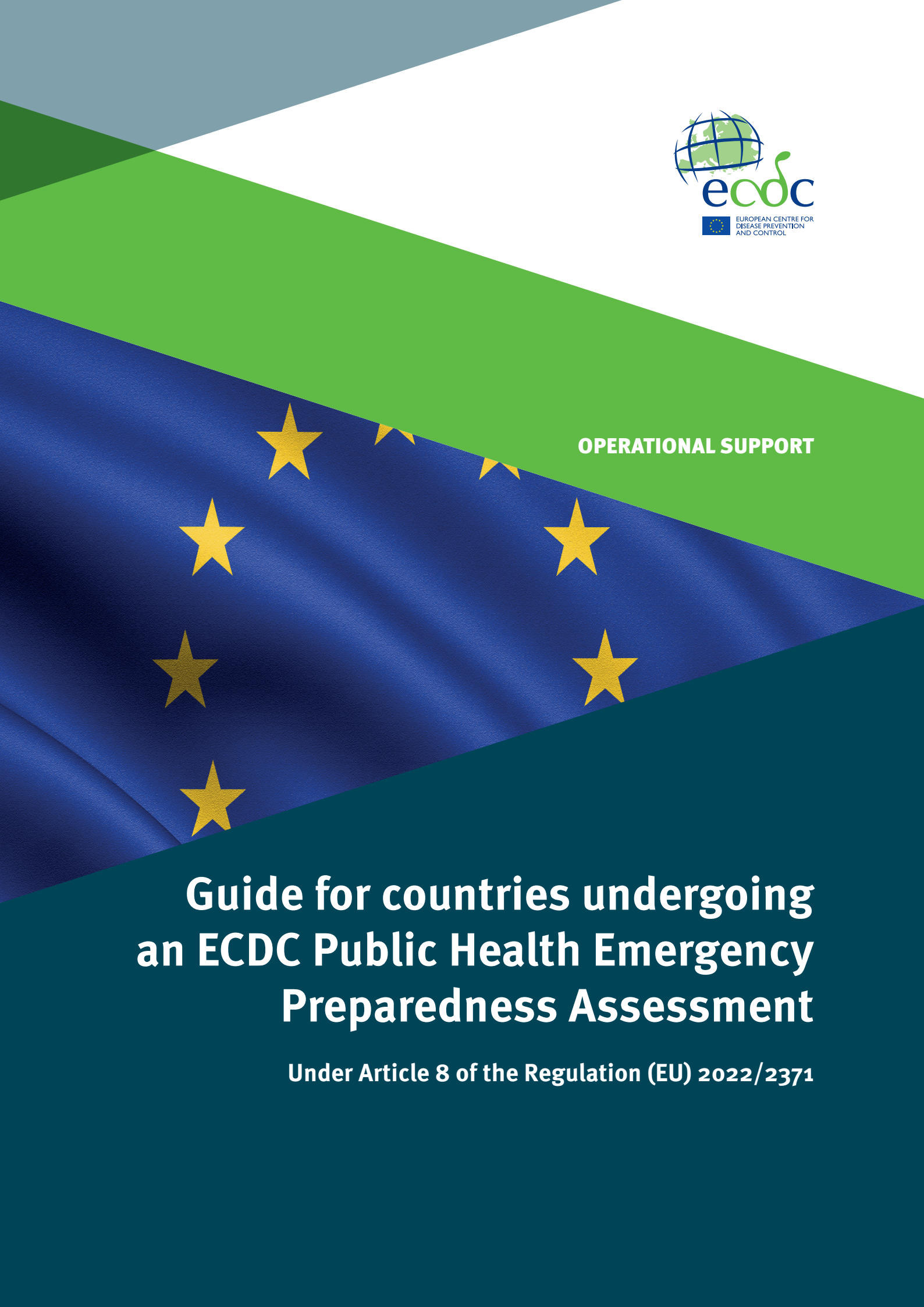

OPERATIONAL SUPPORT

Guide for countries undergoing an ECDC Public Health Emergency Preparedness Assessment

Under Article 8 of the Regulation (EU) 2022/2371

ECDC OPERATIONAL SUPPORT

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Contents

Abbreviations

DG	Directorate General of the European Commission
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EU	European Union
EWRS	Early Warning and Response System
HSC	Health Security Committee
IHR	International Health Regulations
PHEPA	Public Health Emergency Preparedness Assessment
SCBTH	Serious Cross-Border Threats to Health
SPAR	State Party Self-Assessment Annual Report
WHO	World Health Organization
WHO Euro	World Health Organization Regional Office for Europe

1. Introduction

1.1 Purpose of the Guide

This Guide aims to provide relevant information and detail to stakeholders in countries under assessment for them to plan ECDC Public Health Emergency Preparedness Assessments (PHEPAs) on the implementation status of national prevention, preparedness and response plans described under Article 8 of the Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health, and repealing Decision No 1082/2013/EU, hereafter referred to as the SCBTH Regulation[i].

