships with Member States via Competent Bodies".
- The conclusions of this Working Group led to the designation of one Coordinating Competent Body (CCB) per Member State, with one National Coordinator, to serve as the point of contact for all communications between ECDC and the Member State on technical and scientific issues. This proposal was endorsed by the ECDC Management Board in November 2010, and followed by the adoption of Terms of Reference (ToR) for the CCBs in March 2011.
- In order to reflect this change in all levels of ECDC interactions with countries, additional initiatives were proposed and approved by the Management Board:
  - a. To move from the current structure of networks based on ECDC internal areas of work to an approach based on groups of diseases, while preserving a few networks for generic or transversal public health functions.
  - b. To define a clear chain of nominations for experts participating in the networks that can always be traced back to the CCBs (and could eventually be managed online by them).
- In 2011, an ECDC-led Working Group with representatives of eight CCBs was set up to further guide the implementation of the new system. The Working Group developed a draft implementation document, detailing the structures, terms of reference, and interactions for the ECDC work with the CCBs and also emphasising the need for simplicity and a step-wise approach in the initial implementation of the system, not to burden the Member States.
- The draft implementation document was discussed in depth at the ECDC Joint Strategy Meeting in September 2012, and updated according to the input from the Directors and National Coordinators present. It is available for the National Coordinators and Directors of the CCBs on the Coordinating Competent Bodies extranet.
- The document has been updated following a consultation with the National Coordinators in 2019.
- Following the internal ECDC organisational change from 1<sup>st</sup> of January 2020, the document has been updated, namely with the Disease Programmes, and subsequently with the respective ToRs.

## The Coordinating Competent Body structure

### *Disease work and public health functions*

- The CCB shall be able to address requests for interactions regarding specific communicable disease issues as well as public health functions, therefore resulting in a matrix structure with two dimensions.
- The disease groups are as follows (grouped by the ECDC Disease Programme):
  - Antimicrobial resistance (ARHAI Programme)
  - Antimicrobial consumption (ARHAI Programme)
  - Healthcare-associated infections (ARHAI Programme)
  - Emerging and vector-borne diseases (EPR Programme)
  - Food- and waterborne diseases and Zoonoses (EPR Programme)
  - Legionellosis (EPR Programme)
  - Transmissible spongiform encephalopathy (TSE) (EPR Programme)
  - HIV/AIDS, STI and Hepatitis B/C (SBT Programme)
  - Tuberculosis (SBT Programme)
  - Vaccine preventable diseases (VPI Programme)
  - Viral respiratory diseases (VPI Programme)
- The grouping of public health functions reflects the work of ECDC and its interactions with the Member States, as follows:
  - Communication
  - Microbiology
  - Preparedness and Response
  - Public Health Training
  - Scientific Advice Coordination
  - Substances of Human Origin (SoHO)
  - Surveillance
  - Threat Detection, EWRS and IHR

### *Director of CCB, National Coordinator, National Focal Points, and Operational Contact Points*

- The **Director of Coordinating Competent Body** is the Director of the Institution, which is formally designated ECDC Coordinating Competent Body by the relevant authorities. The ECDC interactions with the Directors of CCBs are focused on a strategic level exclusively.
- The overall coordination of interactions between the Member State and ECDC is done by the **National Coordinator (NC)** of the national CCB.
- The NC may identify individuals in the CCBs or from other institutions of the Member States as delegated representatives for disease groups, called **Disease Group National Focal Points (NFPs)**, and public health functions, called **Public Health Functions NFPs**. The Public health Functions NFPs are meant to cover generic issues, cutting across all the disease areas.
- The NFPs play a strategic and coordinating role within their respective area in close collaboration with the NC.

- The NC, supported and advised by the NFPs, may further identify **Operational Contact Points (OCPs)** with special expertise.
- The OCPs should meet cooperation needs of a permanent nature, and the number of OCPs should be kept to the minimum level necessary for an efficient cooperation between ECDC and the Member State.
- Within each disease group there are specific OCPs for Epidemiology, Microbiology, TESSy Interactions and Response, as appropriate. In the disease groups covering many diseases, there may be a need for several Microbiology and Epidemiology OCPs. Other types of OCPs may be nominated if deemed necessary for an efficient work (see "Nominations" below). It is envisaged that many Member States will appoint the same person for several of the OCPs.
- For the public health functions, there may not need to be specific OCPs or the number of OCPs in each area is anticipated to be less than for the disease groups. Some OCPs already identified, include OCPs for EPIET and EUPHEM, respectively, under the National Training Focal Point within the training domain.
- If there is a need to bring in additional Member State expertise on issues that are not permanent in nature, the NC could be asked to nominate a Member State expert for a specific meeting or a time-limited *ad hoc* expert group. This expert would in that capacity not be an OCP.
- The roles and responsibilities of the Director, NC, NFP and OCP, as well as of ECDC, are detailed in specific terms of reference (ToR).
- ECDC identifies a generic e-mailbox or a single contact point within the unit/section/group in the Centre responsible for working with each NFP/OCP.
- The roles and functions described above (Director, NC, NFP, OCP, and Member State experts) refer to the role of the CCBs representing their Member States for technical and scientific interactions with ECDC.

However, experts from the Member States could be involved in the work of ECDC under two additional mechanisms.

- a. For specific scientific tasks, such as participation in the *ad hoc* Scientific Panels mentioned in the ECDC Regulation, ECDC will select individual experts according to their scientific knowledge, not according to country representation. Whilst the national CCBs may be asked to suggest such experts, those will – if selected – serve in their individual capacity, not as Member State representatives.<sup>1</sup>
  - b. Specific activities in the ECDC work programme may be outsourced through public procurement (calls for tender or calls for proposal) to public health institutions (or consortia of such institutions) in the Member States, and carried out by experts in these institutions. The ECDC relationship with these experts will be entirely based on the signed contracts, and they will not be regarded as Member State representatives.
- The National Coordinator should be informed whenever an expert from a CCB is working with ECDC in any of the above capacities.

## Nominations

- Within the Member States, the tasks and responsibilities are cascading down from the NC to the NFPs and further to the OCPs.
- The nominations of NFPs and OCPs are the responsibility of the NC, and the NC has the possibility to change the nominations, for example if the delegation of tasks is not working out in a satisfactory way or the responsibilities of a nominated individual changes. It is anticipated that in many smaller Member States several NFP and/or OCP functions may be delegated to the same person.

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<sup>1</sup> Minutes of the Twelfth Meeting of ECDC Management Board, Stockholm, 18–19 March 2008, paragraph 40.

- It is not necessary for all roles of NFPs and OCPs to be nominated. Neither does the NC need to appoint different persons for all the roles.
- If the lower levels have not been appointed (or are unavailable), the responsibility to ensure that the tasks are carried out rest with the upper level (NC for NFP responsibilities and NFP for OCP responsibilities). There is always a possibility for the NC to appoint an alternate for an NFP.
- When a need arises to have a new type of OCP in a network, the Network Coordination Committee makes a proposal, including draft ToR and envisaged interactions. The proposal will be shared with the NCs, and following the consent, ECDC will ask the NCs to nominate the requested OCPs. The ToRs should as much as possible be generic to fit more than one network.
- Once a person has been nominated, additional personal information might be needed from that person (e.g. declaration of interest, signature of confidentiality forms). These requests will be addressed directly to the nominated person by ECDC, and not channelled via the NC.

### *ECDC Disease and Public Health Networks*

- The Disease Group NFPs and OCPs constitute the **ECDC Disease Networks**, and the Public Health Functions NFPs and OCPs constitute the **ECDC Public Health Networks**.
- The ECDC Networks are progressively covering all aspects of ECDC work within their respective areas. The disease networks have several functions beyond surveillance, with OCPs for Epidemiology, Microbiology, TESSy/IT data management, as appropriate.
- For each network a smaller (maximum 10 members) **Network Coordination Committee** is established from the network members (NFPs and/or OCPs), mirroring both the broad scope of expertise in the network and its geographic diversity.
- The Network Coordination Committee is elected by its member for a period of three years.
- The Network Coordination Committee appoints a chair among its members and works closely with Centre in between the full network meetings, advising on urgent matters and contributing to the agenda of the regular network meetings.
- Depending on the nature of work (and for the Disease Networks the number of diseases covered), the architecture of the networks might differ in its details between the networks.
- The network members may organise themselves in **permanent or ad hoc working groups, task forces** and **sub-networks** as best fitting the needs within the network.
- The frequency of meetings with the full networks and working groups, task forces and sub-networks within the networks are decided by ECDC based on the needs and economic constraints. ECDC and the Network Coordination Committee could decide to invite observers to the meetings.

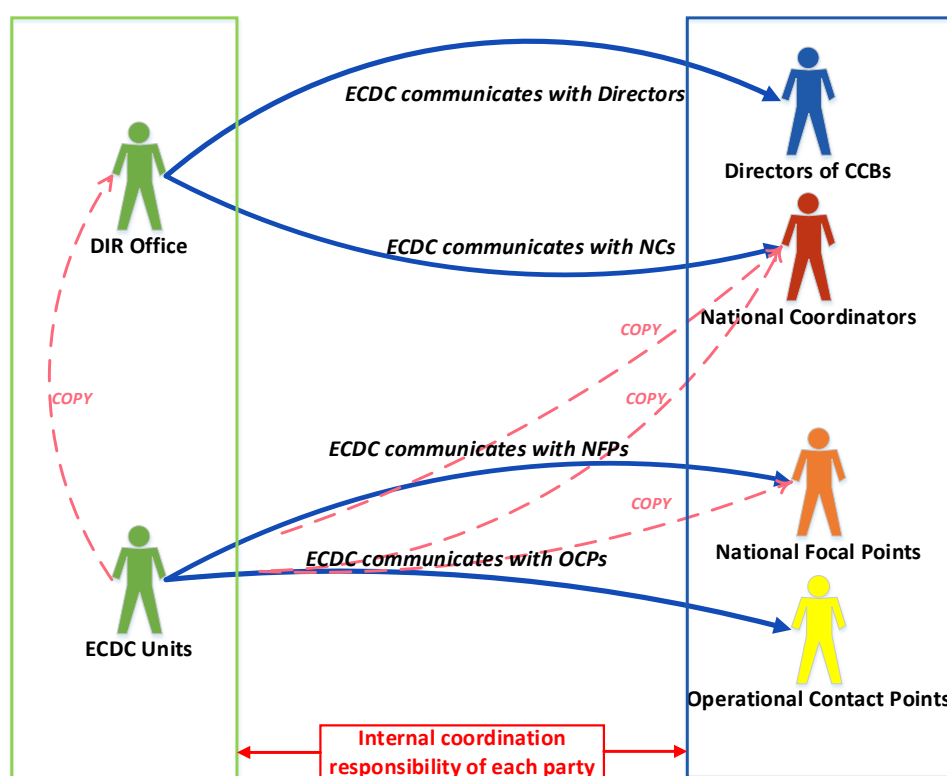
### *Coordination within the Member States*

- To ensure a smooth coordination of work, the NFPs and OCPs within a Member State need to liaise closely with the NC and other relevant NFPs and OCPs, but the exact nature of this coordination is left to each country to decide.

## **Interactions between ECDC and the Coordinating Competent Bodies**

- Interactions between ECDC and the CCBs are principally at three levels, corresponding to the nomination levels described above:
  - a. **High-level relations and coordination interactions** between ECDC and the CCBs are at the level of the **CCB Director** and **NC**, following necessary and appropriate consultation in the country.

- b. **Strategic and overarching interactions** related to a specific disease group or public health function are at the level of the **NFPs**, following necessary and appropriate consultation in the country.
- c. **Technical and operational interactions** related to specific area within the domains of a disease group or public health function are at the level of the **OCPs**, following necessary and appropriate consultation in the country.
- By delegating roles and responsibilities (to NFPs and OCPs), the NC also delegates the interactions with ECDC that follow with these roles and responsibilities.
- All interactions are based on the ToR for specific functions in the structure (NC/NFP/OCP).
- In all interactions, ECDC defines at the beginning of the email who (NC/NFP/OCP) is the recipient of a specific message.
- To facilitate coordination within the Member States, the NC is always copied in the interactions between ECDC and NFPs/OCPs in the Member States and the NFPs always copied in the interactions between the ECDC and the OCPs within his/her domain.
- Further to this, it is the responsibility of the Member State to decide on how the consultation processes within their country will be organised.
- ECDC sets up a similar internal system to ensure the corresponding coordination within the Centre. Only those that have been appointed within ECDC to communicate with the CCBs at the three levels are allowed to do it.
- In specific areas, notably concerning data exchange and clearance related to TESSy), the interactions are more complex and are gradually being developed as needed.
- To provide a comprehensive overview, ECDC will gradually compile the interactions and facilitate efficient work with the Member States through the CCBs.



*Figure 1. Principles for main interactions between ECDC and the CCBs.*

## Supporting information system

- To support the nomination process and the interactions between ECDC and the CCBs, the ECDC Stakeholder Relationships Management (SRM) system has been developed as a primary business system maintaining ECDC's cooperation with stakeholders, by managing contacts and nominations, relationships, responsibilities, and interactions involved in collaborating with experts, networks, organisations and countries.
- Through the SRM system, the NCs have full access to all nominations from his/her country and are responsible for keeping the list of nominations updated.
- SRM fully supports the grouping of nominated persons (NC/NFP/OCP) in disease networks and access to ECDC applications.
- The system ensures that messages between ECDC and the CCBs reach the right person, with appropriate other persons copied.
- To support technical communications between the ECDC and the NCs/NFPs/OCPs, a specific extranet set up for each network. Subsections of these extranets may be reserved for the work of the various working groups and sub-networks within that domain.
- Access to the ECDC information systems (EpiPulse (EPIS), TESSy and extranets) is linked to specific roles within the CCB structure. Once a named person has been assigned a specific role (NC, NFP or OCP) in the SRM, the system automatically ensures that this person obtains access to respective ECDC applications simultaneously, linked to that function.

## Governance and terms of references

- The details governing the implementation of the structure of ECDC relations with the CCBs (this document with annexes) will be updated on a regular basis and the changes agreed with the CCBs in annual meetings.
- In between these meetings, the NC Coordination Committee will make interim decisions on structures and terms of references under this framework.
- The NC Coordination Committee will further decide on the detailed interactions, and facilitate a smooth implementation of the system, including guiding the development of SRM.
- Terms of reference have been developed for the Directors, NCs, the NFPs and OCPs, detailing the responsibilities of these functions and ECDC, respectively. The ToRs consist of a generic part and a part, specific for each type of role.
- Any request from ECDC for an OCP in a new area should first be discussed in the NC Coordination Committee and the need and ToR agreed before ECDC could ask for nominations. If the NC Coordination Committee disagrees with ECDC, all NCs will be consulted.
- Generic ToRs have also been developed for the Network Coordination Committees, and specific ToRs will be developed for any working group and sub-network within the disease and public health networks.
- All agreed ToRs are annexed to this implementation document.

## Implementation

- The nomination process of the CCBs and NCs, NFPs and OCPs is completed.
- Since October 2011, the NCs are being copied in on all interactions which are taking place in the ECDC various areas of work.
- Following the agreement of this implementation document and the terms of reference of the NCs, NFPs and OCPs, the Member States completed nomination of the above noted roles.
- The SRM system is accessible for the National Coordinators. The NCs perform nominations and updates of NFPs and OCPs, and access to EpiPulse (EPIS) and TESSy directly in the system.



- The Customer Relationship Management (CRM) system was rebranded to SRM – Stakeholder Relationship Management - that evolves beyond contacts management towards supporting stakeholder collaboration in a system that can capture, track, and manage interactions, activities, and communication with the Member States and their institutions.

## Evaluation

- In order to improve a collaboration between ECDC and the Member States through the CCBs, it is foreseen to receive feedback and evaluation from the MS during the CCB meetings as well as on daily basis.

## List of Annexes

1. Terms of Reference for the **Director** of the Coordinating Competent Body in EU/EEA Member States
2. Terms of Reference for the **National Coordinator** in the Coordinating Competent Body in EU/EEA Member States.
3. Terms of Reference for ECDC **National Focal Points for Disease Groups** in EU/EEA Member States.
4. Terms of Reference for ECDC **National Focal Points for Public Health Functions** in EU/EEA Member States.
5. Terms of Reference for ECDC **Operational Contact Points for Disease-Specific Interactions** in EU/EEA Member States.
6. Terms of Reference for ECDC **Operational Contact Points for Public Health Training** in field epidemiology (EPIET) and public health microbiology (EUPHEM) as organised in the ECDC Fellowship Training Site Forum (TSF)
7. Terms of Reference for ECDC **Operational Contact Points for Epidemic Intelligence (Epidemic Intelligence network)**
8. Terms of Reference for ECDC **Disease Network Coordination Committees** in EU/EEA Member States.
9. Terms of Reference for ECDC **Public Health Network Coordination Committees** in EU/EEA Member States.
10. Terms of Reference for **Network for the Microbial Safety of Substances of Human Origin (SoHO)**

## Annexes



### Annex 1 to the Coordinating Competent Bodies: Structures, Interactions and Terms of Reference

## Terms of Reference for the Director of the ECDC Coordinating Competent Body in the EU/EEA Member States

#### Background:

According to ECDC's Founding Regulation, ECDC in its relations with the Member States cooperates with the Competent Bodies operating in the technical field of ECDC, in particular, in the area of surveillance (Article 3(2), responses to health threats (Article 4), scientific opinions, scientific and technical assistance, collection of data and identification of emerging health threats (Article 5(4) and public information campaigns (Article 12(3)).

Complementary to the roles of the ECDC Management Board and Advisory Forum, and following the adoption of "One Competent Body" approach (MB20) and Terms of Reference for the Competent Bodies (MB21), in each Member State there is Coordinating Competent Body (CCB) with the Director acting as the main entry point for strategic advice and input between the ECDC and the CCB.

Relevant documentation:

Coordinating Competent Bodies: structures, interactions and terms of reference, 7<sup>th</sup> December 2012

AF28/7 Rev.1 – One national Coordinating Competent Body: Structures and terms of reference

MB23/16 – One Competent Body for ECDC: Structures and terms of reference

MB21/10 - Terms of Reference for the Competent Bodies

MB20/13 Rev.1 - ECDC Work with EU Member States

MB19/12 - ECDC Work with EU Member States

Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004

[Regulation \(EU\) 2022/2370 - ECDC's strengthened mandate](#)

[Regulation \(EU\) 2022/2371 – serious cross-border health threats to health](#)

<b>ECDC team responsible for ensuring smooth, efficient network of excellence with the CCB Director:</b>	Executive Office, Director's Office.
<b>Role and responsibilities of the CCB Director:</b>	<p>The Director of ECDC Coordinating Competent Body (CCB) is the Director of the Institution, which is formally designated ECDC CCB by the relevant authorities. The CCB Director is primarily responsible for the following:</p> <ul style="list-style-type: none"> <li>• Acts as the main entry point between the ECDC and the CCB on high level strategic matters advising the ECDC Director on e.g., ECDC strategy, vision, ECDC priorities, and its multi-annual and annual work plans;</li> <li>• Advises ECDC on international initiatives and collaborations that need coordination between ECDC and the CCB;</li> <li>• Acts as a strategic ECDC partner linking with policy makers in the country; ensures that adequate exchange of information is organised at the MS level to feed the strategic discussions in the relevant governing bodies;</li> <li>• Informs ECDC of relevant national priorities and available resources within the field of work of ECDC;</li> <li>• Informs the Director of ECDC of any difficulties encountered which can prevent the National Coordinator (NC), National Focal Points (NFPs) and Operational Contact Points (OCPs) to fulfil their activities, in particular in relation to the feasibility of the activities requested by ECDC;</li> <li>• Is the entry point for any country visits organised by ECDC including at the ECDC Director level;</li> <li>• Nominates the National Coordinator of the CCB;</li> <li>• Interacts on a regular basis with the NC to ensure the best possible collaboration between the CCB and the ECDC;</li> <li>• Ensures the MS support to the activities of the ECDC in line with the provisions in the Regulation (EU) 2022/2370 and existing resources;</li> <li>• In order for ECDC to plan and execute concrete support to MS (capacity building, technical assistance), support the NC in the identification of nationally prioritised needs through agreed country support mechanisms, and, if later decided to be implemented, advocates/facilitates access for sufficient national resources to implement activities agreed with ECDC;</li> <li>• Participates in the ECDC meetings: <ul style="list-style-type: none"> <li>- A strategic advisory group of CCB Directors that meet face-to-face with the ECDC Director (during spring),</li> <li>- A virtual meeting for CCB Directors and NCs focusing on specific topics (during autumn);</li> <li>- Joint Strategy Meetings (JSM), and other meetings as deemed necessary.</li> </ul> </li> </ul> <p>The CCB Director may delegate any of the above tasks to his/her Alternate or to the NC. The contact profile and the role of the CCB Director is kept up to date by the National Coordinator, which ensures quality of the CCB nominations and real time data stored in the ECDC Stakeholders Relationship Management (SRM) system, in compliance with legal data protection rules.</p>

<b>Responsibilities of the ECDC:</b>	<p>In order to ensure and strengthen efficient collaboration and cooperation between ECDC and the Coordinating Competent Body, ECDC is responsible for the following:</p> <ul style="list-style-type: none"><li>• Seek the advice from the CCB Directors in the strategic planning and execution of the ECDC activities;</li><li>• Ensure that the CCB Directors are fully briefed in a timely manner on all ECDC strategic activities;</li><li>• Organise the meetings for the CCB Directors;</li><li>• Meet the needs and expectations of the CCB Directors through the provision of timely feedback to their requests;</li><li>• Provide an Induction package for the newly nominated CCB Director.</li></ul>
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## Annex 2 to Coordinating Competent Bodies: Structures, Interactions and Terms of Reference:

# Terms of Reference for the National Coordinator in the Coordinating Competent Body in EU Member States and EEA Countries

### Background

According to ECDC's Founding Regulation, ECDC in its relations with the Member States cooperates with the Competent Bodies operating in the technical field of ECDC, in particular, in the area of surveillance (Article 3(2)), responses to health threats (Article 4), scientific opinions, scientific and technical assistance, collection of data and identification of emerging health threats (Article 5(4)) and public information campaigns (Article 12(3)).

To efficiently work with the EU/EEA countries, the ECDC MB adopted the "One Coordinating Competent Body" approach during the MB 20 in 2010, and the Terms of Reference for the Competent Bodies during MB 21 in 2011. For each EU/EEA country, one Coordinating Competent Body (CCB) and one National Coordinator (NC) have been defined, as main entry and liaison for the work between ECDC and the respective country.

Following the implementation of the ECDC strengthened mandate and the action plan of the Stakeholder Satisfaction Consultation in 2023 ECDC was looking into the ways to strengthen the collaboration with the CCBs at a strategic level, as well as reinforce the role of the NC. Based on the current experience, it was clear that the National Coordinators play a central role in the tactical and operational aspects of collaboration between MS and ECDC, hence, it was important to update the responsibilities of the NC accordingly by reinforcing this role.