This document includes an overview of the assessment process and a detailed breakdown of the four-phase approach of the assessment process. It also includes practical information that can be used by the assessed country to prepare for the country visit.

The target audience for this Guide are stakeholders in the assessed country who are working with ECDC and are involved in planning or implementing the assessment.

This Guide includes a series of appendices that support its content, a brief overview of which can be found in Annex 1.

1.2 Legislation and regulatory framework

As per Article 8 of the Serious Cross-Border Threats to Health, ECDC has the responsibility, in coordination with relevant Union agencies and bodies, to conduct assessments of all 30 European Union and European Economic Area (EU/EEA) countries. These assessments should be conducted every three years and concern the state of implementation of the national prevention, preparedness and response plans. The assessment approach is designed to maintain consistency within EU/EEA countries throughout the three-year cycle, while allowing for adaptation of the process if required by the national circumstances.

The legislative package described below defines the scope and objectives of the assessments, which cover all hazards related to the SCBTH Regulation except those included in separate legislations, such as radiation[ii] and food safety[iii] emergencies.

The main regulatory frameworks are:

- Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU[i];
- 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[iv];
- Commission Implementing Regulation (EU) 2023/1808 of 21 September 2023 setting out the template for the provision of information on prevention, preparedness and response planning in relation to serious cross-border threats to health in accordance with Regulation (EU) 2022/2371 of the European Parliament and of the Council[v];
- Implementation of the International Health Regulations (2005): five-year global strategic plan to improve public health preparedness and response, 2018–2023. Seventy-first world health assembly; agenda item 11.2. WHA 71(15) - 26 May 2018[vi];
- Commission Delegated Regulation (EU) 2024/1232 of 5 March 2024 supplementing Regulation (EU) 2022/2371 of the European Parliament and of the Council as regards assessments of the state of implementation of national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan[vii].

i https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R2371
ii https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2014:013:FULL
iii https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002R0178
iv https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32004R0851
v https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32023R1808#ntr1-L_2023234EN.01010701-E0001
vi https://apps.who.int/gb/ebwha/pdf_files/WHA71/A71(15)-en.pdf
vii https://eur-lex.europa.eu/eli/reg_del/2024/1232/oj/eng

1.3 Aim and objectives

The aim of the Public Health Emergency Preparedness Assessments is to improve prevention, preparedness and response planning in EU/EEA countries through the implementation of recommendations following individual country assessments.

The objectives are to:

- Assess the information reported by the countries regarding the 16 capacities covered by the outputs from the most recent Article 7 template, including the International Health Regulation (IHR) State Party Self-Assessment Annual Report (SPAR[i]) (Annex 2).
- Collaborate with countries to identify good practices, challenges, bottlenecks, gaps or areas for improvement concerning the 16 capacities referred to in Article 7.
- Encourage the inclusion of key elements within the prevention, preparedness and response planning structure such as cross-sectorial and cross-border coordination, crisis management, response governance, communication, plan testing, evaluation and regular reviews, according to lessons identified from the response to public health emergencies.
- Use the opportunity of a standardised approach to the assessment process to contribute to the improvement of EU/EEA prevention, preparedness and response capacities by promoting a common understanding of key elements and a coordinated approach.
- Provide support to countries in enhancing their national prevention, preparedness, and response capacities through recommendations based on the assessment, and providing targeted assistance upon request.

[i] https://www.who.int/emergencies/operations/international-health-regulations-monitoring-evaluation-framework/states-parties-self-assessment-annual-reporting

2. Overview of ECDC Public Health Emergency Preparedness Assessments

As per the SCBTH Regulation, the PHEPAs are based on information reported by each country in the Article 7 template, including the most recently available State Party Self-Assessment Annual Report (SPAR) and following the procedures, standards and criteria stated in the Delegated Regulation 2024/1232 supplementing the SCBTH Regulation regarding the implementation of Article 8[vii].