Relevant documentation:

Document AF28/7 Rev.1 – One national Coordinating Competent Body: Structures and terms of reference

Document MB 23/16 – One Competent Body for ECDC: Structures and terms of reference

Document MB21/10 - Terms of Reference for the Competent Bodies

Document MB20/13 Rev.1 - ECDC Work with EU Member States

Document MB19/12 - ECDC Work with EU Member States

Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004

[Regulation \(EU\) 2022/2370 - ECDC's strengthened mandate](#)

[Regulation \(EU\) 2022/2371 – serious cross-border health threats to health](#)

<b>ECDC team responsible for relations with the National Coordinator</b>	Executive Office, Director's Office.
<b>Responsibilities of the National Coordinator (NC)</b>	<p>The NC in the Coordinating Competent Body is formally nominated by the Director of the CCB and responsible for the following:</p> <ul style="list-style-type: none"> <li>• Work in close collaboration with the CCB Director;</li> <li>• Act as the main entry point for interactions between the CCB in the Member State and ECDC;</li> <li>• Ensure coordination of information exchange between ECDC and the CCB in the Member State;</li> <li>• Ensure that the interactions between the NC and the NFP/OCP are properly organised to fulfil their overall technical responsibilities (i.e., nomination, participation to meetings);</li> <li>• Nominate National Focal Points (NFPs) and Operational Contact Points (OCPs), as well as Member State experts for <i>ad hoc</i> working groups and ECDC meetings;</li> <li>• Ensure that the contact details of nominated persons are kept up-to-date in the ECDC Stakeholders Relationship Management System (SRM), and for this task ensure compliance with legal data protection rules;</li> <li>• Handle institutional relations between the Member State and ECDC in relation to nominations;</li> <li>• Coordinate in a timely manner the provision and exchange of scientific and technical information when applicable;</li> <li>• Contribute/provide input into the development/revisions of ECDC strategies related to capacity building for the EU level and MS level;</li> <li>• Identify the needs for support from ECDC in terms of scientific and technical assistance;</li> <li>• Support the dissemination of ECDC publications in the country;</li> <li>• Assist ECDC within its operational areas (disease work and public health functions) when requested.</li> <li>• Participate in the ECDC meetings: <ul style="list-style-type: none"> <li>- An annual face-to-face meeting for the NCs (during spring),</li> <li>- A virtual meeting for CCB Directors and NCs focusing on specific topics (during autumn).</li> </ul> </li> </ul> <p>The NC may delegate some specific strategic and operational interactions to NFPs covering disease groups or public health functions and further day-to-day technical interactions to OCPs, as detailed in the Terms of Reference for these functions. If no delegations are done, these tasks will remain with the NC.</p>
<b>Responsibilities of ECDC</b>	<p>In order to ensure efficient communications between ECDC and the Coordinating Competent Body, ECDC is responsible for the following.</p> <ul style="list-style-type: none"> <li>• Ensure that the NC is briefed in a timely manner on relevant ECDC activities and update about ECDC experts responsible for major projects and programmes;</li> <li>• Organise meetings for the NCs;</li> </ul>



	<ul style="list-style-type: none"> <li>• Inform about ECDC meetings and MS experts working with ECDC;</li> <li>• Send relevant strategic and technical documents (including draft work programme priorities) to the NC for consultation with sufficient time to provide a sound reply.</li> <li>• Facilitate regular networking between the NCs through electronic workspaces and face-to-face meeting.</li> <li>• Provide NCs with timely feedback/replies to their request to ECDC;</li> <li>• Provide an Induction package for the newly nominated members and alternates for the National Coordinator role;</li> <li>• Provide full access to the ECDC SRM and guidance on how to manage within the SRM, and instructions on updated versions of the system.</li> </ul>
<b>Interactions</b>	<p>Based on these Terms of Reference, specific interactions for all areas of work at all levels (NC, NFP and OCP levels) can be developed separately. Key interactions are supported the ECDC SRM system.</p>



### Annex 3 to Coordinating Competent Bodies: Structures, Interactions and Terms of Reference:

## Terms of Reference for ECDC National Focal Points for Disease Groups in EU/EEA Member States

<b>Background:</b>	<p>In order to efficiently work with the EU/EEA Member States the ECDC Management Board has adopted a "One Competent Body" approach (MB20) and Terms of Reference for the Competent Bodies (MB21). For each Member State, one Coordinating Competent Body (CCB) and one National Coordinator (NC), acting as the main entry point for interactions between the country and ECDC, have been identified.</p> <p>Within this system, the NC may delegate some specific strategic interactions to National Focal Points (NFPs) covering disease group issues or public health function issues and further day-to-day technical interactions to Operational Contact Points (OCPs).</p> <p>Relevant documentation:</p> <p>Document - Terms of Reference for the National Coordinator in the Coordinating Competent Body in Member States and EEA/EFTA countries (adopted September, 2012)</p> <p>Document AF28/7 Rev.1 – One national Coordinating Competent Body: Structures and terms of reference</p> <p>Document MB 23/16 – One Competent Body for ECDC: Structures and terms of reference</p> <p>Document MB21/10 - Terms of Reference for the Competent Bodies</p> <p>Document MB20/13 Rev.1 - ECDC Work with EU Member States</p> <p>Document MB19/12 - ECDC Work with EU Member States</p> <p>Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004</p> <p><a href="#">Regulation (EU) 2022/2370 - ECDC's strengthened mandate</a></p> <p><a href="#">Regulation (EU) 2022/2371 – serious cross-border health threats to health</a></p>
<b>ECDC team/section responsible for relations with the NFPs for disease groups:</b>	Disease Programmes (DPR)



<b>Responsibilities of the NFPs for disease groups:</b>	<p>These Terms of Reference are valid for each of the following disease groups (grouped by ECDC Disease Programme):</p> <ul style="list-style-type: none"> <li>• Antimicrobial resistance (ARHAI Programme)</li> <li>• Antimicrobial consumption (ARHAI Programme)</li> <li>• Healthcare-associated infections (ARHAI Programme)</li> <li>• Emerging and vector-borne diseases (EPR Programme)</li> <li>• Food- and waterborne diseases and Zoonoses (EPR Programme)</li> <li>• Legionellosis (EPR Programme)</li> <li>• Transmissible spongiform encephalopathy (TSE) (EPR Programme)</li> <li>• HIV/AIDS, STI and Hepatitis B/C (SBT Programme)</li> <li>• Tuberculosis (SBT Programme)</li> <li>• Vaccine preventable diseases (VPI Programme)</li> <li>• Viral respiratory diseases (VPI Programme)</li> </ul> <p>The NFPs for the disease groups are nominated by the NC of the CCB. By delegation of the NC, the NFP is responsible for overseeing interactions between ECDC and the EU/EEA Member State regarding the activities related to the disease group.</p> <p>If no NFP for a disease group is nominated, all interactions within this area will remain channelled through the NC.</p> <p><b>General responsibilities (same for all NFPs):</b></p> <ul style="list-style-type: none"> <li>• In liaison with the NC, and with other relevant NFPs from their country, identify and advise the NC on nominations of additional experts to serve as OCP for specific technical interactions with ECDC;</li> <li>• Advise the NC on nominations to ECDC ad hoc working groups and other meetings within the area of the disease group;</li> <li>• Contribute/provide input into the development/revisions of ECDC strategies within the area of the disease group;</li> <li>• Contribute/provide input into the development of the ECDC annual work programme priorities within the area of the disease group;</li> <li>• Contribute to the implementation of evidence-based methods in public health;</li> <li>• Provide technical advice on specific project proposals within the area of the disease group;</li> <li>• Provide available information according to agreements adopted in the network about the current situation and status of activities/capacities and national programmes within the area of the disease group in the Member State as needed (including legislation);</li> <li>• Contribute to the identification of Member State's needs for strengthening capacity within the area of the disease group;</li> <li>• Provide strategic advice and suggestions to ECDC regarding further development of networks within the area of the disease group;</li> <li>• Provide strategic advice and suggestions for ECDC work within the area of the disease group;</li> </ul>
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	<ul style="list-style-type: none"> <li>• Advise ECDC on any ad hoc issues within the area of the disease group;</li> <li>• Oversee all other interactions between ECDC and the Member State concerning issues within the area of the disease group;</li> <li>• Participate in ECDC activities within the area of the disease group, unless delegated to Operational Contact Points.</li> <li>• Participate in ECDC consultations within the area of the disease group and provide feedback;</li> <li>• Assist in building awareness and disseminating information within the area of the disease group;</li> <li>• Liaise with ECDC contact points on matters related to ECDC country visits related to the disease group;</li> <li>• Liaise with ECDC contact points on country's requests on matters related to the disease group;</li> </ul> <p><b>Specific responsibilities related to the disease work:</b></p> <ul style="list-style-type: none"> <li>• Provide information about the current epidemiological situation for the diseases in the group;</li> <li>• Participate in consultations of ECDC scientific advice/science based preventive guidance in the area of the relevant Disease Programme and provide feedback;</li> <li>• Suggest experts for ECDC external expert panels in the area of Disease Programme;</li> <li>• Participate in other Disease Programme-related activities</li> </ul>
<b>Responsibilities of ECDC:</b>	<p>In order to ensure efficient communications between ECDC and the Coordinating Competent Body within the area of the disease group, ECDC is responsible for the following.</p> <p><b>General ECDC responsibilities:</b></p> <ul style="list-style-type: none"> <li>• Appoint an ECDC main contact point for issues within the area of the disease group;</li> <li>• Ensure that the NFP is briefed in a timely manner on all key ECDC activities within the area of the disease group;</li> <li>• Sending relevant strategic and technical documents (including draft WP priorities) within the area of the disease group to the NFP for consultation, with time enough for sound reply.</li> <li>• Facilitate regular networking between the national NFPs within the area of the disease group through electronic workspaces and face-to-face meeting;</li> <li>• Provide NFPs within the area of the disease group with timely feedback/replies to their requests to ECDC;</li> <li>• Assure the coordination of the disease networks with the public health functions networks and in particular with the Surveillance and Microbiology networks;</li> <li>• Coordinate requests from the ECDC to MS in sense to minimize duplication of tasks and data requested from different NFPs and OCPs.</li> </ul>



## Annex 4 to Coordinating Competent Bodies: Structures, Interactions and Terms of Reference:

# Terms of Reference for ECDC National Focal Points for Public Health Functions in EU/EEA Member States

<b>Background:</b>	<p>In order to efficiently work with the EU/EEA Member States the ECDC Management Board has adopted a “One Competent Body” approach (MB20) and Terms of Reference for the Competent Bodies (MB21). For each Member State, one Coordinating Competent Body (CCB) and one National Coordinator (NC), acting as the main entry point for interactions between the country and ECDC, have been identified.</p> <p>Within this system, the NC may delegate some specific strategic interactions to National Focal Points (NFPs) covering disease group issues or public health function issues and further day-to-day technical interactions to Operational Contact Points (OCPs).</p> <p>Relevant documentation:</p> <p>Document - Terms of Reference for the National Coordinator in the Coordinating Competent Body in Member States and EEA/EFTA countries (adopted September, 2012)</p> <p>Document AF28/7 Rev.1 – One national Coordinating Competent Body: Structures and terms of reference</p> <p>Document MB 23/16 – One Competent Body for ECDC: Structures and terms of reference</p> <p>Document MB21/10 - Terms of Reference for the Competent Bodies</p> <p>Document MB20/13 Rev.1 - ECDC Work with EU Member States</p> <p>Document MB19/12 - ECDC Work with EU Member States</p> <p>Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004</p> <p><a href="#">Regulation (EU) 2022/2370 - ECDC's strengthened mandate</a></p> <p><a href="#">Regulation (EU) 2022/2371 – serious cross-border health threats to health</a></p>
<b>General Responsibilities for all NFPs:</b>	<p>The NFP is nominated by the NC of the CCB. By delegation of the NC, the NFP is responsible for overseeing interactions between ECDC and the Member State regarding the activities related to the public health function. If no NFP is nominated, all interactions within this area will remain channelled through the NC.</p>

	<p><b>General NFP responsibilities (same for all NFPs):</b></p> <ul style="list-style-type: none"> <li>• In liaison with the NC, and with other relevant NFPs from their country, identify and advise the NC on nominations of additional experts to serve as OCP for specific technical interactions with ECDC;</li> <li>• Advise the NC on nominations to ECDC ad hoc working groups and other meetings within his/her area;</li> <li>• Contribute/provide input into the development/revisions of ECDC strategies within his/her public health function;</li> <li>• Contribute/provide input into the development of the ECDC annual work programme priorities within his/her public health function;</li> <li>• Contribute to the implementation of evidence-based methods in public health;</li> <li>• Provide technical advice on specific project proposals within his/her public health function;</li> <li>• Provide available information, according to agreements adopted in the network, about the current situation and status of activities/capacities and national programmes within his/her public health function in the Member State as needed (including legislation);</li> <li>• Contribute to the identification of Member State's needs for strengthening capacity within his/her public health function;</li> <li>• Provide strategic advice and suggestions to ECDC regarding further development of networks within his/her public health function;</li> <li>• Provide strategic advice and suggestions for ECDC work within his/her public health function;</li> <li>• Advise ECDC on any ad hoc issues within his/her area;</li> <li>• Oversee all other interactions between ECDC and the Member State concerning issues within his/her public health function;</li> <li>• Participate in ECDC activities within his/her public health function, unless delegated to Operational Contact Points.</li> <li>• Participate in ECDC consultations within his/her a public health function and provide feedback;</li> <li>• Assist in building awareness and disseminating information within his/her function;</li> <li>• Liaise with ECDC contact points on matters related to ECDC country visits related to his/her public health function;</li> </ul> <p>Liaise with ECDC contact points on country's requests on matters related to his/her public health function.</p>
<p><b>Specific responsibilities for the NFP for Communication:</b></p>	<p>In order to ensure efficient communications between ECDC and the Coordinating Competent Body, the <b>NFP for Communication</b> is specifically responsible for the following.</p> <ul style="list-style-type: none"> <li>• Support ECDC in its mandated communication role;</li> <li>• Facilitate public access to ECDC information for general public and relevant experts, respectively;</li> <li>• Cooperate with ECDC on public health campaigns;</li> </ul>

	<ul style="list-style-type: none"> <li>• Provide feedback in relation to prior notification of information/press release if relevant.</li> </ul>
<b>Specific responsibilities for the NFP for Microbiology:</b>	<p>In order to ensure efficient communications between ECDC and the Coordinating Competent Body, the <b>NFP for Microbiology</b> is specifically responsible for the following.</p> <ul style="list-style-type: none"> <li>• Provide technical input into design and validation of laboratory capability appraisal tools as well as contribute with national data for monitoring EU-wide and national capabilities according to agreed data collection methods and assessment tools;</li> <li>• Contribute to the development of expert consensus technical guidance on public health microbiology topics in line with ECDC Scientific Advice processes;</li> <li>• Serve as an active and effective link between ECDC and the national public health microbiology system and provide updates on joint activities with ECDC to public health experts and stakeholders in his/her country;</li> <li>• Assist in identifying relevant available expertise and/or reference laboratory capabilities in his/her country in the event of an emerging threat or disease cluster investigations at EU level for which no disease-specific network is currently operating;</li> <li>• Coordinate microbiology interactions with disease group NFPs and ECDC.</li> </ul>
<b>Specific responsibilities for the NFP for Preparedness and Response:</b>	<p>In order to ensure efficient communications between ECDC and the Coordinating Competent Body, the <b>NFP for Preparedness and Response</b> is specifically responsible for the following.</p> <ul style="list-style-type: none"> <li>• Facilitate links within the health sector and with other sectors for the operational aspects of preparedness and response plans;</li> <li>• Ensure dissemination of information to, and consolidating input from relevant sectors of the administration, including those responsible for other functions related to preparedness and response (surveillance, laboratories, clinics, public health services);</li> <li>• Ensure quick and easy contacts with ECDC for urgent matters;</li> <li>• Review Risk Assessments and other documents together with ECDC before making them public.</li> </ul>
<b>Specific responsibilities for the NFP for Training:</b>	<p>In order to ensure efficient communications between ECDC and the Coordinating Competent Body, the <b>NFP for Training</b> is specifically responsible for the following.</p> <ul style="list-style-type: none"> <li>• Provide feedback on implementation to practice of knowledge and skills obtained by training, evaluation of training efficiency, development of lists of core competencies in public health disciplines, etc.);</li> <li>• Provide strategic advice and suggestions for future developments of EPIET, EUPHEM and similar training programmes;</li> <li>• Advise ECDC regarding selection/prioritisation of participants to ECDC training activities;</li> <li>• Advise on implementation and review of the EPIET, EUPHEM training objectives;</li> </ul>

	<ul style="list-style-type: none"> <li>Participate in or identify experts for other training-related activities (e.g. training needs assessment, evaluation of training programmes/training sites).</li> </ul>
<b>Specific responsibilities for the NFP for Scientific Advice Coordination:</b>	<p>In order to ensure efficient communications between ECDC and the Coordinating Competent Body, the <b>NFP for Scientific Advice Coordination</b> is specifically responsible for the following.</p> <p><b>Scientific services and tools – Assist with the provision of scientific services supporting scientific advice within the mandate of ECDC:</b></p> <ul style="list-style-type: none"> <li>Priority setting for scientific advice on issues falling within the mandate of ECDC;</li> <li>Assessment of the impact of scientific advice produced by ECDC;</li> <li>Recommendation of external experts;</li> <li>Collection and assessment of declarations of interest of external experts;</li> <li>Managing conflicts of interest of external experts;</li> <li>Documentation of scientific advice repository and management system;</li> <li>Provide - when necessary – <i>ad hoc</i> methodological support to the provision of scientific advice delivered jointly by ECDC and the relevant national authorities;</li> <li>Provide support for implementation on the Burden of infectious diseases tools provided by ECDC (e.g. BCoDE toolkit).</li> </ul> <p><b>Evidence-based medicine and public health (EBM/EBPH) – Contribute to the development and implementation of methods of EBM/EBPH:</b></p> <ul style="list-style-type: none"> <li>EBM/EBPH Training activities organised by ECDC and/or MS;</li> <li>Methods development (e.g. standard for grading of evidence in EBM/EBPH);</li> <li>Support the application of EBM/EBPH methods.</li> </ul> <p><b>Liaison interface – Assist with liaising with relevant national agencies and bodies charged with delivering of scientific advice:</b></p> <ul style="list-style-type: none"> <li>Promote synergies and collaboration on issues of common interest related to scientific advice e.g. exchange of information, tools and training material, organisation of joint workshops etc;</li> <li>Improving engagement with EU research funders and other relevant scientific stakeholders.</li> </ul>
<b>Specific responsibilities for the NFP for Surveillance:</b>	<p>In order to ensure efficient communications between ECDC and the Coordinating Competent Body, the <b>NFP for Surveillance</b> is specifically responsible for the following.</p> <ul style="list-style-type: none"> <li>Be ultimately responsibility for data coming from the country, including timely interactions with TESSy (specific TESSy-related tasks will be specified in the ToR for "OCP for TESSy Interactions" within each disease group) (it is expected that in most countries, the operational tasks will be delegated);</li> <li>Approve for publication draft surveillance reports based on data from the country;</li> </ul>

	<ul style="list-style-type: none"> <li>• Ensure that agreed surveillance data calls from ECDC are responded to and supported;</li> <li>• Ensure that data source information in TESSy are created/updated and the data source from which the surveillance data is collected is described;</li> <li>• Ensure that data previously uploaded are approved (this action confirms that ECDC can use this data in its reports) and maintain the accuracy of data previously uploaded;</li> <li>• Ensure that requests from ECDC for complementary information regarding potential quality issues in the previously uploaded and approved data are responded to;</li> <li>• Provide feedback and approve metadata changes.</li> <li>• Coordinate general surveillance and epidemiological related interactions with Disease group NFPs and ECDC.</li> </ul>
<b>Specific responsibilities for the NFP for Threat Detection, EWRS &amp; IHR:</b>	<p>In order to ensure efficient communications between ECDC and the Coordinating Competent Body, the <b>NFP for Threat Detection, EWRS &amp; IHR</b> is specifically responsible for the following.</p> <ul style="list-style-type: none"> <li>• Ensure timely professional communication of relevant public health events;</li> <li>• Assess threats related to the country upon request from ECDC</li> <li>• Coordinate distribution of ECDC epidemic intelligence outputs (CDTR and RT reports);</li> <li>• Contribute to ECDC regional and international threat detection activities;</li> <li>• Share information related to risk assessments developed by ECDC when those have been required.</li> </ul>
<b>Responsibilities of ECDC:</b>	<p>In order to ensure efficient communications between ECDC and the Coordinating Competent Body within the public health functions, ECDC is responsible for the following.</p> <ul style="list-style-type: none"> <li>• Appoint an ECDC main contact point for issues falling within each of the public health functions;</li> <li>• Ensure that the NFP is briefed in a timely manner on all key ECDC activities within the respective public health function;</li> <li>• Sending relevant strategic and technical documents (including draft WP priorities and data calls) to the respective public health function NFP for consultation;</li> <li>• Facilitate regular networking between the national NFPs within each public health function through electronic workspaces and face-to-face meeting;</li> <li>• Provide the NFPs with timely feedback/replies to their requests to ECDC;</li> <li>• Ensure timely notification to Member States of health threats detected by ECDC;</li> <li>• Assure the coordination of the public health functions networks and in particular with the Surveillance and Microbiology Networks with the disease networks;</li> </ul>

	<ul style="list-style-type: none"><li>• Coordinate requests from the ECDC to MS in sense to minimize duplication of tasks and data requested from different NFPs and OCPs.</li></ul>
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## Annex 5 to Coordinating Competent Bodies: Structures, Interactions and Terms of Reference:

# Terms of Reference for ECDC Operational Contact Points for Disease-Specific Interactions with EU Member States and EEA countries

### Background:

In order to efficiently work with the EU Member States and EEA countries, the ECDC Management Board has adopted a "One Competent Body" approach (MB20) and Terms of Reference for the Competent Bodies (MB21). For each EU Member State or EEA country, one Coordinating Competent Body (CCB) and one National Coordinator (NC), acting as the main entry point for interactions between the country and ECDC, have been identified.

Within this system, the NC may delegate some specific strategic interactions to National Focal Points (NFPs) covering disease group issues or public health function issues. The NC may further delegate day-to-day technical and operational interactions to Operational Contact Points (OCPs).

Within each disease group, there may be specific OCPs for epidemiology, microbiology, TESSy interactions, bioinformatics, entomology. In the disease groups covering many diseases, there may be a need for several epidemiology and microbiology OCPs. The number of OCPs should be kept to the minimum level necessary for an efficient cooperation between ECDC and Member States, and it is envisaged that many Member States will appoint the same person for several of the OCPs.

If no OCP for disease specific interactions within a given disease/disease group is nominated, all interactions within this area will remain channelled through the NFP or NC.

When a need arises to have a new type of OCPs in a network, the NFPs in consultation with the NCs will make a proposal, including draft terms of reference (ToRs) and envisaged interactions. The proposal will be discussed in the National Coordinators Coordination Committee, and if approved, ECDC will ask the NCs to nominate the requested OCPs.