2.1 State Party Self-Assessment Annual Report

The State Party Self-Assessment Annual Report (SPAR) is a tool developed by the World Health Organization (WHO) and proposed to State Parties to fulfil their obligations under Article 54 to report annually to the World Health Assembly on the implementation of the International Health Regulations[i] (2005), especially as regards the development and maintenance of minimum core capacities for surveillance and response.

All capacities considered in the SPAR are assessed in the PHEPA, except for food safety and radiation emergencies.

2.2 Article 7 of the Serious Cross-Border Threats to Health Regulation

Article 8 of SCBTH Regulation states that; such assessments shall be based on a set of agreed indicators and shall aim to assess prevention, preparedness and response planning at national level with regard to the information referred to in Article 7.

The Article 7 template, developed and published under the Commission Implementing Regulation (EU) 2023/1808, serves to provide an update on elements of emergency prevention, preparedness and response planning, in particular in country governance, capacities and resources. It is complementary to the SPAR in many areas. However, it also includes questions to address elements beyond the scope of the SPAR. Hence, as per the Regulation's recommendations 'the templates […] shall be, as far as possible, consistent with templates used under the IHR State Parties reporting framework.' The adopted template has been aligned, where possible, with the SPAR including in the five-level structure.

2.3 The Delegated Regulation

The Delegated Regulation[ii] lays down procedures, standards and criteria for the assessments, in accordance with Article 8 of the SCBTH Regulation.

The procedure outlines the four-phase approach further detailed in Section 4. The standards and criteria for assessing the countries' state of implementation of their national prevention, preparedness and response plans for each of the 16 capacities are listed in a table in the Delegated Regulation (Annex 2).

[i] World Health Organization – The International Health Regulations https://www.who.int/health-topics/international-health-regulations#tab=tab_1

[ii] European Commission. Commission Delegated Regulation (EU) 2024/1232 of 5 March 2024 supplementing Regulation (EU) 2022/2371 of the European Parliament and of the Council as regards assessments of the state of implementation of national prevention, preparedness and response plans and their relation with the Union prevention, preparedness and response plan. https://eur-lex.europa.eu/eli/reg_del/2024/1232/oj/eng

3. Assessment methodology

The primary goal of the assessment approach is to provide support and facilitate improvement according to each country's individual needs, without engaging in comparative evaluations between countries. The focus is on non-judgmental collaboration between the country and the assessment team, ensuring that assessments contribute meaningfully to progress and development in prevention, preparedness and response planning.

3.1 Assessment approach

The aspects assessed during each PHEPA in the three-year assessment cycle (hereafter called the cycle) refer to information reported by EU/EEA countries in 16 capacities under Article 7 of the SCBTH Regulation and the SPAR, with the support of the additional documentation provided by the country. All criteria included in the level indicated for a certain question should be met by the country and supported by the appropriate documentation provided for the PHEPA. As well as assessing the 16 capacities, an in-depth assessment of five capacities was performed in each cycle to be able to identify good practice, challenges, bottlenecks and actions for improvement regarding national capabilities regarding prevention, preparedness and response planning.

The capacities assessed in-depth vary for each cycle and are chosen by ECDC based on outcomes of the first/previous assessment cycle(s), lessons-learned from past disease outbreaks and health emergencies, and consultations with countries and international partners. For the first cycle, four capacities were selected by ECDC, i) Laboratory, ii) Surveillance, iii) Health Emergency Management and iv) Antimicrobial resistance (AMR) and healthcare-associated infections (HAIs). The fifth capacity is selected by the country.

The outlined approach reviews the status of all capacities in each three-year assessment cycle whilst also performing a detailed review of selected capacities where more specific recommendations can be made. Starting from the second cycle onwards, the implementation of the recommendations from the previous cycle(s) and the national action plan will be assessed. The assessment has a results-based approach and is limited in its focus. Different countries can use different methods to achieve the best result, and this is considered in the assessments.

3.2 The Assessment tool

To ensure a systematic and consistent approach, the experts from the assessment team conduct semi-structured group discussions following an assessment tool, developed by ECDC with the support of other European Commission services, agencies and bodies. It is used to initiate and guide discussion with national experts during the country visit. This tool is shared with the countries at the start of the planning process for a PHEPA.

The tool should be considered as a guideline to orient the assessment, in particular the semi-structured group discussion that takes place during the country visit. It is flexible and adapts to the national context.