- Regulation (EC) No 853/2004 of the European Parliament and of the Council of 21 April 2004
- Coordinating Competent Bodies: structures, interactions and terms of reference

<b>ECDC team/section responsible for relations with the OCPs for disease specific interactions:</b>	As of ECDC Internal Procedures, there is one named main responsible internal focal point for official interactions with each OCP (across the Member States), using functional ECDC mailboxes supported by the SRM system.
<b>Disease groups:</b>	<p>These Terms of Reference are valid for each of the following disease groups:</p> <ul style="list-style-type: none"> <li>• Antimicrobial resistance (ARHAI Programme)</li> <li>• Antimicrobial consumption (ARHAI Programme)</li> <li>• Healthcare-associated infections (ARHAI Programme)</li> <li>• Emerging and vector-borne diseases (EPR Programme)</li> <li>• Viral respiratory diseases (VPI Programme)</li> <li>• Food- and waterborne diseases and Zoonoses (EPR Programme)</li> <li>• Legionellosis (EPR Programme)</li> <li>• Transmissible spongiform encephalopathy (TSE) (EPR Programme)</li> <li>• HIV/AIDS, STI and Hepatitis B/C (SBT Programme)</li> <li>• Tuberculosis (SBT Programme)</li> <li>• Vaccine preventable diseases (VPI Programme)</li> </ul>
<b>Overall responsibilities of OCPs:</b>	If delegated by the NC (as decided by each country), the OCP is responsible for overseeing interactions between ECDC and the EU Member State or EEA country regarding the specific activities he/she is in charge of within a specific disease network.
<b>Coordination of tasks within the CCBs:</b>	Below specific responsibilities of OCPs are subject to the specific national settings, and it is for each Member State to organise its work independent of the ECDC CCB structure. If specific tasks mentioned below are shared between different individual staff members within the CCB system, it is anticipated that necessary coordination takes place within the CCB system, e.g. forwarding mails/tasks to the appropriate person, without specific involvement of ECDC.
<b>Responsibilities of disease-specific OCPs for Epidemiology:</b>	<p>Within available resources:</p> <ul style="list-style-type: none"> <li>• Review draft surveillance reports produced by ECDC and contribute to the interpretation of surveillance results;</li> <li>• Inform ECDC about data sources and surveillance systems;</li> <li>• Oversee implementation of TESSy metadata changes at national level;</li> <li>• Collaborate closely with epidemiology OCPs from other Member States, as required;</li> <li>• Otherwise interact with ECDC on issues related to surveillance and control of specific pathogens/diseases as appropriate from a national context.</li> </ul>
<b>Responsibilities of disease-specific OCPs for Microbiology:</b>	<p>Within available resources:</p> <ul style="list-style-type: none"> <li>• Provide information about the current status of laboratory capacities for the specific disease / disease group and keep it up to date;</li> <li>• When available and legally possible, ensure flow of national laboratory surveillance data to OCP for TESSy interactions for upload</li> </ul>

	<p>to TESSy;</p> <p><b>or:</b></p> <p>Ensure upload of national laboratory data to TESSy according to permissions by NC, and/or NFP (when available and legally possible);</p> <ul style="list-style-type: none"> <li>• Encourage participation of the national reference centre (or laboratory with equivalent function) in EQA schemes sponsored by ECDC;</li> <li>• Collaborate closely with microbiology OCPs from other countries as specified by ECDC grant or service contracts, as required.</li> <li>• Otherwise interact with ECDC on issues related to the microbiology of specific pathogens as appropriate from a national context.</li> </ul>
<b>Responsibilities of disease-specific OCPs for TESSy interactions:</b>	<p>Within available resources:</p> <ul style="list-style-type: none"> <li>• Prepare national surveillance data files in accordance with ECDC requirements and upload the data for the specific disease / disease group to TESSy</li> <li>• Approve uploaded data (if delegated by the NC/NFP);</li> <li>• Reply to enquiries from ECDC regarding data validation;</li> <li>• If original surveillance data were flawed, upload corrected data to TESSy (if delegated by the NC/NFP);</li> <li>• Implement TESSy metadata changes at national level (if delegated from the epidemiology OCP).</li> </ul>
<b>Responsibilities of disease-specific OCPs for Bioinformatics<sup>2</sup>:</b>	<p>Within available resources:</p> <ul style="list-style-type: none"> <li>• Maintain an overview of the public health bioinformatics activities and systems within the Member State;</li> <li>• Keep up to date with current state of art within public health bioinformatics;</li> <li>• Be the primary contact point for ECDC regarding cross-disease bioinformatics activities and trainings;</li> <li>• Participate in activities and trainings, and taking part in discussions related to public health bioinformatics;</li> <li>• Facilitate upload of genomic surveillance data to TESSy and EpiPulse.</li> </ul>
<b>Responsibilities of ECDC:</b>	<p>In order to ensure efficient communication and collaboration between ECDC and the Coordinating Competent Body<sup>3</sup> within the area of the disease/disease group and ensuring European added value, ECDC is responsible for the following:</p> <ul style="list-style-type: none"> <li>• Form the coordinating and communication hub for all European disease network activities, providing the scientific secretariat and administrative support;</li> <li>• Provide and maintain an IT platform enabling NCs to nominate NFPs and OCPs and to keep the nominations up to date;</li> </ul>

<sup>2</sup> The nomination of OCP for Bioinformatics can be associated with several disease groups which are considered relevant (and depending on the sequencing activities in the Member State).

<sup>3</sup> NC, NFP or OCP as agreed with the CCB.

	<ul style="list-style-type: none"><li>• Appoint network coordination committees from among the OCPs and NFPs to closely link ECDC and the networks;</li><li>• Organise and fund regular network meetings to share data and best practices and discuss strategic choices within and across disease networks;</li><li>• Foster technical and scientific collaboration within and across disease networks;</li><li>• Produce or outsource production of network outputs and ensure their visibility;</li><li>• Liaise with other relevant stakeholders (e.g. WHO, EU agencies) on behalf of the disease networks to coordinate activities, share data, facilitate cooperation or reduce MS burden (e.g. multiple reporting), as appropriate;</li><li>• Ensure the coordination of the disease networks with the public health functions networks, in particular with the surveillance and microbiology networks;</li><li>• Coordinate requests from ECDC in order to minimise duplication of tasks and data requested from different OCPs and NFPs;</li><li>• Ensure that all requests to the OCPs are based on a clear EU added value;</li><li>• Provide OCPs with timely feedback/replies to their requests to ECDC;</li><li>• Provide final versions of relevant strategic and technical documents within the area of disease specific networks to OCPs and when appropriate also provide OCPs with draft documents for consultation with time enough for sound reply.</li></ul>
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## Annex 6 to Coordinating Competent Bodies: Structures, Interactions and Terms of Reference:

# Terms of Reference for ECDC Operational Contact Points for Public Health Training in field Epidemiology (EPIET) and Public Health Microbiology (EUPHEM) as organised in the ECDC Fellowship Training Site Forum (TSF)

### Background:

In order to efficiently work with the EU Member States and EEA countries, the ECDC Management Board has adopted a "One Competent Body" approach (MB20) and Terms of Reference for the Competent Bodies (MB21). For each EU Member State and EEA country, one Coordinating Competent Body (CCB) and one National Coordinator (NC), acting as the main entry point for interactions between the country and ECDC, have been identified.

When a need arises to have a new type of OCPs in a network, the NFPs in consultation with the NCs will make a proposal, including draft terms of reference (ToRs) and envisaged interactions. The proposal will be discussed in the National Coordinators Coordination Committee, and if approved, ECDC will ask the NCs to nominate the requested OCPs.

ECDC's established mechanism of interaction with the Member States is through Competent Bodies, and strategic subjects related to training are addressed through the National Focal Points for Public Health Training (NFPTs) in the broader context of the ECDC Training Strategy.

For the ECDC Fellowship Programme the EPIET Training Site forum has been established since the integration of EPIET into ECDC in 2007, and later complemented with a EUPHEM Training Site Forum – now combined to a Fellowship Training Site Forum.

These forums were established to address day-to-day technical matters regarding fellowship activities. As such, its members have been regarded as OCPs for Public Health Training within the established CCB structure.

This document describes the Training Site Forum, hereinafter referred to as TSF, in terms of its constitution and mandate, including its members' roles and responsibilities, and the role of its members as OCPs. It specifies conditions for membership, and its remit in relation to the ECDC Fellowship Programme.

	<p>Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004, amended by Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022</p> <p>Coordinating Competent Bodies: structures, interactions, and terms of reference.</p>
<b>ECDC team/section responsible for relations with the OCPs for Public Health Training interactions:</b>	The Head of the Fellowship Programme has the main responsibility for the interactions with the TSF.
<b>Overall responsibilities of the Training Site Forum (TSF):</b>	<p><b>Role and Tasks of the Training Site Forum</b></p> <p>The role of the TSF is to be a platform for interaction between the training sites, the NFPTs and the Public Health Training Section at ECDC in order to provide special expertise regarding fellowship activities.</p> <p>The TSF will:</p> <ul style="list-style-type: none"> <li>• Provide technical input from training sites in terms of feedback on the curriculum and current programme (e.g., on administration, communication, training resources and tools, preparation and execution of modules, including proposing suitable venue, etc.);</li> <li>• identify and inform about training needs for fellows, supervisors and facilitators;</li> <li>• participate in the selection of fellows and facilitators;</li> <li>• advise on relevance and applicability of training objectives and graduation criteria;</li> <li>• advise on fellowship selection criteria and process;</li> <li>• provide advice, input and guidance for the site visit process; and</li> <li>• advise on the timing of the curricular cycle.</li> </ul> <p><b>Remit</b></p> <p>The TSF has no decision-making function. It is an expert group whose role is to provide special expertise, advice and guidance on scientific and practical matters relevant to the ECDC Fellowship Programme, and feedback on administrative operations. It looks backwards in terms of outputs and evaluation and looks forward in terms of planning, curriculum development, and advice.</p>
<b>Composition and working mode of the TSF:</b>	<p><b>Training sites</b></p> <p>The TSF represents acknowledged training sites. The definition of an acknowledged training site is published in the Administrative Decision of the ECDC Fellowship Programme and is periodically revised in consultation with the TSF and NFPT.</p> <p><b>Composition of the TSF</b></p> <p>The TSF is composed of:</p> <p>1) OCPs:</p> <p>The OCPs are recognised representatives of the ECDC CCB structure. One representative proposed by each of the acknowledged training sites for</p>

	<p>each of the EPIET or EUPHEM paths, formally nominated to ECDC by the respective National Coordinator (NC) or by delegation, by the NFPT.</p> <p>Training site appraisal reports should reflect the name of the proposed OCP, and be shared with the NFPT. ECDC will notify the NC and NFPT when an acknowledged training site are at risk of losing the acknowledgement.</p> <p>2) Non-OCP representatives:</p> <ul style="list-style-type: none"> <li>• Two representatives from the EAN board, if possible, an alumnus from each of the EPIET and EUPHEM paths,</li> <li>• Two representatives from the current Fellowship Cohorts, one from the EPIET path and one from the EUPHEM path,</li> <li>• Scientific Coordinators of the Fellowship Programme and staff from the ECDC Public Health Training Section</li> <li>• Supervisors of the fellows currently under training.</li> </ul> <p><b>Chairpersons and "Committee of four"</b></p> <p>The TSF will elect one chairperson and one co-chairperson from among the representatives of acknowledged training sites for each one of the paths (EPIET and EUPHEM).</p> <p>The two chairpersons contribute to co-chairing the annual meetings and will serve as main contact points with the ECDC PHT section.</p> <p>The co-chairperson will serve in the same capacity as the chairperson of the respective path in his/her absence.</p> <p>Together, the chairpersons and co-chairpersons will form a "Committee of four". This committee will:</p> <ul style="list-style-type: none"> <li>• draft the agenda of the yearly meetings, supported by the PHT section;</li> <li>• propose improvements to the fellowship programme; and</li> <li>• participate in strategic discussions regarding the focus of the Fellowship Programme.</li> </ul> <p>The committee of four is also part of the Public Health Training Coordination Committee</p> <p><b>Meetings and other interactions of the TSF</b></p> <p>The TSF/OCPs and the non-OCP representatives (except from active supervisors) will meet face-to-face at least once a year. Depending upon budget availability and meeting topic relevance, ECDC may also invite the active supervisors that are non-OCP representatives to the face-to-face meetings. The TSF should try to reach consensus in its work.</p> <p>In between the physical meetings, virtual consultations should be maintained by an online workspace, tele/videoconference, or email, as necessary.</p> <p>The Chairpersons can propose to the Head of Fellowship Programme, to organise teleconferences with the TSF members (OCPs and non-OCP representatives) to discuss topics of relevance to the Fellowship Programme.</p> <p>The Chairs can also, after discussions with the Head of the Fellowship Programme, establish specific working groups, and call for advisory electronic polls among TSF members on fellowship-relevant matters.</p>
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	Head of Section should be involved when a TSF/NFPT working group is established.
<b>Path specific issues:</b>	<p>For aspects related to the specific disciplines of field epidemiology (EPIET) and public health microbiology (EUPHEM), the respective Chairs, co-Chairs and Training Sites may organise specific and ad-hoc working groups during and/or between the TSF meetings or sessions during meetings of the TSF. The Head of Fellowship Programme, and other relevant staff, if necessary (including scientific coordinators), should be invited to these conferences.</p> <p>This applies in particular to curricular and scientific aspects that are specific to the respective discipline, always with the vision of knowledge developments, and the future needs of professionals and institutes in this field.</p>
<b>Responsibilities of ECDC:</b>	<p>Secretariat functions for the TSF and its chairs is provided by ECDC, and will ensure the necessary support, both scientific and administrative.</p> <p>ECDC facilitates the communications and interactions of the TSF by providing relevant information and materials, organising meetings, teleconferences and access to platforms for the exchange of opinions; taking minutes of meetings and making them available for transparency and consensus of the final advice provided.</p> <p>ECDC supports the contacts between the TSF and the NFPTs, in order to ensure consistency and alignment, in particular when translating training needs and in the area of administration of the Fellowship, coordinating the collation of advice from those bodies in a coherent and transparent way.</p> <p>ECDC provides the NFPTs with minutes and reports from the TSF meetings (and vice versa).</p> <p>ECDC takes the views of the TSF into specific consideration in its decision-making process.</p>





## Annex 7 to Coordinating Competent Bodies: Structures, Interactions and Terms of Reference:

### Terms of Reference for ECDC Operational Contact Points for Epidemic Intelligence (Epidemic Intelligence network)

#### Background:

ECDC's mission<sup>4</sup> is to identify, assess and report on current and emerging threats to human health from communicable diseases (Regulation 2022/2371). To meet its mission, the Centre coordinates networks involving EU Member States and EEA countries (EU/EEA MS) in fields within its mission, shares information, expertise and best practices, and supports epidemic and outbreak response. In this context, close collaboration with EU/EEA MS to strengthen global epidemic intelligence (EI) is vital.

In order to efficiently work with the EU/EEA MS, the ECDC Management Board has adopted a "One Coordinating Competent Body" approach (MB20) and Terms of Reference for the Competent Bodies (MB21). For each EU/EEA MS, the Coordinating Competent Body (CCB) and the National Coordinator (NC) act as the main entry point for interactions between the country and the ECDC. Topics related to EI and threat detection strategy are addressed through the National Focal Points (NFPs) for Threat Detection, EWRS and IHR.

Since the COVID-19 pandemic and given technological advances, there has been an increased interest in EI and threat detection. In parallel, evaluations have shown the usefulness of using EI sources for monitoring disease trends, especially when indicator-based surveillance has not been set up, e.g. during emerging events. The changing EI landscape and the ECDC mission in the area of early detection and warning bring new demands on working and collaborating in these fields.

To better support and enhance the functions and regular activities of the NFPs for Threat Detection, EWRS and IHR, ECDC proposed nomination of Operational Contact Points (OCPs) for EI and creation of a new network

<sup>4</sup> [EUR-Lex - c11541 - EN - EUR-Lex \(europa.eu\)](#)

in Regulation (EU) 2022/2370 of the European Parliament and of the Council amending Regulation (EC) No 853/2004 establishing a European Centre for Disease Prevention and Control (ECDC) and in Regulation (EU) 2022/2371 on serious cross-border threats to health

	<p>(EI network). The proposal for establishment of a formal EI network in EU/EEA was supported by EI experts from different EU/EEA MS attending ECDC-organised meeting on strengthening collaborative EI (Stockholm, 31/05-01/06/2023), as well as by the NFPs for Preparedness and Response, Threat Detection, EWRS and IHR at their Annual Meeting (Stockholm, 12-13 September 2023).</p> <p>The overall objective of the EI network will be to enhance threat detection and epidemic intelligence activities in EU/EEA MS.</p> <p>The key areas of work of the network will include:</p> <ul style="list-style-type: none"> <li>• Exchanging information on ongoing public health events;</li> <li>• Sharing and validating signals detected from open sources;</li> <li>• Sharing experiences on methods and tools (e.g., EIOS) for EI;</li> <li>• Training in methods and tools used for EI;</li> <li>• Collaborating on the development, innovation and implementation of EI methods (e.g., through communities of practice).</li> </ul> <p>This document describes the EI network in terms of its constitution and mandate, including its members' roles and responsibilities. It specifies conditions for membership, and its remit in relation to ECDC's EI activities.</p>
<b>ECDC team/section responsible for relations with the OCPs for Epidemic Intelligence interactions:</b>	The Group Lead of ECDC Epidemic Intelligence Group is the main responsible focal point for official interactions with the OCPs for EI.
<b>Public health functions:</b>	These Terms of References are valid for the Threat Detection, EWRS and IHR function.
<b>Overall responsibilities of the OCPs for Epidemic Intelligence (EI network):</b>	<p>In every country, the NC will nominate the OCP(s). The OCP will be responsible for supporting the NFP for Threat Detection, EWRS and IHR in operational interactions between ECDC and the EU/EEA MS in EI activities.</p> <p>The key responsibilities of the OCPs will include:</p> <ul style="list-style-type: none"> <li>• Providing technical input from EU/EEA MS on current threat detection activities (e.g., on methods, outputs, communication, and collaboration, etc.);</li> <li>• Contributing to identifying EI training needs in EU/EEA MS;</li> <li>• Providing advice on the relevance and applicability of EI network objectives and activities for the EU/EEA MS;</li> <li>• Participating in consultations on ECDC scientific advice and providing feedback on ways to improve and enhance EI, taking in consideration innovative approaches (e.g., process automation, web scraping, artificial intelligence, monitoring and evaluation of EI processes and activities);</li> <li>• Disseminating any relevant information about EI (e.g., methodological aspects) to colleagues at the national level;</li> <li>• Attending the annual in-person EI network meeting (which will be organised in a EU/EEA MS, if feasible) and actively participating in ad hoc or regular online meetings on public health events of interest;</li> <li>• In coordination with the NFPs, replying to enquiries from ECDC and communicating on public health events of interest, including through EpiPulse or other EI or alerts platforms;</li> </ul>

	<ul style="list-style-type: none"> <li>• Providing feedback on the use of EI tools (e.g., EIOS) and their use in different contexts;</li> <li>• Contributing to scientific and other technical communication on EI, e.g., peer-reviewed or other articles, reports disseminating EI outputs, and other documents.</li> </ul> <p>If the OCP for EI has not been appointed (or are unavailable), the responsibility to ensure that the tasks are carried out rests with the NFP for Threat Detection, EWRS and IHR.</p>
<b>Composition and working mode of the OCPs for Epidemic Intelligence (EI network):</b>	<p>The EI network structure and activities will enhance and extend the collaboration with the EU/EEA MS. Strategic issues related to the EI OCPs network composition and working mode will be addressed in the Joint Coordination Committee for Early Detection, Preparedness and Response.</p> <p>Until 2023, there was no separate Coordination Committee for Threat Detection, EWRS and IHR. A Joint Coordination Committee will be formed to represent NFPs for Preparedness and Response and the NFPs for Threat Detection, EWRS and IHR. The Coordination Committee will include a maximum of 10 members (5 NFPs for Preparedness and Response and 5 NFPs for Threat Detection, EWRS and IHR), elected for a period of three years. Any NFP member or their alternate from both NFPs networks is eligible for participating in the Coordination Committee.</p>
<b>Responsibilities of ECDC:</b>	<ul style="list-style-type: none"> <li>• Secretariat function to ensure necessary support, both scientific and administrative;</li> <li>• Facilitating communications and interactions within the EI network by providing relevant information and materials, organising meetings, teleconferences and access to platforms (including EpiPulse-EI domain) for the exchange;</li> <li>• Taking minutes of the meetings and making them available to OCPs and NFPs to ensure transparency;</li> <li>• Aiming for consensus in discussions involving the EI network;</li> <li>• Supporting the contacts between the EI network and the NFPs, in order to ensure consistency and alignment, in particular when translating training needs in the area of EI and coordinating the collation of advice from those bodies in a coherent and transparent way;</li> <li>• Providing the NFPs with minutes and reports from the EI network meetings and ensuring the EI network is fully briefed on discussions and strategic decisions taken by the NFPs and the Coordination Committee;</li> <li>• Sending relevant strategic and technical documents to the EI network as well as to the NFPs for consultation, with enough time for sound reply;</li> <li>• Providing OCPs with timely feedback/replies to their requests to ECDC;</li> <li>• Organising one annual in-person network meeting and ad hoc, online meetings based on public health events of interest;</li> <li>• Exploring and defining objectives and opportunities for MS participation at the ECDC roundtable meetings;</li> <li>• Supporting EU/EEA MS in using different EI tools and platforms (e.g., EIOS, EpiPulse);</li> <li>• Providing support with routine and enhanced EI, including through training activities, as required and with considerations to the context and processes at different EU/EEA MS;</li> </ul>

	<ul style="list-style-type: none"><li>• Facilitating rapid sharing of information from open sources;</li><li>• Communicating about public health events with the NFPs and the EI network;</li><li>• Facilitating communication with EU bodies/agencies (such as JRC, EFSA, HERA) and other international partners (WHO, WHO Pandemic Hub) in areas related to EI.</li></ul>
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## Annex 8 to Coordinating Competent Bodies: structures, interactions and terms of reference:

# Terms of Reference for ECDC Disease Network Coordination Committees in EU Member States and EEA countries

<b>General background:</b>	<p>In order to efficiently work with the EU Member States and EEA countries, the ECDC Management Board has adopted a "One Competent Body" approach (MB20) and Terms of Reference for the Competent Bodies (MB21). For each EU Member State or EEA country, one Coordinating Competent Body (CCB) and one National Coordinator (NC), acting as the main entry point for interactions between the country and ECDC, have been identified.</p> <p>Within this system, the NC may delegate some specific strategic interactions to National Focal Points (NFPs) covering disease group issues or public health function issues. The NC may further delegate day-to-day technical and operational interactions to Operational Contact Points (OCPs).</p> <p>The Disease Group NFPs and OCPs constitute the external ECDC Disease Networks. For each network there will be a smaller Disease Network Coordination Committee (DNCC) selected from among the network members, ideally mirroring both the broad scope of expertise in the network and its geographic diversity. The DNCC will work closely with the Centre in between the full disease network meetings, advise ECDC on urgent matters and contribute to the agenda of the regular disease network meetings. This document describes the roles, tasks, composition, selection, work procedures and interactions of the DNCCs.</p> <p>For more background information please refer to the following documents:</p> <p>Document - Coordinating Competent Bodies: structures, interactions and terms of reference</p>
<b>ECDC staff responsible for Disease Networks Coordination committees:</b>	Disease Programmes (DPR)