This tool is developed based on and complementary to questions under the Article 7 template and SPAR. It is not meant to be used as a self-assessment tool, and the country is not expected to provide a response to the questions prior to the country visit. The guiding questions are meant to trigger a discussion with national experts. Follow-up questions which are not in the assessment tool could be asked by the assessment team to adapt the discussion to the national context in each session.

3.3 Assessment team

The assessments are led and coordinated by ECDC. The team includes ECDC experts and experts from relevant European Union agencies and bodies, and from the Directorate-General for Health and Food Safety (Section B2) from the European Commission if needed. Each team comprises of at least one team leader and five experts from ECDC, one for each capacity assessed in-depth. Additionally, the WHO Regional Office for Europe (WHO Euro) is invited to join the assessment team, depending on specific circumstances and upon the country's request. Experts from another EU/EEA country (from now on 'Other EU/EEA country expert') can also be part of the assessment team if agreed with the assessed country. This option is offered with the objective of broadening the expertise of the team, providing mutual learning, and strengthening cross-border collaboration as well as adding the perspective from another EU/EEA country to the assessment. European Commission Directorates-General other than the Directorate-General for Health and Food Safety (Section B2) , can join as subject-matter experts for specific capacities assessed in-depth. A description of the role and responsibilities for each member of the team can be found in Appendix 1in the supporting documents.

The team composition may vary based on specific requirements of the assessment in each country. However, ECDC will ensure the team has the necessary expertise to cover the capacities being assessed and is available from desk review to report production. Maintaining consistency with the same team members throughout the entire assessment facilitates a smoother process and enhances communication with the assessed country.

3.4 National experts

The assessed country is involved in all phases of the assessment. Each country identifies a Focal Point, who could be an individual or a team, that ensures the coordination of the assessment process at the country level. The Focal Point should remain the same throughout the assessment. National experts also have an important role during the assessment process. The role and responsibilities of the country for each phase is detailed in the chapters below.

There should be one person assigned to each capacity assessed, the Capacity Lead, and they should be identified by the Focal Point as the coordinator and the moderator for this capacity. This person ensures smooth coordination for the assessment of the assigned capacity, both by coordinating the national fellow experts and acting as their representative with the assessment team.

National experts participating in the assessment should represent a comprehensive range of levels and sectors involved in preparedness and response for public health threats. As a golden rule, all stakeholders and bodies to which reference is being made during the discussions, should participate in the assessment process and/or the country visit. It is crucial to have regional representation during the assessment process, especially for the assessment of capacities where they hold relevant competencies within the country. However, representation of all the regions is not necessary. A list of proposed stakeholders to be involved in the assessment process is available in Appendix 2 in the supporting documents.

3.5 Alignment with other assessments

Other upcoming or recent assessments conducted in the country, such as the Joint External Evaluation, or the One Health Fact Finding missions lead by the Directorate-General for Health and Food Safety (Section F2) in the European Commission, are considered during the planning and implementation of a PHEPA. The ECDC assessment team always seeks to use all available information from recent assessments, provided by the country or other organisations, as part of the country assessment. To this end, if a country wishes to align the PHEPA process with other similar assessments and integrate the two, this is possible upon country request to ECDC and the other organisations involved. The goal is always to minimise the burden on countries whilst still achieving the planned outcomes for both assessment processes.

4. PHEPA – the four-phase approach

The assessment process consists of four phases.

- Preparatory period - Initiation, coordination and communication of the assessment process
- Phase 1 – Desk review
- Phase 2 – Country visit
- Phase 3 – ECDC assessment report
- Phase 4 – Country development or review of their action plan.

The timeline from Phase 1 to the end of Phase 3 is around 14 weeks. Phase 4 could take up to nine months after the delivery of the ECDC assessment report. A detailed timeline with the estimated time required for completing the assessment process is available in Annex 3.

A document with a summary of the key steps during the four phases and other instructions and tips is available in Appendix 3 in the supporting documents.

4.1. Preparatory period – initiation, coordination and communication of the assessment process

All activities are coordinated by ECDC and planned in collaboration with the responsible authorities in EU/EEA countries, as well as liaising with relevant European Commission Services.