<b>Role and tasks of the Disease Networks Coordination committees:</b>	<p>The DNCC shall support further development of the ECDC disease work and networks, by providing important but non-binding advice to the respective ECDC Disease Programmes (DP) with respect to all aspects of its work including surveillance, prevention and control or any other technical, epidemiological or scientific aspects, thus enabling the network to improve its effectiveness and added value.</p> <p>Complementary to consultations with the full network, the DNCCs will specifically provide support to the following:</p> <ul style="list-style-type: none"> <li>• provide advice on the implementation of relevant ECDC strategies and annual DP work plans;</li> <li>• provide rapid advice to ECDC on scientific/technical issues within the disease programme area, as requested;</li> <li>• discuss priorities in the future activities of the ECDC DPs with respect to prevention and control including surveillance, public health microbiology, guidance, training, capacity building and other aspects;</li> <li>• contribute to the identification of Member States' needs in terms of strengthening capacity in the area of the DP;</li> <li>• review selected technical reports and guidance documents produced by the ECDC or its contractors and make suggestions for improvement, as requested by ECDC;</li> <li>• contribute to the agenda of the regular meetings of the DP network (including identifying topics; key note speakers, working group sessions and others);</li> <li>• review the methodologies to improve DP specific data collections, data presentation and interpretation of surveillance results;</li> <li>• review the effectiveness of surveillance systems and analytical tools for surveillance within the domain of the DP and make suggestions for improvement;</li> <li>• review the disease-specific laboratory surveillance activities, incl molecular microbiology, and foster the integration with epidemiological surveillance;</li> <li>• review the need for specific disease network working groups, advisory groups, ad hoc expert panels and task forces which would report to the Coordination Committee on specific issues (i.e. guidance; surveillance methods or variables);</li> <li>• closely liaise with any other ECDC DNCCs, DPs or Working Groups that may be set up to work on technical issues in the area of DP.</li> </ul> <p>The DNCCs will act at an overarching level covering the (broad) fields of ECDC DPs and will complement but not replace ECDC consultations with other groups (specifically the ECDC Advisory Forum but also the ad hoc expert panels, technical advisory groups, etc.), bodies and fora as well as other EU Agencies, in accordance with ECDC internal rules and procedures.</p>
<b>Composition of the Disease Networks Coordination committees:</b>	<p>The DNCCs will consist of a maximum of 10 members (the final number will be decided by each network) selected from and representing the disease network, including the OCPs and NFPs for the disease or disease</p>

	<p>group in question, to mirror the broad scope of activities to be addressed by the DNCCs.</p> <p>The DNCCs may also agree (by majority) to include as observers individuals from other organisations with a significant role in the prevention and control of the disease-specific area covered by the ECDC DP, such as experts from WHO Regional Office for Europe, the European Commission, other EU Agencies, or other external experts following agreement with ECDC. The DNCCs may also agree to form smaller time-limited sub-groups to undertake well defined specific pieces of work.</p> <p>Ideally, in selecting the composition of the DNCCs, there should be some balance between functional expertise (i.e., between epidemiologists and microbiologists, prevention specialists, scientific input, behavioural science) as well as for gender and geography.</p> <p>The appointment of members will be for three years. Members can be re-appointed through the regular election procedure. The secretariat of the DNCCs shall be provided by ECDC.</p>
<b>Selection procedure:</b>	<p>The ECDC Director will formally appoint the members of the DNCCs following an election by the disease network members. The network members, when nominating and electing the DNCC members, should consider the composition and eligibility criteria listed above.</p> <p>In the election process, each CCB has one vote, coordinated by the respective NFP. The election process is done via e-mail with all NFPs in CC.</p> <p>The election is based on nominations, including self-nominations, by the NFPs and OCPs in the network, following a call from ECDC. If equal or less nominations than the agreed maximum number of DNCC members, these nominated candidates will be appointed by the Director without an election process, following an opportunity for the network members to comment on the proposed committee.</p> <p>In case of more nominations than the agreed maximum number of DNCC members, the CCBs are asked to mark candidates on the list with the number of marks corresponding to the agreed maximum number of DNCC members. The candidates with most marks will be considered elected.</p> <p>In the election process, each CCB has one vote, coordinated by the respective NFP. The election process is done via e-mail with all NFPs in CC.</p> <p>The DNCC will elect a Chair and a Vice Chair from among its members.</p>
<b>Work procedures:</b>	<p>The DNCC will meet face-to-face at least once a year. In between these physical meetings, communication between the members of the committee should be maintained by extranet workspace, tele/video conference, email, fax, etc. as needed.</p> <p>ECDC will, in consultation with the DNCC Chair and Vice Chair, draft the agenda and organise the DNCC meetings.</p> <p>The secretariat, provided by ECDC, will take minutes of these meetings which will be circulated to the members for approval no later than four weeks following the meeting. The final report will be distributed to all the members of the disease-specific network and the NCs of the CCBs.</p>

	<p>Agreement on the DNCCs opinions or advice will be achieved by consensus. In the event of not reaching consensus the Chair will refer all the opinions, including minority opinions of the DNCC to the ECDC for a final decision.</p> <p>When urgent advice is necessary, ECDC will consult the DNCC through its Chair / Vice Chair.</p> <p>These terms of reference should be reviewed periodically, and any proposed changes may be passed on to the ECDC for further consideration.</p>
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### Template "Administrative Decision on the appointment of Disease Network Coordination Committees"

## Administrative Decision on the appointment of Disease Network Coordination Committees

**Purpose:** To establish the XXX Network Coordination Committee, composed of members of the ECDC XXX Network.

**Background:** Documents: - Coordinating Competent Bodies: structures, interactions and terms of reference, Annex 8 to Coordinating Competent Bodies: structures, interactions and terms of reference: Terms of Reference for ECDC Disease Network Coordination Committees in EU Member States and EEA countries.

**Description:** This Administrative Decision establishes the appointment of the next ECDC Disease Network Coordination Committee for the XXX Network, in line with the ECDC procedure set out in the above background documents.

In accordance with the Terms of Reference referred to above, calls for nominations (including self-nominations) for the Disease Network Coordination Committee from among the network members (XXX NFPs and OCPs) was initiated and received by [date]. The following nominees were presented to the network with the deadline of [date] to raise any objections regarding the proposed committee.

Name	Country	E-mail address
...		
...		

No objections were received from the XXX network, and the members are appointed for a period of three years, starting on the date of adoption of this Decision. Following the appointment, the Network Coordination Committee, will elect a Chair and a Vice Chair from among its members.





## Annex 9 to Coordinating Competent Bodies: structures, interactions and terms of reference:

### Terms of Reference for ECDC Public Health Network Coordination Committees in EU Member States and EEA countries

<b>General background:</b>	<p>In order to efficiently work with the EU Member States and EEA countries, the ECDC Management Board has adopted a “One Competent Body” approach (MB20) and Terms of Reference for the Competent Bodies (MB21). For each EU Member State or EEA country, one Coordinating Competent Body (CCB) and one National Coordinator (NC), acting as the main entry point for interactions between the country and ECDC, have been identified.</p> <p>Within this system, the NC may delegate some matters related to specific diseases to National Focal Points (NFPs) covering disease group issues or public health function issues. The NC may further delegate day-to-day technical and operational interactions to Operational Contact Points (OCPs).</p> <p>The structure of ECDC Competent Bodies identifies NFPs and sometimes OCPs for seven public health functions (health communication, microbiology, preparedness &amp; response, public health training, scientific advice coordination, surveillance, and Threat Detection, EWRS and IHR). These Public Health Function NFPs and OCPs constitute the external ECDC public health networks within the mandate of the Centre.</p> <p>At the request of each network there will if relevant be a smaller Public Health Network Coordination Committee (PHNCC) selected from among the network members, ideally mirroring both the broad scope of expertise in the network and its geographic diversity. The PHNCC will work closely with the Centre in between the full network meetings, advise ECDC on urgent matters and contribute to the agenda of the regular network meetings. This document describes the roles, tasks, composition, selection, work procedures and interactions of the PHNCC.</p> <p>For more background information please refer to the following document: “Coordinating Competent Bodies: structures, interactions and terms of reference (7 December 2012)”</p>
<b>ECDC staff responsible for Public Health Network Coordination Committees:</b>	<p>Head of Section in the relevant ECDC unit.</p>

<b>Role and tasks of the Public Health Network Coordination Committees:</b>	<p>The PHNCCs shall support further development of the ECDC public health work and networks, by providing important but non-binding advice to the relevant ECDC units with respect to the public health function for which they have been appointed as NFP, thus enabling the network to improve its effectiveness and added value.</p> <p>Complementary to consultations with the full network, the PHNCC will specifically provide support to the following:</p> <ul style="list-style-type: none"> <li>• provide advice on the implementation of strategies and annual section work plans;</li> <li>• provide rapid advice to ECDC on scientific/technical issues within the public health function, as requested;</li> <li>• contribute to the identification of Member States' needs in terms of strengthening capacity in the area of the public health function.</li> <li>• review selected technical reports and documents produced by the ECDC or its contractors and make suggestions for improvement, as requested;</li> <li>• contribute to the agenda of the annual meetings of the network (including identifying topics; key note speakers, working group sessions and others);</li> <li>• review the methodologies to improve specific data collections, data presentation and interpretation of project results;</li> <li>• review the need for specific public health function working groups, advisory groups, ad hoc expert panels and task forces which would report to the PHNCC on specific issues (i.e. specific pilot projects and research initiatives);</li> <li>• closely liaise with any other ECDC PHNCC or Working Groups that may be set up to work on technical issues in the public health function at hand;</li> <li>• liaise with ECDC Disease Network Coordination Committees on important shared topics as relevant.</li> </ul> <p>The PHNCCs will act at an overarching level covering the (broad) public health functions of ECDC and will complement but not replace ECDC consultations with other groups (specifically the ECDC Advisory Forum but also the ad hoc expert panels, technical advisory groups, etc.), bodies and fora as well as other EU Agencies, in accordance with ECDC internal rules and procedures.</p>
<b>Composition of the Public Health Network Coordination Committees:</b>	<p>The PHNCCs will consist of a maximum of 10 members (the final number will be decided by each network) selected from and representing all the NFPs and OCPs for a specific public health function, to mirror the broad scope of activities to be addressed by the PHNCCs.</p> <p>The PHNCCs may also agree (by majority) to include as observers individuals from other organisations with a significant role in the public health function in question, such as experts from WHO Regional Office for Europe, the European Commission, other EU Agencies, or other external experts following agreement with ECDC. The PHNCCs may also agree to form smaller time-limited sub-groups to undertake well defined specific pieces of work.</p>

	<p>The appointment of members will be for three years. Members can be re-appointed through the regular election procedure. The secretariat of the PHNCCs shall be provided by ECDC.</p>
<b>Selection procedure:</b>	<p>The ECDC Director will formally appoint the members of the PHNCCs following an election by the network members. The network members, when electing the PHNCC members, should consider the composition and eligibility criteria listed above.</p> <p>In the election process, each CCB has one vote, coordinated by the respective NFP. The election process is done via e-mail with all NFPs in CC.</p> <p>The election is based on nominations, including self-nominations, by the NFPs and OCPs in the network, following a call from ECDC. If equal or less nominations than the agreed maximum number of PHNCC members, these nominated candidates will be appointed by the Director without an election process, following an opportunity for the network members to comment on the proposed committee.</p> <p>In case of more nominations than the agreed maximum number of PHNCC members, the CCBs are asked to mark candidates on the list with the number of marks corresponding to the agreed maximum number of PHNCC members. The candidates with most marks will be considered elected.</p> <p>The PHNCC will elect a Chair and Vice Chair from among its members.</p>
<b>Work procedures:</b>	<p>The PHNCC will meet face-to-face at least once a year. In between the physical meetings, communication between the members of the committee should be maintained by extranet workspace, tele/video conference, email, fax, etc. as needed.</p> <p>ECDC will, in consultation with the PHNCC Chair and Vice Chair, draft the agenda and organise the PHNCC meetings.</p> <p>The secretariat, provided by ECDC, will take minutes of these meetings which will be circulated to the members no later than four weeks following the meeting. The final approved report will be distributed to all the members of the PHF network and the NCs of the CCBs.</p> <p>Agreement on the PHNCCs opinions or advice will be achieved by consensus. In the event of not reaching consensus the Chair will refer all the opinions, including minority opinions of the PHNCC to the ECDC for a final decision.</p> <p>When urgent advice is necessary, ECDC will consult the PHNCC through its Chair / Vice Chair.</p> <p>These terms of reference should be reviewed periodically, and any proposed changes may be passed on to the ECDC for further consideration.</p>

**Template “Administrative Decision on the appointment of Public Health Network Coordination Committees”****Administrative Decision on the appointment of Public Health Network Coordination Committees**

**Purpose:** To establish the XXX Network Coordination Committee, composed of members of the ECDC XXX Network.

**Background:** Documents: Coordinating Competent Bodies: structures, interactions and terms of reference, Annex 9 to Coordinating Competent Bodies: structures, interactions and terms of reference: Terms of Reference for ECDC Public Health Network Coordination Committees in EU Member States and EEA countries.

**Description:** This Administrative Decision establishes the appointment of the next ECDC Public Health Network Coordination Committee for the XXX Network, in line with the ECDC procedure set out in the above background documents.

In accordance with the Terms of Reference referred to above, calls for nominations (including self-nominations) for the Public Health Network Coordination Committee from among the network members (XXX NFPs and OCPs) was initiated and received by [date]. The following nominees were presented to the network with the deadline of [date] to raise any objections regarding the proposed committee.

Name	Country	E-mail address
...		
...		

No objections were received from the XXX network, and the members are appointed for a period of three years, starting on the date of adoption of this Decision. Following the appointment, the Network Coordination Committee, will elect a Chair and a Vice Chair from among its members.



## Annex 10 to Coordinating Competent Bodies: structures, interactions and terms of reference: Terms of Reference for Network for the Microbial Safety of Substances of Human Origin (SoHO)

### Background

The ECDC's *Network for the Microbial Safety of Substances of Human Origin* (hereinafter SoHONet) is established for interaction between ECDC and the European Union (EU)/European Economic Area (EEA) Member States (hereafter Member States). SoHONet is part of the ECDC Coordinating Competent Body structure which is described in the *ECDC Coordinating Competent Bodies: Structures, Interactions, and Terms of Reference* document.

SoHONet ensures implementation of the requirements on the ECDC's relations with the Member States stated in the Regulation (EC) No 851/2004<sup>5</sup>, regarding strategic and operational collaboration on technical and scientific issues, surveillance, responses to health threats, scientific opinions, scientific and technical assistance, collection of data, identification of emerging health threats, and public information campaigns related to the safety of substances of human origin (hereinafter SoHO).

This collaboration brings together nominated EU/EEA professionals working in all types of SoHO entities and establishments - those dedicated to blood, tissues and cells, medically assisted reproduction, and human organs. It particularly aims to provide a communication and collaboration platform for nominated SoHO experts involved in and/or responsible for quality assurance of SoHOs, in terms of microbial safety and the release of SoHOs for human application.

### Objectives of SoHONet

Main objectives of the SoHONet 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.

Other objectives are to:

- Support the detection, monitoring and reporting on serious cross-border threats to health related to SoHO;

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<sup>5</sup> 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

- Obtain technical and scientific expertise from ECDC;
- Enhance preparedness and response planning activities in the Union.

## The SoHONet structure

SoHONet is a public health function network within the ECDC *STI, Blood-borne viruses and Tuberculosis Section*.

### *The SoHONet members*

The SoHONet consists of four groups of members:

#### 1. National Focal Points groups:

The core of SoHONet consists of four groups of National Focal Points<sup>6</sup> (hereafter NFP) and their alternates nominated according to their particular field of expertise:

- National Focal Points for SoHO - blood
  - one representative and one alternate from the Blood Entity from each Member State
- National Focal Points for SoHO - tissues and cells
  - one representative and one alternate from the Tissues/Cells Entity from each Member State
- National Focal Points for SoHO - medically assisted reproduction (MAR)
  - one representative and one alternate from the MAR Entity from each Member State
- National Focal Points for SoHO – human organs
  - one representative and one alternate from the Organs Entity from each Member State

Sub-groups of experts can be established if needed, for example: on living donors with members from the groups NFP - tissues and cells and NFP - human organs.

#### 2. Observers group:

In addition to NFPs, SoHONet can have observers. The observer group consists of one representative:

- per relevant EU/EEA/global professional association such as European Blood Alliance (EBA), European Association of Tissue Banks (EATB), European Society of Human Reproduction and Embryology (ESHRE), The European Society for Organ Transplantation (ESOT)
- of the DG SANTE SoHO team
- of European Medicines Agency (EMA)
- of European Directorate for the Quality of Medicines and Health Care (EDQM)
- of World Health Organization (WHO)

#### 3. ECDC's SoHO team.

### *The SoHONet Coordination Committee*

A Network Coordination Committee (hereinafter NCC) is established from the network members, mirroring the expertise in the network and its geographic diversity.

The task of the NCC is to work closely with ECDC in between the network group's plenary meetings, provide advice on urgent matters, and contribute to the agenda of the regular network meetings.

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<sup>6</sup> The roles and responsibilities of the NFPs are detailed in specific terms of reference (ToR).

NCC consists of nine members, two for each SoHO field. For the tissues and cells field three NCC members will be elected – two from the field of solid tissues banking and one from the field cells banking (primarily haematopoietic stem cells).

Members of the NCC are elected by the SoHONet members for a period of three years. The members of the NCC can be re-elected.

NCC appoints a chair among its members.

### *Nominations*

The nominations of NFPs for SoHONet are the responsibility of the Member State's National Coordinators (hereinafter NCs). In the process of selecting the candidates for SoHONet NFP (and alternates), NCs should work in close and active cooperation with corresponding SoHO National Competent Authorities to ensure the best possible professional contribution to the future work of the SoHONet.

### *Coordination within the Member States*

To ensure a smooth coordination of work, the Member States' NFPs should liaise closely with the SoHO National Competent Authorities, SoHO Entities, and relevant national professional organisation in the SoHO field.

## **Interactions between ECDC and the SoHONet**

ECDC and SoHONet communication and cooperation is realised through different types of meetings:

- Annual meeting of National Focal Points groups. If needed additional virtual NFP groups meetings can be organised
- Meeting of the Network Coordination Committee, three/four times per year
- Ad-hoc working groups for specific planned tasks, according to the annual work plan
- Ad-hoc emergency meetings of the experts relevant for the topic, according to the needs

Plenary meetings of the entire network will not be organised on a regular basis. Continuous communication across the NFC groups is ensured through NCC members representing all four fields. Exceptionally, when there are topics of critical importance for all SoHO fields or other duly justified reasons a plenary meeting can be organised.

ECDC will function as the secretariat of SoHONet and the NCC and will call meetings, prepare a draft agenda and the meeting report or minutes in close collaboration with the NCC chair. Furthermore, ECDC will perform tasks such as distribute information, documents, launch surveys, and collect data.

ECDC will have a generic e-mailbox for communication with SoHONet members and the ECDC's SoHO team.

## **Supporting information systems**

To support the nomination process and the interactions between ECDC and SoHONet, the ECDC Stakeholder Relationships Management (SRM) system is being used as the primary business system maintaining ECDC's cooperation with stakeholders.

The NFPs will have access to the ECDC information system EpiPulse. EpiPulse is ECDC's portal that facilitates collection, analysis, and dissemination of indicator- and event-based surveillance data on infectious diseases and associated health issues, including global epidemic intelligence, whole-genome

sequencing, and health determinants. It facilitates interdisciplinary collaboration and connects users from different sectors under a One-Health approach.

The platform will enable better preparedness and management of threats from infectious diseases at the EU and global level, through real-time monitoring of outbreak signals and events.

The EpiPulse platform does not substitute the rapid alert tool for SoHO threats, which remains within existing EC's Rapid Alert Blood (RAB) and Rapid Alert Tissues and Cells (RATC) platforms.

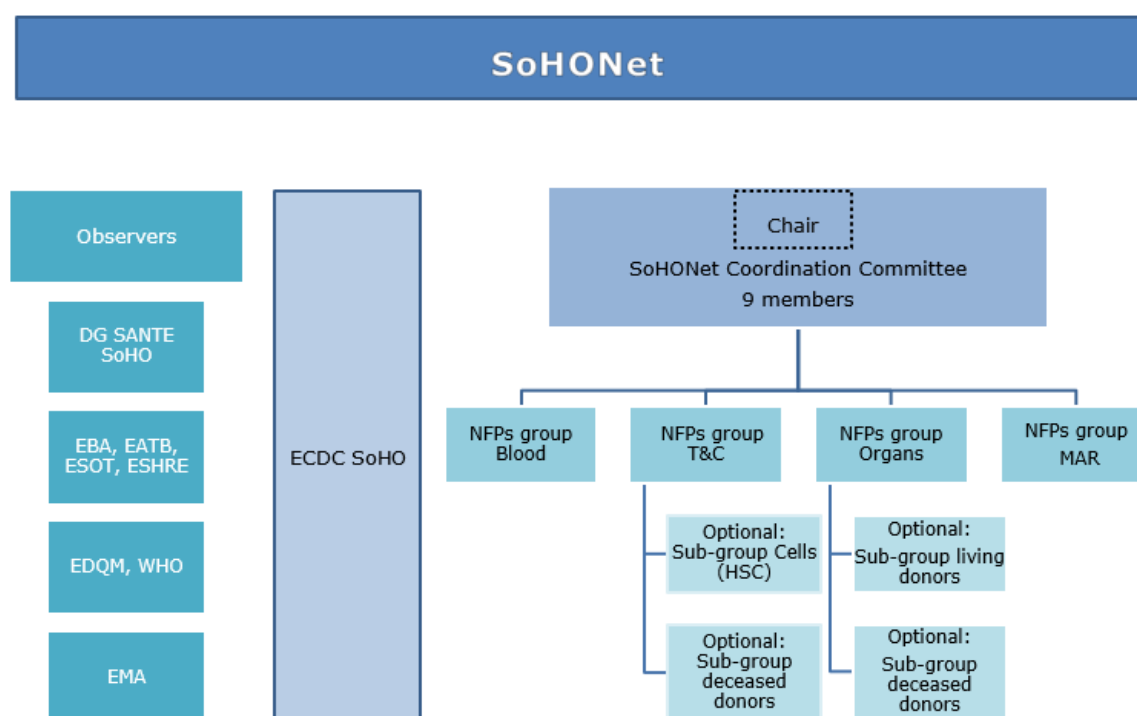
## Governance and terms of references

Generic Terms of reference (ToR) for the NFPs and NCC have been developed and described in the *ECDC Coordinating Competent Bodies: Structures, Interactions and Terms of Reference* document detailing the responsibilities of these functions and ECDC, respectively.

### Specific responsibilities of the NFP for SoHO

- Cooperate closely and communicate with appropriate National Competent Authority-ies (hereinafter NCA) on all topics relevant for the microbial safety of SoHO, particularly all information from/to SoHONet relevant to both the NCA and SoHONet.
- Support and advice NCA in the establishment of the national communication networks, encompassing all SoHO Entities, and national response networks regarding the issues of microbial safety of SoHOs (communication between NCA and SoHO Entities and among 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.

### Scheme of the SoHONet structure





## *Supporting information systems*

### *SRM*

Through the SRM system, the National Coordinators have full access to nominations from their country and are responsible for keeping the list of nominations updated.

The system ensures that messages between ECDC and the SoHO NFPs reach the right person, with appropriate other persons copied.

### *EpiPulse*

EpiPulse information system is linked to specific roles within the SoHONet. Once a nominated person has been assigned a specific role in the SRM, the system automatically ensures that this person obtains access to respective ECDC applications linked to that function.

The SoHO part of EpiPulse is a communication platform for communication between SoHONet members, observers, and ECDC.

SoHONet members can use the EpiPulse platform for confidential information sharing and discussion regarding potential SoHO microbiological safety events that are of importance nationally or internationally, including the discussion on and impacts of potential preventive and/or corrective actions. The EpiPulse platform can also be used to exchange news or other relevant information.