4.1.1 Country selection and scheduling

An initial schedule for the 30 assessments planned in the three-year cycle is proposed and presented at the Health Security Committee (HSC). The order in which the countries are assessed can be adapted to the countries' preference if necessary and the HSC remains the primary platform and most appropriate forum for discussions on this. ECDC tries to ensure an even distribution of countries to be assessed across the assessment cycle to allow the assessment teams and ECDC to have sufficient resources to conduct them.

According to the SCBTH Regulation, countries and ECDC have a collaborative legal obligation to implement the assessments every three years. The sequence in a cycle should, where possible, be similar to the previous cycle, with at least a two-year gap between assessments for each country.

ECDC is required to assess the countries in accordance with the applicable legislation. If circumstances arise preventing the completion of an assessment during a particular cycle, ECDC will endeavour to find a mutually acceptable solution with the affected country.

4.1.2 Invitation letter and communication

ECDC together with the Directorate-General for Health and Food Safety in the European Commission initiates the assessment process with a co-signed official invitation letter to the HSC member of the respective EU/EEA country. The letter is sent approximately six months prior to the start of the assessment. The country should reply confirming the dates of the country visit, appointing a country Focal Point and providing additional key information for the PHEPA planning. The nominated Focal Point acts as the contact person(s) for ECDC throughout the whole assessment process. The Focal Point ensures the coordination of the assessment process at the country level (e.g. agrees on the Terms of Reference, obtains and uploads all documentation, arranges meetings as needed, invites intersectoral stakeholders to the assessment etc). Further information on the Terms of Reference and the roles and responsibilities for the nominated country Focal Point are available in Appendix 1 in the supporting documents.

4.1.3 Logistical preparatory meetings

A series of preparatory meetings take place with the country Focal Point to present the assessment approach and agree on the logistical and practical aspects of the assessment. Aspects like the agenda, the national experts' participation, the selection of the fifth capacity to be assessed in-depth, the venue and other aspects are discussed during these meetings.

The first meeting takes place around five months before the country visit and at least two additional meetings are held. Additional ad-hoc meetings can be scheduled following any specific need and a constant communication between the country Focal Point and PHEPA assessment team facilitates the preparation process.

4.2. Phase 1 — Desk review

4.2.1 Purpose of the desk review

The main aim of this phase is to initiate the assessment of all 16 capacities by reviewing the responses to the self-assessment questions and the documents provided by the country. During this phase the assessment team identifies aspects to be further discussed during the country visit including potential gaps and areas for improvement, however, this phase does not pre-empt the assessment discussions during the country visit.

It is important to note that there is no additional self-assessment exercise required from the countries before the country visit and the country are not requested to respond to additional tools apart from the Article 7 template and SPAR.

4.2.2 Documents for desk review

Documents for desk review include:

- Self-assessment country reports, especially the Article 7 template and the SPAR. For the SPAR, the most recent available version should be submitted. Regarding the Article 7 self-assessment template, if the submitted version contains details that are outdated, specific notes clarifying this matter could be added in a separate supporting document;
- Documents uploaded by countries as part of answering the self-assessment template of Article 7 (e.g. Tracking AMR Country Self-assessment Survey);
- Documents identified in the template as supporting evidence to enable completion (e.g. prevention, preparedness and response plan);
- Documents identified by the country under assessment that would be important to inform the understanding of the self-assessed level of prevention, preparedness and response planning. ECDC also provides a list of suggested documents that are shared with the country (Appendix 4 in the supporting documents). This list should serve to guide the country, who should select and provide the documents that are relevant for the assessment process.

Related to each capacity, countries are invited to upload a limited number of documents considered relevant to support the assessment of the aspects included in the PHEPA process. As an indication, a number between three to eight documents per capacity is sufficient, taking into account the differences between capacities and countries' context.

The assessment team will review the documents relevant to evaluate the status of prevention, preparedness and response planning. The deadline for the submission of all documents is six weeks in advance of the country visit.

Documents can be provided in the original language in case they are not available in English. Documents that are not in English are translated with the eTranslation tool, the European Commission's machine translation system[i].

A brief description of the main documents provided would be useful to support the assessment team during the desk review phase.

Alternatively, providing an orienting document for each of the 16 capacities, outlining its most relevant aspects, could be beneficial to the assessment team while preparing for the assessment. These cover letters would complement the brief descriptions of the documents suggested above. However, providing only one of the two could be sufficient.

The protocols for storing and accessing documents are described in Section 5

[i] https://commission.europa.eu/resources-partners/etranslation_en

4.2.3 Technical preparatory meetings

Prior to the country visit, a series of virtual meetings between the national experts and members of the assessment team take place to plan for the in-depth capacity assessment by establishing an advanced understanding of each specific capacity and its context in the country. The aim is to clarify any questions and finalise the preparations for the country visit, especially for the five in-depth capacities.

During the technical meetings, the country i) presents an overview of the capacity including, if relevant, the legal framework, the structure and functions, the main coordination mechanisms and relevant stakeholders, and other aspects considered key for the purpose of the assessments, ii) goes through the main documents shared and highlights any key aspects regarding their content to facilitate the work of the assessment team during the desk review. The assessment team then addresses any issues that arose during the desk review, including requests for additional material, if appropriate. A template and further instructions to prepare this presentation are available in Appendix 6 in the supporting documents.

These meetings are scheduled in the weeks leading up to the country visit and around 30 minutes are allocated to discuss each of the five capacities.

4.3. Phase 2 – Country visit

4.3.1 Purpose of the country visit

The purpose of the country visit is to identify challenges, bottlenecks, gaps or areas for improvement following discussions with national experts. The desk review provides a provisional understanding of the structure and functioning of the country's prevention, preparedness and response planning. However, face- to- face meetings allow the assessment team to clarify any outstanding technical matters, fill in gaps, and request further information, as necessary, for the assessment to be completed. Additionally, the in-depth assessments look further into qualitative aspects related to each capacity under assessment, to help identify any barriers to improvement and to discuss potential solutions.

4.3.2 Practical arrangements

ECDC and relevant Union agencies and bodies, Commission services and, if part of the assessment team, WHO Euro, are responsible for covering the expenses of the experts from their organisations. In the case of an expert from another EU/EEA country joining the country visit, ECDC covers the expenses related to their participation. The assessed country is responsible for organising the venue and covering potential costs incurred by attendance to the meetings of their national experts. Regarding the set-up of the venue, a round table or board room set up had shown to facilitate discussions better than a theatre set up.

English is the working language of the assessment team. In case interpretation or translation is necessary, the most appropriate solution is sought together with the country to ensure good communication during the assessment.

Further details, such as the number of rooms required, along with any other technical aspects such as specific requirements for interpretation services, are discussed and agreed during the preparatory period.

Terms of Reference for the country visit, which should be agreed upon with country counterparts before the country visit, are available under Appendix 1 in the supporting doucments. The Terms of Reference specify all relevant details, including the assessment team and national experts, the duration of the visit, and the programme of the visit.

4.3.3 Country visit outline: discussion with national stakeholders

For the first cycle, the country visit is structured in two main parts: a plenary discussion aimed at reviewing the capacities not assessed in-depth, and parallel sessions focusing on the five capacities designated for in-depth assessment. More comprehensive information regarding the planning of the country visit is available as a proposed agenda in Appendix 5 in the supporting documents.

The duration of a standard country visit is between four and five working days.

A standard country visit could be structured as detailed below:

- An opening session where all assessment team experts participate, as well as the national HSC member, representatives from government institutions of the country, country Focal Point, Capacity Leads and other national experts. This meeting sets the scene for the country visit process and includes a presentation detailing the context and the assessment strategy. The assessed country presents an overview of their public health system structure and the preparedness and response mechanisms available. The coordination mechanisms in place between the health and other relevant sectors to respond to health emergencies are also included. Additionally, the country presents an overview of the available generic and specific plans for health threats available in the country relevant to the assessment. A template and further instructions to prepare this presentation are available in Appendix 7 in the supporting documents.
- Session to explore cross-cutting aspects. The aim of this session is to have a plenary discussion with key stakeholders on topics that are relevant for several capacities such as response governance, communication, coordination or surge capacity. A scenario to facilitate the discussion is proposed, together with a series of questions addressing the relevant topics. No specific action is required from the country to prepare for this session, other than ensuring the participation of relevant stakeholders at the national and/or regional level as considered appropriate according to the country's circumstances. The tool that is used to guide the discussion, with further details about the session, is available in Appendix 9 in the supporting documents.
- Detailed technical level discussions on each capacity assessed in-depth. The semi-structured group discussions occur through breakout sessions, focusing on specific in-depth capacities, each led by experts from the assessment team guiding the process. Each breakout session focuses on the technical details of one or more capacities, combining them based on their relevance to one another and the expertise required to assess them. These sessions have a duration of half a day to one full day per capacity and are with national experts of the assessed capacities. Prior to the discussion of each capacity, a presentation of key aspects and responses to the self-assessment questionnaires (Article 7 template and SPAR) is offered by the country. The purpose is for the audience to have a common understanding of the key aspects that will drive the discussion. A template and further instructions on how to prepare this presentation are available in Appendix 8 in the supporting documents. The assessment team uses the questions of the Assessment tool as a starting point to further understand the replies of the country to the self-assessment questions provided under Article 7 template and SPAR, and explore opportunities for improvement, as outlined in the above purpose of the country visit. A joint review between the ECDC assessment team and the national experts of strengths, weaknesses, opportunities, and recommendations takes place for each capacity.
- A plenary session to assess the capacities not assessed in-depth during the cycle. All the experts from the assessment team support this process and are present during the discussion of all capacities. These sessions have a duration of 45 to 90 minutes, each focusing on one or two capacities, and engage all relevant national experts for each session. Prior to the discussion of each capacity, a presentation of maximum 10 minutes including key aspects and responses to the self-assessment questionnaires (Article 7 template and SPAR) is offered by the country. The purpose is for all the audience to have a common understanding of the key aspects that drive the discussion. A template and further instructions to prepare this presentation are available in Appendix 8 in the supporting documents.
- A debrief and closing meeting at the end of the country visit with all experts involved from the assessment team and from the country. The country can invite other relevant stakeholders as deemed appropriate. During this meeting the ECDC assessment team presents the main findings and preliminary recommendations in a plenary session, and the relevance and feasibility are discussed with the national experts. The next steps, including the delivery of the assessment report and work on the action plan, are also discussed during this session.

4.4 Phase 3 – ECDC assessment report

Based on the findings from the desk review process combined with the outcome of the country visit, ECDC, with the input of the assessment team members, produces a draft report with an overview of the assessment including key findings, conclusions and recommendations. These recommendations are tailored to the circumstances of each country. The aim is to support the development, update and enhance the national prevention, preparedness, and response plans in the countries.

ECDC shares the draft report for one round of revision to receive country's feedback and comments before finalising it. The report should ideally be distributed internally to all the national stakeholders who were involved in the process. The report is in English. Areas where consensus and agreement cannot be achieved are also documented in the report, providing perspectives from both the assessment team and the country, coordinated by the ECDC assessment team leader. While the publication of the report is considered good practice, the decision to publish all or part of it rests with the national authorities of the country assessed.

The final assessment report is sent to the country and the Commission.

4.5. Phase 4 – Country action plan

Within nine months of receipt of the assessment report, the country should produce an action plan addressing the recommendations from the report, together with corresponding actions and milestones.

As indicated in Article 8 of the EU Regulation 2022/2371, the action plan may include regulatory actions, training initiatives or preparation of an overview of good practice. The action plan should be communicated to the European Commission and ECDC. Countries may consider following the WHO approach for developing National Action Plans for Health Security (NAPHS)[i] as a global standard for action plans; however, they are free to adopt the format as they see fit. If the country already has an action plan in place, this can be updated according to the recommendations.

For the implementation of specific aspects of the action plan, the country can request support to ECDC through the EU Health Task Force[ii].

If a country decides not to follow a recommendation, it shall state its reasons why, as per the SCBTH Regulation. To facilitate follow-up of the recommendations, a template is available in Appendix 10 in the supporting documents.

Subsequent assessment cycles will also consider how the action plan has been implemented by the country, what activities have taken place and what impact they have had in closing the gaps highlighted in the previous ECDC assessment report(s). This could result in countries re-evaluating their action plan every three years as part of the assessment process to promote a continuous cycle of improvement. This does not preclude countries updating their action plan more regularly in the interim.

5. Knowledge management and storage

During the time of the assessment process, any relevant documents, including self-assessment reports and relevant documents shared by the country, are stored in SharePoint at ECDC, where each country possesses a dedicated country-specific storage site. In each country-specific storage site, there are 16 numbered folders –one folder per capacity – and a 'general' folder where practical documents and the self-assessment reports from the country are shared. Each folder is accessible only to the assessment team, including ECDC experts and other experts joining the assessment process, and the designated country Focal Point. These folders contain documents with essential information about the assessment process. The country is informed about the experts who are part of the assessment team in due time. Further details are available in Appendix 1 in the supporting documents.

A final version of the ECDC assessment report and the action plan are stored in the prevention, preparedness and response country space of the Early Warning and Response System.

Once the assessment process is finalised and after the country has delivered the action plan, the country is able to choose how to manage the documents stored in SharePoint. Options include removing access for all users or for non-country users only, and/or deleting some or all supporting documents, and/or migrating documents to a country-owned server for archiving purposes. Further details are available in Appendix 1 in the supporting doucments.

[i] National Action Plan for Health Security (who.int)
[ii] EU Health Task Force (EUHTF) (europa.eu)

Annex 1. Support for the appendices

The table below serves as a reference tool to enable the reader to navigate the various appendices that complement this Guide.

Appendix name	Function	When to use it	Purpose
1. Terms of reference for the PHEPA	ToR for the PHEPA including practical aspects, assessment team experts' ToR and declaration of confidentiality.	Preparatory period, before the country visit	To be completed by ECDC and the country
2. Stakeholder list	List of suggested national stakeholders relevant for the assessment process	Preparatory period, before the country visit	For information
3. Planning checklist	Checklist to support the country during the planning phase of the assessment process	Preparatory period, before and during the country visit and afterwards	For information
4. List of core documents	List of suggested documents to be provided by the country to conduct the assessment process	Preparatory period, before the country visit	For information
5. Country visit agenda	Proposed agenda for the country visit	Preparatory period, and during the country visit	To be completed by ECDC and the country
6. Country presentation – technical preparatory meeting	Template to be used by the country to prepare the technical preparatory meetings' presentations	Preparatory period, during the technical preparatory meetings	To be used by the country
7. Country presentation – country overview	Template to be used by the country to prepare the overview presentation	During the country visit – Monday AM	To be used by the country
8. Country presentation – capacity session	Template to be used by the country to prepare each capacity's presentation	During the country visit – Monday PM to Thursday	To be used by the country
9. Cross-cutting session - scenario	Guiding document to drive the cross-cutting session	During the country visit – Monday AM	For information
10. Country follow-up to ECDC PHEPA recommendations	Follow-up of the recommendations after receiving the final assessment report	After receiving the final assessment report	To be used by the country

Annex 2. List of capacities included in the assessment process as per Article 7

International Health Regulations 2005 capacities	
Capacity 1.	IHR implementation and coordination
Capacity 2.	Financing
Capacity 3.	Laboratory
Capacity 4.	Surveillance
Capacity 5.	Human resources
Capacity 6.	Health emergency management
Capacity 7.	Health service provision
Capacity 8.	Risk communications and community engagement (RCCE)
Capacity 9.	Points of Entry and border health
Capacity 10.	Zoonotic diseases and threats of environmental origin, including those due to the climate
Capacity 11.	Chemical events
Additional capacities as per Regulation (EU) 2022/2371	
Capacity 12.	Antimicrobial resistance (AMR) and healthcare-associated infections (HAIs)
Capacity 13.	Union level coordination and support functions
Capacity 14.	Research development and evaluations to inform and accelerate emergency preparedness
Capacity 15.	Recovery elements
Capacity 16.	Actions taken to improve gaps found in the implementation of prevention, preparedness and response plans

Annex 3. Timeline

The assessment process consists of several phases that follow the timeline detailed below.

Q4 - 2023		• Country completes and submits the questionnaire on Article 7
Starting		• The official letter is sent to Country, initiating the process
Week 1 Week 2 Week 3	3 weeks	• Country responds and agrees to the assessment process • Country nominates a Focal Point (FP)
Week 4 ... ... Week 23	20 weeks	• FP shares relevant documents with ECDC • ECDC prepares and shares an agenda (with country visit dates agreed) and ToR with Country
Week 24 Week 25 Week 26 Week 27	4 weeks	• Phase 1 - ECDC conducts desk review
Week 28	1 week	• Phase 2 - Country visit
Week 29 Week 30	2 weeks	• Phase 3 – ECDC conclusions and recommendations report o ECDC to draft recommendations report o ECDC to share the report with Country
Week 31 Week 32 Week 33 Week 34	4 weeks	• Phase 3 – ECDC conclusions and recommendations report o Country to review the report and provide feedback
Week 35 Week 36 Week 37	3 weeks	• Phase 3 – ECDC conclusions and recommendations report o ECDC to produce and share final report with Country
+ 9 months	39 weeks	• Country to prepare and produce an Action Plan (if applicable) • Country to present the Action Plan to the Commission and the ECDC

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